Teaching health statistics

LESSON AND SEMINAR OUTLINES

Second edition

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Dedicated to the late C. R. Lowe, C.B.E., Emeritus Professor of Community Medicine, Welsh National School of Medicine, Cardiff, Wales

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* Seminar.

Preface

The need for a statistical approach is now well recognized in epidemiology and public health, since these fields are concerned with communities or populations where the laws of large numbers and random fluctuations clearly apply. Teachers of health workers and students, however, have been slow to recognize the need for a knowledge of statistics, even though all aspects of diagnosis and prognosis are affected by rules of probability.

This book is intended to contribute to the long-term reorientation of the health information systems of Member States, by bringing about improved data generation, handling, processing and use, in order to meet future health requirements.

The extent of statistical knowledge and skills that students need to acquire varies from country to country, according to such factors as the common health problems and methods of delivering health care in the country, and the career prospects of the students on graduation. Nevertheless, there is a core of statistical knowledge that all students need to have, irrespective of their country of training.

The present set of outlines is a revised version of *Teaching health statistics: twenty lesson and seminar outlines* (Lwanga SK & Tye C-Y, eds. Geneva, World Health Organization, 1986). The topics covered form an internationally acceptable standard basic curriculum for teaching health statistics. While based on those of the first edition, the lesson and seminar outlines have been revised and updated in both content and orientation. They cover not only the conventional topics of data collection, presentation and analysis, probability and vital statistics, but also such topics as health indicators, use of computers and rapid methods of interim assessment. The concepts highlighted by the outlines should be useful to all students in the health field, and are meant to be used selectively by teachers of statistics in preparing their courses.

This new edition is a result of close collaboration between a number of eminent teachers of statistics, and has been coordinated and edited by Mr S. K. Lwanga, Statistician, Department of Health Systems, World Health Organization, with valuable assistance from Dr O. Ayeni, Biostatistician, Special Programme of Research, Development and Research Training in Human Reproduction, Department of Reproductive Health and Research, World Health Organization.

The preparation of the first edition of this book was conceived by Dr Boga Skrinjar-Nerima while she was Chief Medical Officer at the World Health Organization in charge of the development of health statistical services. Her contribution is still highly appreciated.

The World Health Organization wishes to thank the following eminent teachers who made invaluable contributions to this edition of lesson and seminar outlines: Professor E. Bamgboye, Department of Family and Community Medicine, College of Medicine, King Saud University, Riyadh, Saudi Arabia; Professor R. Biritwum, Department of Community Health, University of Ghana Medical School, Accra, Ghana; Professor A. Indrayan, Division of Biostatistics and Medical Informatics, University College of Medical Sciences, Delhi, India; and Professor K. Sümbüloglu, Department of Biostatistics, Hacettepe University, Faculty of Medicine, Ankara, Turkey. Thanks are also due to all the teachers and colleagues who contributed to the first edition of the book or reviewed the various drafts of this revised version.

This publication is specially dedicated to the memory of the late Ron Lowe, C.B.E., Emeritus Professor of Community Medicine, Welsh National School of Medicine, Cardiff, Wales, who helped and guided the Organization's efforts towards the improvement of the teaching of statistics and their use in epidemiology and public health.

Introduction

Historical background

Over the past twenty years, the World Health Organization has been devising strategies for improving the teaching of statistics to health personnel, in recognition of the need to train future health workers in information support to health care delivery and management. Earlier efforts were directed towards improving the teaching abilities of teachers by promoting modern educational techniques. This was done through workshops, seminars and meetings. The main products of these efforts were:

- A manual for teachers of medical students,[1] sponsored jointly by WHO and the International Epidemiological Association; this was a direct result of one of the recommendations made by a group of teachers who participated in a WHO travelling seminar in 1973.
- A report of the Inter-Regional Conference on Teaching Statistics to Medical Undergraduates, held in Karachi, Pakistan, in 1978.
- A guide on organizing a workshop for those responsible for teaching statistics to medical students.

The extent of the statistical knowledge and skills that health workers need to acquire varies from country to country, depending on the health problems of the country, the technological capacity of the country to handle these problems, and the career prospects of the students on graduation. Nevertheless there is a core of statistical knowledge that all students need to have, irrespective of their country of training. In recognition of this need, the 1978 Inter-Regional Conference in Karachi recommended:

". . . the development, under WHO, of an internationally acceptable standard basic curriculum for teaching health statistics to medical students, which could be adapted by medical schools to meet the needs and conditions of their own countries."

In response to this recommendation, the World Health Organization coordinated the development of a series of lesson and seminar outlines, published in 1986 as *Teaching health statistics: twenty lesson and seminar outlines*. Those outlines were prepared by a group of teachers with long experience of teaching statistics to medical undergraduates. The outlines aimed at offering teachers of statistics to medical undergraduates a starting point for organizing the material they should teach.

[1] Lowe CR, Lwanga SK, eds. *Health statistics: a manual for teachers of medical students*. Oxford, Oxford University Press, 1978.

Rationale for revising the outlines

Since the publication of the original outlines, there have been extensive technological developments in data handling and information communication. The aim of health care is no longer merely to cure illnesses, but also involves the prevention of illness and the maintenance of health. The broad field of health is now seen as encompassing the social, biological and economic environment of people. The principle of primary health care is now accepted by all countries. The delivery of health care (in its broad sense) is, therefore, no longer the responsibility of medical doctors alone.

Educational material to improve the capability of health workers to handle data and use these data in monitoring their activities should, therefore, be aimed at all future health workers, not medical students alone. The training material should also cover areas relevant to the objective monitoring of health programmes and activities. With these requirements in mind, the outlines have been revised to guide the teacher in deciding what to teach health workers (not necessarily medical students only) if they are to be objective in monitoring their activities.

The following new topics have been included in the revised version:

- indicators of levels of health;
- health information systems;
- use of computers in health sciences;
- rapid methods for interim assessment.

Need for a comprehensive course in health statistics

Knowledge of, and competence in, the application of statistical principles and methods are necessary, not only for an understanding of the biological and medical sciences, but also for effective practice in any of the health professions. Because of the variability of biological, clinical and laboratory data, the science of statistics is necessary and central to their understanding and interpretation.

Every student training in the health field should complete a course in health statistics for the following reasons.

- A knowledge of statistics is required in order both to understand the rationale on which diagnostic, prognostic and therapeutic decisions are — or should be — based, and to appreciate that medicine is highly dependent on concepts of probability.
- Within their competence, health workers need to interpret laboratory tests and bedside observations and measurements in the light of a knowledge of physiological, observer and instrument variation.
- Health workers must know and understand the statistical and epidemiological facts about the etiology and prognosis of the diseases that they treat in order to give the best advice to their patients about how to avoid or limit the effects of these diseases.
- Health workers are the primary generators of the data on which health statistics are based. They therefore need to know how data can and should be

used, both for the benefit of their own practices, and for the organization and delivery of health care in their countries.

- Health managers need to know how to interpret and draw inferences from the indicators that describe health levels, trends and resources.
- The study of statistics helps to foster in students the critical and deductive faculties that they will need throughout their studies and, after graduation, in their practices.

Well organized training in statistics contributes to the long-term reorientation of country health information systems to respond to future health requirements, by improving data generation, handling, processing and use.

The course

Health statistics as a basis of epidemiological methods is the foundation upon which health managers can assess health trends and situations, and monitor the progress of the various interventions.

Some teachers may find that some of the topics they would like to teach are not included in this book. Others may find that topics they would not consider important have been covered at length. The choice of topics was, in fact, based on the Karachi recommendations, taking into account the consensus view of those preparing the outlines in consultation with teachers of the different cadres of health workers. It was felt that the topics not included in these outlines are generally best taught at the postgraduate level.

Since the revised material is aimed at all trainee health workers, teachers will have to be selective as to what to include in the curricula of the different types of students. Many teachers may also find that not enough time is allocated for the statistics course to enable them to cover all the material. In such a situation, they should concentrate on what they regard as the high priority topics.

In recognition of the diversity of teachers and teaching methods, the lesson and seminar outlines given here are deliberately presented in a variety of ways. An attempt has been made, however, in each case to include a clear statement of the aims and enabling objectives. Similarly, class exercises are presented in a variety of ways. The emphasis of the exercises should not be on computational skills but on the ability to interpret the results.

References for use by teachers and students are given for each outline. Where examples are extracted from published documents or books, full references are given to allow teachers to refer to the original if they so wish.

The outlines are intended to be a guide for teachers in preparing lessons and seminars, and in deciding on course content. They are not intended to be substitutes for fully prepared lessons and seminars. Moreover, they are written neither as self-instructional material for students, nor as a textbook in statistics for teachers lacking in formal statistical training.

The outlines are divided into three parts:

- Part I (Outlines 1 to 10) covers statistical principles and methods;

- Part II (Outlines 11 to 16) covers health statistics, including demography and vital statistics;
- Part III (Outlines 17 to 23) covers statistics in medicine, including medical records.

Handouts for students are appended to all the outlines. Teachers should judge whether the examples contained in the handouts are of relevance to their students and make any necessary adjustments. For example, if the data used in the handout are not applicable to the country in which the teaching is carried out, appropriate data for that particular country should be used instead.

There is no fixed number of sessions for each lesson or seminar. Teachers should feel free to design lessons and seminars themselves, on the basis of the outlines. The number of sessions will depend on teachers' preferences and on the availability of time. Time should be provided for class exercises.

The teaching of statistics should not be carried out in isolation from the other disciplines in the health curriculum, but should be integrated whenever possible. The role of a statistics course in providing training in information support for the health field should not be forgotten. Statistics should not be taught as an end in itself, but as a means through which other disciplines may be better understood and implemented.

PART I

Statistical principles and methods

OUTLINE 1 Introduction to the role of statistics in health sciences and health care delivery

Introduction to the lesson

Statistical methods are consciously or subconsciously applied in health care delivery at the community and individual patient levels. At the community level, they are used to monitor and assess the health situation and trends, or to predict the likely outcome of an intervention programme. At the patient level, they are used to arrive at the most likely diagnosis, to predict the prognostic course and to evaluate the relative efficacy of various modes of treatment. Knowledge of statistics is also essential for a critical understanding of the medical literature. Statistical principles are essential for planning, conducting and interpreting biomedical, clinical and community health research.

Objective of the lesson

The objectives of this lesson are to introduce the students to the role of statistics in the health sciences, health care delivery, the study of human populations, and the management of uncertainty. The lesson also aims to create an awareness of the need to acquire an understanding of statistical principles and methods.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain various meanings of the term statistics.

(*b*) Indicate, through examples (without necessarily going into great detail), how statistical principles and concepts are relevant in the following situations:

- handling of variation in characteristics (for example, physiological or chemical) encountered in the field of health care;
- diagnosis of patients' ailments and health problems of communities;
- prediction of likely outcomes of disease intervention programmes in communities or of diseases in individual patients;
- selection of appropriate forms of treatment for individual patients;
- public health administration and planning;
- planning, conducting, analysing, interpreting and reporting of medical research.

(*c*) List sources of uncertainty in health sciences and health care delivery.

(*d*) Describe the role of statistics in the management of uncertainty in health sciences and health care delivery.

Required previous knowledge

The foundation blocks of a course on health statistics are:

- experience of making and using measurements that have demonstrated inter-individual and intra-individual variation, and variations due to observers, methods or instruments;
- knowledge of the concerns of medicine and of health systems;
- knowledge of the broad meaning of diagnosis, prognosis and treatment.

Should any of these be missing, then that gap should be bridged before proceeding any further.

Lesson content

Meaning of statistics

In everyday use the term statistics means data, numerical observations or quantitative information, such as:

- the number of trained community health workers in different districts of a country;
- the birth weight of babies born in a hospital during a specified period;
- the number of homosexual men in a defined location who are HIV positive;
- the prevalence rate of schistosomiasis per 1000 population in various districts of a country;
- the amount of creatinine in mg per litre in a 24-hour urine specimen.

Statistics is also defined as a discipline or a science of managing uncertainties in decision processes — the scientific methods of collecting, processing, reducing, presenting, analysing and interpreting data, and of making inferences and drawing conclusions from numerical data.

Main uses of statistical methods

Statistical methods are mainly used in the following three activities:

(*a*) Collection of data in the best possible way by:

- adopting a suitable and appropriate method for selecting subjects for study, to minimize the role of uncertainty (example: selecting people for a health interview by means of lots);
- designing valid data collection instruments, such as questionnaires and schedules (example: construction of a questionnaire to collect data on anaemia in pregnant women);
- organizing the data collection procedures for clinical and laboratory research, epidemiological studies and population surveys to minimize the chances of errors (example: standardization of definitions, and training of workers involved in collecting data on births and deaths).

(*b*) Description of the characteristics of a group or a situation, accomplished mainly by:

- data presentation in terms of tables and graphs;

- calculating summary measures, such as averages, which can adequately represent the structure of the data set.

(*c*) Analysing data and drawing conclusions from such analysis: this involves analytical techniques and the use of probability concepts in drawing conclusions.

Uses of statistical concepts and methods in health sciences and health care delivery

The use of statistics is essential for making judicious decisions in health care delivery, at the levels of both the community and individual patients. Medicine, as a discipline, deals with individuals who exhibit variations in different characteristics, such as weight, blood pressure, cholesterol level and lung functions. The healthy state for each characteristic varies from person to person depending upon biological factors, such as the person's age, sex and genetic constitution. Environmental factors, such as diet, stress and strain, lifestyles and the availability of health facilities, can also affect these characteristics. No two persons or groups of persons are ever exactly alike. Notwithstanding these variations, decisions on the delivery of health care are based on experience with other patients or communities with similar biological and social characteristics.

Because of these variations, the outcomes of decisions cannot be predicted exactly: they are always accompanied by an element of uncertainty. This is the probabilistic nature of medicine. It is thus necessary to be conversant with the proper techniques for dealing with such variations and uncertainties.

Statistical skills are also helpful in developing a critical thinking faculty, in order to be able to:

- think scientifically, logically and critically about health problems;
- properly assess the available evidence for decision-making;
- be aware of possible risks associated with medical decisions;
- identify decisions and conclusions that lack a scientific and logical basis.

Statistical principles and methods are applied in various aspects of health sciences and delivery of health care. For example:

Handling of variation

Variation in a characteristic (or factor or measurement) occurs when its value changes from subject to subject, or from time to time or instrument to instrument within the same subject, or from observer to observer. Nearly all characteristics encountered in health care delivery, whether environmental, physiological, biochemical or immunological, exhibit such variation. For example, there is variation in blood pressure from person to person, from morning to evening, before and during an excitement, in sitting and supine positions, in recordings by different people, and in measurement by mercury and aneroid instruments.

These variations require that appropriate methods be used when trying to: summarize a characteristic for a group of patients or for a community; decide, for a

particular characteristic, the ideal or normal or average value; and compare two groups of patients, or two communities, with respect to a particular characteristic. Only when the various aspects of variation have been clearly defined can appropriate statistical methods for summarizing or comparing characteristics (or factors or measurements) be decided on.

Diagnosis of patients' ailments and communities' health problems

Diagnosis is the process of identifying the factors responsible for a specific disease in an individual or group of individuals. Distinct disease entities, based on clustering of signs, symptoms and values of biochemical measurements, are often established by procedures employing implicit statistical methods. There is always a risk of being wrong in identifying the health status of an individual or a community with one of the diagnostic categories. The signs and symptoms may not be fully typical of a particular diagnosis and may occur in more than one diagnostic category. For example, complaints of abdominal pain, vomiting and constipation of long duration are frequently seen in abdominal tuberculosis but can also occur in amoebiasis and hepatitis. The reason for high maternal mortality in a given area could be malnutrition of the women (because of ignorance or poverty) or poor sanitary practices at the time of delivery (because of ignorance, poverty or the unavailability of adequate maternal services).

Statistical reasoning is often unconsciously employed when a disease category is selected as being the most likely to be correct. Explicit statistical methods are available for ordering disease categories according to their probabilities of being the correct diagnosis.

Prediction of likely outcome of an intervention programme in a community or of treatment of individual patients

Prognosis is the assessment or prediction of the likely outcome of an intervention programme in a community or of disease in patients in the light of the presenting symptoms, signs and circumstances. An outcome is predicted when the chances of its occurrence are high and the associated uncertainty is low. The exercise of prediction is thus inherently statistical.

Data are needed to achieve a more reliable prediction of the likely outcome of an intervention programme in a community or of treatment of individual patients. Characteristics observed at the outset of the programme or at initial examination and during treatment, and the eventual outcome of the disease in the community or in patients previously seen by the clinician must, therefore, be recorded and kept. The records can then be analysed to determine the trends in the results for different types of communities or individuals. Prediction of the outcome of a new intervention programme or treatment is based on the results of such an analysis. For example, to assess the effect of improved water supply on the health of a community, information is needed on the health problems of the community before the introduction of the improved water supply.

Selection of appropriate intervention for a patient or a community

This is based on the following:

- previous experience with similar patients or communities that had received the intervention;

- reports of clinical trials or experiments to assess the relative efficacy of different drugs and other methods of treatment;
- objective assessment of the health worker's previous experience.

The design, execution and analysis of medical experiments and intervention programmes must employ sound statistical and epidemiological principles and methods if the findings and conclusions are to be valid. Otherwise, interventions may unknowingly be ineffective and even harmful.

Public health, health administration and planning

The major application here is the use of data relating to health and illness in the population in order to make a community diagnosis. This requires knowledge of:

- population characteristics, such as size, and age and sex structure;
- the health profile of the population in terms of disease risk factors;
- the influence of environmental factors on different aspects of health;
- other factors affecting population dynamics: data on births, deaths and migration.

In health administration and planning, use is also made of data on the distribution of health care resources (need, availability, utilization and so on) by different segments of the population at all levels.

Health workers need to know how to interpret and use these statistical indices. As the main generators and users of these statistics, they have to ensure that the statistics they use are accurate.

Planning, conducting, analysing, interpreting and reporting of medical research

All medical studies, whether in the form of analytical research or descriptive surveys, depend on proper collection, analysis and interpretation of relevant data. The validity of such studies depends on the application of sound statistical and epidemiological principles.

In order to keep abreast of developments in their profession, health workers must be able to read, understand and critically evaluate medical reports.

NEW TERMS AND CONCEPTS

Data collection, processing, reduction, summary, analysis and presentation; health statistics; probabilistic approaches; probability; statistics; uncertainty and error; variation; vital statistics.

Structure of the lesson

The lesson content may be presented in the following sequence. Examples taken from current medical literature as well as other publications (including daily newspapers when appropriate) should be liberally used throughout the lesson to illustrate the important nature of information in health science and in the delivery of health care.

(*a*) As an introduction, discuss the general and specific objectives of the course as a whole, making it clear that it is not intended to produce health statisticians, but health workers who will be able to make rational decisions in their work. Emphasize the use of statistics as a tool rather than as an end. Give an overview of the course, its structure, organization, teaching methods and timetable.

(*b*) Explain the meaning of "statistics" and "statistical methods", giving examples of their application in health care. Explain the need for data in decision-making. Hence, explain the importance of the study of survey design, instrument calibration, and data collection, processing, analysis, presentation, interpretation and communication.

(*c*) Discuss the problems posed by variation and uncertainty in: the study of disease etiology, causation or risk factors; the evaluation of response to treatment; the determination of "normal", "usual" and "ideal" values of characteristics; and hence the methods needed to handle them.

(*d*) Explain the essential role of statistics in the field of health (for example, in acquiring and using medical knowledge, and in medical practice). Use examples to show how decisions are made by health workers in the course of their duties (for example, in making a diagnosis, assessing prognosis and deciding on the correct treatment for a patient), and by health administrators, planners and evaluators.

(*e*) Point out the widespread use of statistical methods in medical journals. Progressive health workers depend, to a considerable extent, on literature to update their knowledge. Sometimes the handouts distributed by pharmaceutical firms also contain statistical results. Readers, therefore, need to have the ability to evaluate the validity and reliability of the information in these reports. They also need to be familiar with the basic technical language of the statistical and epidemiological methods which are commonly used in the medical literature. Health workers themselves may have to use this language in the reports of their work.

Lesson exercises

Lesson exercises should test the students' ability to describe the importance and uses of statistical methods in the field of health, and should give as many examples as possible. The exercises should, therefore, be of such a nature as to elicit from the students examples of the need for statistics and their use in solving health problems.

■ What statistics would be required to decide whether to build a clinic for a village in a district ?

■ Give four areas in health care delivery where the science of statistics is applied.

■ Describe the importance of including somebody with knowledge of statistics in a District Health Management Team (DHMT) which has the responsibility of health services development in a district.

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Sources of uncertainty in health and medicine

(*a*) Uncertainty is caused by variations in:

- biological factors (for example, age, sex, birth order, heredity);
- environmental factors (for example, nutrition, addictions, stresses, water supply, sanitation, socioeconomic status, availability and use of health facilities);
- methodological factors (for example, relating to observers, instruments, laboratory techniques, chemicals and reagents, questionnaires or record forms, diagnostic tools such as X-ray);
- chance and unknown factors (for example, difference in birth weight of identical twins, or varying results from repeated samples of blood, urine and tissue).

(*b*) Other sources of uncertainty include:

- incomplete information on the person or patient (patient in coma, lack of facilities for medical investigations, illiteracy, recall failure, etc.);
- an imperfect tool (false positive and false negative results of laboratory and radiological investigations, clinical signs and symptoms are sometimes not specific, lack of accepted measure of important concepts such as community health, etc.);
- poor compliance with the prescribed regimen (non-compliance with treatment schedule, imperfect post-surgical care, breakdown of a vaccine cold chain, non-acceptance of family planning advice, etc.);
- inadequate medical knowledge (lack of treatment for AIDS, unknown causes of many cancers, inability to restore severely malignant tissues, lack of a universally applicable cheap and effective method to break the parasite–vector–host cycle in malaria transmission, unknown specific factors causing women to live longer than men, unknown relationship between the mind and physiological and biochemical mechanisms, etc.).

OUTLINE 2 Health data: sources, levels and quality of measurement

Introduction to the lesson

The systematic and continuous process of health policy formulation, planning, programming, budgeting, implementation, and general integration of different programmes within the overall health system depends on good information support. The types of data gathered and the analysis applied to them depend on the potential users and the kind of information they are likely to need. The quality of the information given depends on the sources of the data, how they are collected, the instruments (equipment, recording forms, etc.) used for data collection, and the statistical methods used for analysis. In addition, the amount of information that can be obtained from the data and the choice of statistical methods for the analysis depend in part on the scale or level (nominal, ordinal or interval) on which the data have been measured.

Objective of the lesson

The objective of this lesson is to enable the students to understand the nature, sources, types and collection of data needed for the planning and management of health programmes and activities.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Describe the possible sources of health data.

(*b*) Distinguish between regular and ad hoc health data collection systems.

(*c*) Describe the procedures for health data collection.

(*d*) Discuss the major differences between the three data measuring procedures:

- instrumental — measurement done technically, without human intervention in the decision on the value of the measurement;
- human — measurement done by persons who decide on the measurement value;
- by interaction between humans and equipment.

(*e*) Explain the concepts of reliability and validity with regard to measurement, and discuss their implications for the use of health data.

(*f*) Distinguish between the four principal scales of measurement (nominal, ordinal, interval and ratio), indicating their respective application for health data collection.

(*g*) Distinguish between quantitative and categorical data.

(*h*) Distinguish between random errors and fluctuations.

Required previous knowledge

The meaning of "statistics" and "statistical methods", and their role in the health field, as discussed in Outline 1.

Lesson content

Sources of health data

There are two main sources of health data: regular or routine systems; and ad hoc systems.

Regular or routine data collection systems

A regular or routine data collection system usually consists of established procedures for collecting data as they become available. Some systems are national with legal backing or are demanded by international regulations, while others are subnational or even institution-specific.

Examples:

- A national vital statistics registration system of births, deaths, marriages and divorces.
- A disease notification system to collect information under the International Health Regulations[1] on cholera, plague and yellow fever.
- A reporting system for cancer cases (cancer registry).
- Registration systems in health care facilities, to collect information on patients attending the various clinics (in-patient and out-patient).

An advantage of this source is the availability of health data. A major difficulty is that such a system may not exist. Even where it exists, there may be deficiencies. The records may not be uniform, or they may be unreliable because they are incomplete or inaccurate.

Ad hoc data collection systems

Ad hoc data collection is usually in the form of a survey to gather information that is not available on a regular basis. This may include special investigative studies or merely the collection of additional information as part of routine data collection.

Examples:

- A national survey of health personnel.
- A survey to estimate the proportion of children with malnutrition in a defined population.
- A study to investigate whether the use of hormonal contraceptives affects the nutritional status of the user.
- An investigation of breastfeeding practices among women who registered a birth in the previous year.

[1] See Handout 2.2.

One advantage of the ad hoc system is that it provides accurate and reliable data in response to the specific needs of the user. Disadvantages include the logistics and expenses involved in ad hoc data collection.

Procedures for data collection

Regular or routine system

The procedure for regular data collection is usually along the following lines (but not necessarily in the stated order):

- Decision on items of data to be collected according to the requirements of the health information system (for example, health programme monitoring, management of the health system).
- Establishment of rules and regulations instituting the system, and giving it legal backing, especially if it is to be a nationwide system. These rules and regulations are enacted by a competent authority.
- Physical establishment of office facilities, recruitment of personnel, and dissemination of appropriate information to the public.
- Design of forms and registers to be used for recording information.
- Specification of the recording procedure (for example, who supplies the information, when the information has to be registered).
- Specification and design of registration receipts: these are tokens given to the person registering an event to indicate compliance. Examples are hospital registration cards, birth and death registration certificates.
- Training personnel.

Ad hoc system

The steps involved in the organization of data collection on an ad hoc basis are:

- Definition or statement of the objectives of the collection exercise, indicating what type of information is needed, the data to be collected, and how the information is to be used.
- Definition of the population for which information is required (the reference or target population).
- Decision on whether information will be collected from all or some of the units in the reference population.
- Decision on how many respondents (those from whom information will be collected) are to be included in the study (sample size).
- Decision on how these respondents will be selected.
- Design of the instruments (forms, etc.) to be used for data recording.
- Selection and training of personnel to collect the data.
- Mode of data collection (for example, personal interview, self-administered questionnaire, telephone).
- Identification of selected units and data collection.

Data measuring procedures

There are three main types of data measuring procedures:

(*a*) Instrumental: measurement is done technically, without human intervention in the decision on the value of the measurement.

Examples: electronic equipment such as weighing scales, thermometers, spectrophotometers, sphygmomanometers, blood testing equipment.

(*b*) Human: measurement is done by persons who decide on the measurement value.

Examples: auscultation of the heart, grading spleen enlargement, taking a patient's medical history, reading mercury column sphygmomanometers, reading weight using a spring scale.

(*c*) Combination of human and instrumental.

Examples: reading of X-ray films, reading of blood films.

Quality of measuring instruments

Two desirable characteristics of data measuring procedures are reliability and validity.

Reliability

Reliability deals with the inherent performance of the procedure. A reliable procedure is one that gives consistent results when it is applied more than once to the same subject under similar conditions. Major factors affecting reliability are:

(*a*) The inherent variation of the procedure itself. Examples: fluctuating zero mark in a weighing scale, non-stability of chemical reagents.

(*b*) Fluctuations in the variable being measured. Examples: patients giving different answers, depending on their understanding of the questions, during history taking.

(*c*) Observer error: a single observer may obtain different results in repeated measurements of the same unit. Examples: repeated blood pressure measurements; age determination (when date of birth is unknown); repeat microfilaria count on a stained slide; temperature reading off a mercury thermometer.

(*d*) Inter-observer error (observer variation): differences between observers. Examples: blood pressure measurements; reading of X-rays; reading of blood films.

Validity

A measurement is valid if it measures what it is supposed to measure. (It is easier to illustrate the concept of validity by identifying situations in which a measurement may not be valid).

Examples:

- Fever may not be a valid "measure" (sufficient indicator) for malaria in areas with low malaria transmission levels.

- Answers obtained from oral interviews in some societies may not be indicative of local abortion practices.
- A married couple not having a child may not be a valid "measure" (indicator) of infertility.

Sensitivity and specificity are two important components of assessing the validity of "measuring" procedures.

The sensitivity of a test, a procedure, or a measuring instrument, is its ability to respond to the changes in the factor to which it is being applied. For example, if a chemical concentration is being measured, and if a change in the concentration produces a large change in the measurement given by a test, the test is said to be sensitive. In epidemiology, sensitivity is defined as the proportion of true positive observations correctly identified by a test. Using the notation shown in Table 2.1, sensitivity is given by the relation $a/(a + c)$.

Specificity is defined as the extent to which a test, a procedure, or a measuring instrument gives a response for the presence of a given variable and is non-responsive to the presence of all other variables. In epidemiology, specificity is defined as the proportion of true negatives correctly identified by a test. Using the notation shown in Table 2.1, specificity is given by the relation $d/(b + d)$.

Other components of validity in screening tests are the positive and negative predictive values of a test. These values may be described using the notation for test validation shown in Table 2.1. The probability that a positive result in the test indicates a genuinely positive result is the positive predictive value of the test: $a/(a + b)$. The probability that a negative result is genuinely negative is the negative predictive value of the test: $d/(c + d)$.

Table 2.1 ***Notation for test validation***

	True picture		
Test results	**+**	**−**	**Total**
+	a	b	$a + b$
−	c	d	$c + d$
Total	$a + c$	$b + d$	

Sensitivity	$= a/(a + c)$
Specificity	$= d/(b + d)$
Positive predictive value	$= a/(a + b)$
Negative predictive value	$= d/(c + d)$

Variables and attributes

A quantitative variable describes a characteristic in terms of a numerical value; the value may vary from subject to subject or from time to time in the same subject. The value is expressed in units of measurement. Examples: height in metres, blood pressure in mmHg (or kPa).

A qualitative or attributive variable describes the attribute of a characteristic (by classifying it into categories to which a subject either belongs or does not belong) or a property or quality that a subject either possesses or does not possess. Examples: access to some form of health care, sickness, hospitalization, blood group, sex.

Some characteristics can be dealt with in only one way as attributes, while others are amenable to transformation from measurement variable to descriptive attributes. For example, body weight may be studied either as a measurement variable (weight in kg) or as an attribute (overweight/not overweight). Which form is used depends on the reason for the measurement, the requirements of objectivity, reliability and validity, and the properties of the different measurement scales. These considerations are explained below.

Continuous and discrete variables

A continuous variable is one with potentially an infinite number of possible values in any interval. It can assume either integral or fractional values and can be measured to different levels of accuracy by using more or less refined methods of measurement. Examples: height (in metres): 1.8, 1.76, 1.758; weight (in kg): 11, 10.8, 10.79.

A discrete variable can only have a finite number of values in any given interval. The values are invariably whole numbers. They are integers. Examples: number of children in a family; number of households in a community; white blood cell count; number of beds in a hospital ward.

Scales of measurement

It is necessary to express clinical impressions (for example, extent of an individual's illness or the health level of a community) in clear measurements, either in units of some physical device, or categories such as disease stage. Each level of measurement is, however, defined by the degree of accuracy and sophistication of the measuring device.

The four principal scales used to measure data are the nominal, ordinal, interval and ratio scales.

A nominal or classificatory scale is one in which names, labels or tags are given to distinguish one measurement from another on the basis of certain qualities or attributes. Measurement on this scale does not include any notion of magnitude.

Examples:

- Outcome of disease in a patient can be measured as survival or death.
- National commitment to primary health care may be judged as existent or non-existent.
- Psychiatric patients may be classified as psychotics, neurotics, manic depressives or schizophrenics.

An ordinal or a ranking scale has the characteristics of the nominal scale described above, with an implicit order relationship among the measurements.

Examples:

- Lack of proper food for nursing mothers and children in a drought-stricken area may be classified as critical, severe, moderate or slight.
- Social status of patients may be measured as upper, middle or lower class.

An interval scale is characterized by a numerical unit of measurement, such that the difference between any two measurements is explicitly known in terms of an interval between the two measured points. The unit of measurement and the zero point (the origin or starting point) of the scale interval are arbitrary and only fixed by convention. Example: body temperature is usually measured on an interval scale, of which the unit may be, for example, degrees Celsius (°C).

Although the ordinal scale can be transformed into a pseudo-interval scale by assigning scores to its measurement categories, it retains the qualities of an ordinal scale.

The ratio scale has all the characteristics of the interval scale, as well as a true or absolute zero, so that the ratio between two values on the scale is a meaningful measure of the relative magnitude of the two measurements. Examples: height in metres; weight in kg.

Certain arithmetical operations are permissible on each scale.

Nominal scale. The arithmetical operation of "equivalence" is permissible on this scale. For example, one "woman" is equivalent to another "woman". Equivalent measurements can be aggregated into a particular category and counted. Proportions belonging to each measurement category out of the total number measured can be calculated.

Ordinal scale. On this scale one measurement can be equal to another (equivalent) or described as greater (higher) than or less (lower) than the other. The difference between one measurement and another is not explicit, and differences between adjacent measurements are not equivalent. Again, equivalent measurements can be aggregated into a measurement category and counted, and the proportion in each category calculated.

Interval scale. Arithmetical operations permissible on this scale include all those allowed on the ordinal scale; in addition, measurements can be added, subtracted, divided and multiplied by a constant, to yield interpretable results. Comparison between intervals on this scale is meaningful, and is independent of the unit of measurement or the system of assigning scores.

Ratio scale. All arithmetical operations are permissible, and the ratio of any two measurements is meaningful and independent of the unit of measurement.

Quantitative and categorical data

Data can be divided into two broad categories according to the strength of the scale of measurement: categorical data and quantitative data.

Categorical data are measurements in which the notion of magnitude is absent or implicit. Such variables are measured either on a nominal or an ordinal scale. These data are also referred to as attributive or qualitative.

Quantitative data have numerical magnitude. They are measured either on an interval or on a ratio scale.

NEW TERMS AND CONCEPTS (see Handout 2.1)

Ad hoc sources of data; attribute; categorical data; continuous scale; descriptive statistics; discrete variable; objective measurement; predictive value (positive and negative); qualitative description; quantitative data; quantitative description; reliability; routine sources of data; scales of measurement; sensitivity; specificity; subjective measurement; validity; variable.

Structure of the lesson

The contents of the lesson may be covered in the following sequence, using illustrative examples from the literature, wherever possible.

(*a*) Explain the meaning and importance of health data and their place in medical information and knowledge.

(*b*) Discuss the different types of health data sources, and the systems and procedures of data collection. Explain their relative usefulness, quality of data, and cost.

(*c*) Differentiate between routine and ad hoc data collection systems. Discuss the status and usefulness of the following data collection systems: vital registration, disease surveillance, service reporting, specific health programmes, and administration in your locality.

(*d*) Differentiate between quantitative and qualitative description, objective and subjective measurement criteria, and quantitative and categorical or attributive data.

(*e*) Describe the four scales of measurement and explain their properties in terms of the amount of information conveyed, reliability and validity.

(*f*) Describe the various instruments for measuring data and how to assess their qualities.

Lesson exercises

The teacher should show data sets on about four or five variables from different sources. The exercises should focus on the identification of the source, distinguishing between continuous and discrete data, and identification of the scales of measurement. Additional exercises should test the understanding of validity, reliability and types of errors that may be associated with the data sets collected.

Ask class members to do the following exercises.

■ List three variables or attributes used in the area of public health, and for each one, state:

- its scale of measurement;
- the type of variable (quantitative, attributive);
- whether it is discrete or continuous;
- the type of instrument used for its collection.

■ List five items of information collected within the national health information system through:

- a regular data collection system;
- ad hoc survey methods.

■ Describe three situations in which measurements are made in the clinic or public health setting (one for each data measuring procedure). State the factors that may cause the procedures to be unreliable.

■ Describe how data are classified in general, and the different scales of measurement of data.

■ Distinguish between sensitivity and specificity of a diagnostic test.

■ Illustrate with two examples how a variable can be measured on more than one scale.

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Definitions of new terms and concepts

Attribute: An attribute is a variable that describes a characteristic by classifying it into categories to which a subject either belongs or does not belong. It is a property or quality that a subject either possesses or does not possess.

Categorical variable: A categorical variable has measurements in which the notion of magnitude is absent or implicit.

Continuous variable: A continuous variable is one with potentially an infinite number of possible values in any interval.

Discrete variable: A discrete variable has measurements that occur as integers. It can only have a finite number of values in any given interval.

Reliability: Reliability deals with the inherent performance of the procedure. A reliable procedure is one that gives consistent results when it is applied more than once to the same unit under similar conditions.

Sensitivity: The sensitivity of a screening test is a measure of the probability of correctly diagnosing a case. It is the proportion of truly diseased persons in the screened population who are identified as diseased by the screening test.

Specificity: Specificity is a measure of the probability of correctly identifying a non-diseased person with a screening test. It is the proportion of persons who are not truly diseased, who are so identified by the screening test.

Validity: A measurement is valid if it measures what it is supposed to measure.

Variable: A variable is any attribute, phenomenon or event that can have different values.

International vaccination requirements[1]

International Health Regulations

The purpose of the International Health Regulations, adopted by the World Health Assembly in 1969, is to help prevent the international spread of diseases and, in the context of international travel, to do so with the minimum of inconvenience to the passenger. This requires international collaboration in the detection and reduction or elimination of the sources from which infection spreads rather than attempts to prevent the introduction of disease by legalistic barriers that over the years have proved to be ineffective. Ultimately, however, the risk of an infective agent becoming established in a country is determined by the quality of the national epidemiological services and, in particular, by the day-to-day national health and disease surveillance activities and the ability to implement prompt and effective control measures.

No regulations can be expected to foresee every disease eventuality and, in certain situations, diseases and conditions other than those covered by the International Health Regulations may be of concern to national health authorities and the travelling public. The International Health Regulations obviously cannot refer specifically to diseases that were not known at the time they were last revised; this is the case with acquired immunodeficiency syndrome (AIDS). Nevertheless, any requirement of an HIV antibody test certificate ("AIDS-free certificate") is contrary to the Regulations.

The International Health Regulations are currently being revised in accordance with a resolution adopted by the World Health Assembly in 1995. The purpose of the revision is to develop Regulations that are adapted to the present volume of international traffic and trade and take account of current trends in the epidemiology of communicable diseases, including emerging disease threats.

Smallpox

The eradication of smallpox was confirmed by WHO nearly 20 years ago. Smallpox vaccination is no longer indicated, and may be dangerous to those who are vaccinated and those in close contact with them.

Cholera

Vaccination against cholera cannot prevent the introduction of the infection into a country. The World Health Assembly therefore amended the International Health Regulations in 1973 so that cholera vaccination should no longer be required of any traveller.

The traditional parenteral cholera vaccine conveys incomplete, unreliable protection of short duration and its use is therefore not recommended.

Yellow fever vaccination certificate

Urban and jungle yellow fever occur only in parts of Africa and South America. Urban yellow fever is an epidemic viral disease of humans transmitted from infected to susceptible persons by the *Aedes aegypti* mosquito. Jungle yellow fever is an enzootic viral disease transmitted among nonhuman primate hosts, and occasionally to humans, by a variety of mosquito vectors.

[1] Adapted from *International travel and health*. Geneva, World Health Organization, 1998: Chapter 2.

A yellow fever vaccination certificate is now the only certificate that should be required in international travel, and then only for a limited number of travellers.

Many countries require a valid International Certificate of Vaccination from travellers arriving from infected areas or from countries with infected areas, or who have been in transit through those areas. Some countries require a certificate from all entering travellers, including those in transit. Although there is no epidemiological justification for this latter requirement, which is clearly in excess of the International Health Regulations, travellers may find that it is strictly enforced, particularly for people arriving in Asia from Africa or South America.

On the other hand, vaccination is strongly recommended for travel outside the urban areas of countries in the yellow fever endemic zone, even if these countries have not officially reported the disease and do not require evidence of vaccination on entry.

The vaccination has almost total efficacy, while the case–fatality rate for the disease is more than 60% in adults who are not immune. Tolerance of the present vaccine is excellent. The only contraindication to its use, apart from true allergy to egg protein, is cellular immunodeficiency (congenital or acquired, the latter sometimes being only temporary).

The period of validity of an international certificate of vaccination against yellow fever is 10 years, beginning 10 days after vaccination. If a person is revaccinated before the end of this period, the validity is extended for a further 10 years from the date of revaccination. If the revaccination is recorded on a new certificate, travellers are advised to retain the old certificate for 10 days until the new certificate becomes valid.

OUTLINE 3 Health information systems

Introduction to the lesson

A health information system (HIS) provides information for the management of a health programme or system and for monitoring health activities. A HIS is made up of mechanisms and procedures for acquiring and analysing data and providing information (such as management information, health statistics and health literature) needed by:

- all levels of health planners and managers for the planning, programming, budgeting, monitoring, control, evaluation and coordination of health programmes;
- health care personnel, health research workers and educators in support of their respective activities;
- national policy makers, socioeconomic planners and the general public outside the health sector.

Objective of the lesson

The objective of this lesson is to provide the students with an understanding of the importance of information-based health services management and a health care delivery system.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain the importance of information-based health services management.

(*b*) Describe the role of health personnel in the health data generation process.

(*c*) Identify the relevant sources of data for a HIS.

(*d*) Describe the various types of HIS (for example, public, hospital, private sector).

(*e*) Describe the various levels of a HIS.

(*f*) Describe the uses of a HIS in decision-making.

Required previous knowledge

Sources of health data, the structure of the health care delivery system, International Classification of Diseases.

Lesson content

Definition and description of a health information system

A HIS is made up of mechanisms and procedures for acquiring, analysing, using and disseminating health data for health management.

The role of a health information system in health services

The main use of a HIS is to support decision-making by helping to identify areas for action, setting priorities and evaluating the results of the decision made.

Decision-making process based on health information

The decision-making process follows the following steps:

- identification of issues;
- examination of relevant information for allocating priorities to the problems;
- setting of goals;
- selection of possible solutions to the problems;
- deciding which solutions to implement;
- implementation of the chosen solutions;
- assessment of the results.

The role of health personnel in generating health data

All categories of health personnel are involved in the generation and use of health information at all levels of the health system. Accurate recording of health events, good record keeping, correct analysis and prompt reporting of health data determine the quality and usefulness of the HIS.

Types of health data collection system

Health data are either collected routinely or obtained through ad hoc exercises (see Outline 2). Data are usually collected from all the health reporting units. In certain circumstances, however, sentinel reporting units can be established to provide special or additional information for the HIS.

Sentinel reporting units are specially selected health units used as observation windows of the health data reporting process. The selected units may receive special attention and support because of their HIS-related activities.

Relevant sources of data (health information subsystems)

A HIS may be divided into five different subsystems:

- disease surveillance;
- service reporting;
- specific health programmes;
- administration;
- vital registration and census.

Various types of HIS may exist in the same country: the national (public) system, the private sector information systems and others. Each type of system often has several levels, from the community level (small health units), through the district, regional or provincial levels, to the national level. The system relies

on feedback procedures continuously to improve the quality of data and information.

Health information system data management

The data generated by a HIS has to be managed correctly and efficiently to yield the desired information. This management is carried out at the micro (collection point) level and macro (district, national, etc.) level. Data management involves collation, checking on accuracy and completeness, storage, processing, analysis, report generation and information communication. Computers are useful tools for data management at all levels of a HIS.

Desirable characteristics of a health information system

The key desirable characteristics of a HIS are that it should be:

- used by and cover all levels of the health system;
- affordable and manageable;
- flexible, functional, useful, reliable and relevant.

NEW TERMS AND CONCEPTS (see Handout 3.1)

Decision-making; health information system; health policy; health programmes; health system management; feedback; disease surveillance; vital registration.

Structure of the lesson

When presenting this lesson, the teacher should:

(*a*) Clearly define what a HIS is, explaining the roles played by the users of the health system, the health care providers and the managers.

(*b*) Discuss the need for information-based decision-making, and the importance of an information system and its subsystems in this process.

(*c*) Build up the description of a HIS from the simple information system of a health unit in a small community (for example, the village health worker's information system), through other referral health facilities in a district, to the region, and finally to the national level.

(*d*) Describe the information systems of departments of a health facility, through the system of the whole facility, to the complex country system.

(*e*) Prepare a package of the forms used by the national HIS to show to the students. Prepare a handout listing the forms (see Handout 3.2).

(*f*) Draw examples from the students' environment to illustrate:

- the structures (from the peripheral units, medical records departments of hospitals, up to the headquarters);
- management (dates and frequency of reporting, local analysis and feedback mechanisms);
- use (development of indicators and setting of priorities) of a HIS.

(*g*) Explain the types and training of the personnel of the system, with particular reference to the country of interest to the students. For example, the personnel of the HIS may consist of the following:

- Medical records department: records officer, assistant records officers, records assistants, statistical assistants.
- National health statistics unit: medical statistician, records officer, biostatistics assistants, computer system analysts, computer programmers.

(*h*) Describe the health data collecting forms in use in the HIS (see Handout 3.2). If possible, the forms should be reviewed for any improvements that may be warranted.

(*i*) Explain the system of reporting and all the legislation regarding health information reporting.

(*j*) Explain the use of computers in a HIS, for storage, retrieval and processing of health data.

Lesson exercises

The teacher should set exercises that test the students' knowledge of the various components of a HIS, the relevant forms for data collection, the factors that affect the quality of the data, and the usefulness of the data.

■ List six important forms in use in one health information subsystem of your country. For each form, describe the information to be derived and how it is used.

■ Give five factors that can affect the quality and timely reporting of information from the HIS.

■ Select one of the forms in use in the HIS and describe its use, in covering:

- frequency of reporting;
- latest date for submission of forms;
- channel of reporting;
- required local analysis;
- feedback.

■ Describe the characteristics, advantages and disadvantages of a sentinel reporting system in your country.

■ Describe the contribution of the nongovernmental sector to the national HIS.

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HANDOUT 3.1

Definitions of new terms and concepts

Disease surveillance: The continuing scrutiny of all aspects of occurrence and spread of diseases to detect changes in trends or distribution, as a basis for instigating control measures.

Feedback: The process by which information is passed back to the people providing the data. To be effective the information should have useful analytical comments.

Health information system (HIS): The mechanisms and procedures for acquiring and analysing data, and providing information (for example, management information, health statistics, health literature) for the management of a health programme or system, and for monitoring health activities.

Health policy: A set of statements and decisions defining health priorities and main directions for attaining health goals.

Health system management: The management of the interrelated component parts, both sectoral and intersectoral, as well as within the community itself, which produce a combined effect on the health of a population.

Vital registration: The formal recording of events of human life, such as births, deaths, marriages and divorces.

HANDOUT 3.2

List of health forms used in a national health information subsystem for disease surveillance in Ghana

Monthly report on inpatients

For all health units admitting patients: data on discharges and deaths, by diagnosis.

Report on outpatients (summary of outpatient daily register)

Patients are counted by diagnosed disease, by age (whether under or over 5 years), and by whether or not they were referred to another department or health institution.

Consolidated monthly maternal and child health (MCH) reports

Summary of MCH monthly data; antenatal clinic; daily register of children under 5 years, including immunizations and malaria prophylaxis.

Number of first or subsequent visits by normal or underweight children; first visits to antenatal clinic and for complications of pregnancy; number and type of vaccine doses given to children under 5 years.

Monthly report of infectious diseases

Data are classified as: (*a*) diseases for which quarantine is required; (*b*) diseases of global surveillance; and (*c*) communicable diseases.

Regional/district summary monthly reports of health inspection

Information is collected from inspections of villages, buildings, meat, drugs issued by health assistants, immunization programmes, infectious disease cases, sanitation improvements and water supply protection.

Annual report on health personnel

Information is collected on all professional and technical staff, according to type of work, age, sex, and marital status.

OUTLINE 4 Organization and presentation of data

Introduction to the lesson

Useful information is usually not immediately evident from a mass of raw data. Collected data need to be organized in such a way that the information they contain clearly reveals the patterns of variation. Precise methods of analysis can be decided upon only when the data structure and characteristics are understood.

Objective of the lesson

The objective of this lesson is to provide the students with an understanding of the purpose and ways of reducing and presenting data.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) State the circumstances under which health data reduction and presentation would be necessary.

(*b*) Recognize the relative advantages and disadvantages of tabular and diagrammatic presentation of data.

(*c*) Explain the uses and the methods of construction of:

- an ordered array;
- frequency tables (absolute, relative and cumulative);
- cross-tabulations;
- bar charts;
- pie charts;
- histograms;
- frequency polygons (line charts);
- an ogive.

(*d*) Tabulate a given set of data using an appropriate method.

(*e*) Use an appropriate diagrammatic method to present tabulated data.

(*f*) Describe at least three ways in which diagrammatic presentation of data can be misused.

Required previous knowledge

Sources and types of health data and scales of measurement.

Lesson content

Organization of data

Different ways (either manual or using computers) and stages of bringing together data items (assembling data collection forms, extracting the data from the forms to create data sets or files, etc.).

Reasons for health data reduction and presentation

To provide a concise or compact view of the data set and its principal characteristics. This is the first step in the description and analysis of statistical data (see Handout 4.2, Example 1).

Tabular and diagrammatic data presentation

Data grouping

Classes or intervals into which the range of the variable has to be divided, including the class limits and class marks.

Tabular presentation

Presentation of data in tables so as to organize them into a compact and readily comprehensible form. For example, a frequency distribution table gives the number of observations at different values of the variable.

(*a*) Single variable frequencies:

- for a qualitative variable (such as the distribution of occupation among the 188 people in the study in Handout 4.2, Example 2);
- for a large data set on a quantitative variable, requiring grouping of the data into classes (such as the distribution of intra-ocular pressure of the right eye, in Handout 4.2, Example 1).

(*b*) Cross-tabulation:

- Two-dimensional tables, in which two variables are cross-classified (such as, the cross-classification of angular stomatitis and occupation, as shown in Table 4.3 of Handout 4.2).
- Three-dimensional tables, in which three variables are cross-classified (for example, outcome of treatment by sex and by age group).

Diagrammatic presentation

Diagrammatic presentation is the use of a diagram to show the distribution of data. Some methods of diagrammatic presentation of data which should be covered in this lesson are:

(*a*) For qualitative or categorical data:

- Pie charts
  - — A circle is divided into sectors with areas proportional to the frequencies or the relative frequencies of the categories of the variable.

- Bar charts
  - — The bars are constructed to show the frequency, or relative frequency, for each category of the attribute.
  - — Usually, the bars are equal in width.
  - — It is important that the vertical scale should start at zero; otherwise the heights of the bars are not proportional to the frequencies.

(*b*) For quantitative data:

- Frequency histograms
  - — The chosen class intervals should not overlap and should cover the full range of the data.
  - — The area of each bar (not its height) should be proportional to the frequency. Unequal class intervals are taken into account by the area of the bars.
- Frequency polygons (line charts)
  - — Constructed by joining the midpoints of the top of each bar.
  - — Provide ease of visual comparison between two or more distributions drawn on the same chart.
- Cumulative frequency polygons and cumulative frequency charts (ogives)
  - — The cumulative frequencies are plotted against the upper tabulated limit for each class.
  - — In principle, the ogive can be used to estimate, by interpolation, the frequency of occurrence of a value of the variable less than or equal to a specified value, for example the percentage of a population $\leqslant 30$ years of age.

(*c*) Others:

- Maps

Examples should be given of the misuse of diagrammatic presentation of data:

— Complexity: presenting too much information on one diagram.

— Suppression of zero on the vertical scale may lead to misrepresentation of the appearance of changes.

— Choice of scale: stretching or suppressing the scale can mislead readers.

Labelling of tables and diagrams

The need for proper (self-explanatory) titles for tables and diagrams should be emphasized. Table columns and rows, and axes of diagrams should be labelled.

Advantages and disadvantages

Tabular presentation has the advantage of displaying the characteristics of the

data more clearly than raw data. Diagrammatic presentation gives a better visual appreciation of the characteristics than tabular presentation.

The disadvantage of both tabular and diagrammatic presentations is that, since both are based on summarized data, individual values are lost.

NEW TERMS AND CONCEPTS (see Handout 4.1)

Bar chart; class; class interval; class limits; class marks; cross-tabulation; cumulative frequency; cumulative relative frequency; diagrammatic presentation; frequency; frequency polygon; frequency table; histogram; ogive; ordered array; pie chart; relative frequency; tabular presentation.

Structure of the lesson

Throughout the lesson, examples should be given to illustrate the various methods of data presentation. Whenever possible, use of computers for data tabulation and diagrammatic presentation should be demonstrated and practised by the students. It would be helpful if a public domain general purpose computer software (for example, Epi Info) were used for the demonstrations. The teacher should:

(*a*) Explain the use of the ordered array for showing distribution patterns in a small set of observations.

(*b*) Explain the use of the frequency table for showing distribution patterns, and show how frequency tabulations can be produced either manually or by computer. In particular, mention:

- the number of classes sufficient to show the distribution patterns;
- the dependence of class interval or size on the number of classes and range of values;
- the use of equal or unequal classes (intervals) in relation to distribution patterns;
- the use of open-ended classes in order to cope with extreme values in a distribution, and to ensure that the classification is exhaustive at both ends of the distribution (even if these end classes contain no observations);
- the proper statement of class intervals so that classes are mutually exclusive and exhaustive.

(*c*) Explain the use of the relative frequency distribution (for example, percentage distribution) for comparing two or more distribution patterns. Note that relative frequencies and relative cumulative frequencies in the tables are useful for comparative purposes. Stress that it is better to use several simple tables than one complicated table.

(*d*) Explain the use of cross-tabulation to obtain the frequency distribution of one variable by subsets of another variable (for example, age and sex).

(*e*) Describe the use of the cumulative frequency distribution and how it is obtained from a basic frequency table. Make special note of the way in which the definition of class marks is modified in a table of cumulative frequencies.

(*f*) Explain the concept of the distribution pattern of a variable. Give examples from the medical literature to illustrate distributions of different shapes (bell-shaped, unimodal, bimodal, skewed, etc.), and what these distribution patterns may suggest for disease transmission.

(*g*) Explain how distribution patterns of data are more readily discerned by using diagrams instead of tabulated data. Describe how the following diagrams should be constructed, either manually or using a computer, from data given in frequency tables: frequency histogram, frequency polygon, cumulative frequency polygon and cumulative frequency chart (ogive), bar chart, pie chart.

Lesson exercises

The teacher should organize a set of raw data suitable for tabular and graphic presentation. The exercises should give emphasis mostly to the process of data reduction, tabulation and graphic presentation, including the uses and interpretation of graphs and other diagrams.

■ Using data on intra-ocular pressure (in Example 1 in Handout 4.2) indicate the type(s) of diagram that would be appropriate to present the data set on each of the variables.

■ Using the data on intra-ocular pressure in Annex A (A.1), draw a frequency polygon for one of the variables and produce cross-tabulations for any two variables.

■ List four different graphic methods for presenting data from a survey on family planning in a village. Illustrate with two variables for each graphic method.

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HANDOUT 4.1

Definitions of new terms and concepts

Bar chart: Diagrammatic presentation of frequency data for nominal classes by bars whose length is proportional to the class frequencies.

Class: One of the intervals into which the entire range of the variable has been divided (for example, each of the intervals 3.0–3.3, 3.4–3.7, . . . , 5.0–5.3 is a class).

Class frequency: The number of observations in each class, also known as the absolute class frequency.

Class limits: The true values at the beginning and end of each class, which depend on the accuracy of measurement (for example, if measurement is accurate to the nearest tenth, then the class limits for the class 3.0–3.3 are 2.95 and 3.34).

Class marks: The variable values that demarcate each class (for example, 3.0 and 3.3 are, respectively, the lower and upper class marks of the class 3.0–3.3).

Classification: The process of subdividing the range of values of a variable into classes or groups.

Cross-tabulation: A frequency table involving at least two variables that have been cross-classified (tabulated against each other).

Cumulative class frequency: The number of observations up to the end of the particular class. It is obtained by cumulating the frequencies of previous classes, including the class in question.

Frequency polygon: Diagrammatic presentation of the frequency distribution of a quantitative variable, with class frequencies plotted against class midpoint marks, the points being joined by straight lines.

Frequency table or distribution: A tabular arrangement showing the number of times that data with particular characteristics occur within a data set.

Histogram: Diagrammatic presentation of the frequency distribution of a quantitative variable, with areas of rectangles proportional to the class frequency.

Ogive: Graph of the cumulative relative frequency distribution.

Ordered array: Simple rearrangement of the individual observations in order of magnitude.

Pie chart: Sectors of a circle, with areas proportional to class frequencies, used to present data in nominal classes.

Relative class frequency: The absolute class frequency expressed as a fraction of the total frequency.

Illustrative examples of data presentation

Example 1

Extract of data on intra-ocular pressure measurements of 135 adults (for the full data set see Annex A). The data are given in mmHg, but may also be expressed in kPa (1 mmHg = 0.133 kPa).

Age (yrs)	Sex	Rt[a]	Lt[b]	Diff[c]	Potential for glaucoma
24	M	20	27	−7	high
52	M	18	12	6	high
26	M	16	13	3	low
71	F	14	14	0	normal
49	M	13	14	−1	normal
.	.	.	.	.	.
.	.	.	.	.	.
.	.	.	.	.	.
39	M	21	16	5	high
71	M	14	12	2	low
32	F	13	12	1	normal
38	F	13	12	1	normal
33	F	9	8	1	normal

[a] Right eye (mmHg).
[b] Left eye (mmHg).
[c] Difference between the right and left eye measurements.

Using seven equal intervals, data on intra-ocular pressure in the right eye may be presented in a frequency distribution table as in Table 4.1.

Table 4.1 ***Frequency distribution table of intra-ocular pressure (right eye)***

Intra-ocular pressure (mmHg)	Number of observations	Relative frequency
0–3	0	0
4–7	1	0.7
8–11	16	11.9
12–15	63	46.7
16–19	40	29.6
20–23	13	9.6
24–27	2	1.5
Total	**135**	

Evident features of the distribution of right eye intra-ocular pressure values, among the 135 subjects studied, include their variation from 4 to 27 and the fact that an appreciable number of persons have values between 12 and 15.

Example 2

In a (hypothetical) study of the relationship between angular stomatitis and occupation, the occupation of each individual was recorded as: P (professional), S (skilled) or U (unskilled). There were 88 people with angular stomatitis (+) and 100 without the disease (−). A partial list of the disease and occupation characteristics of the individuals could be represented as in Table 4.2.

Table 4.2 ***Listing of data on angular stomatitis***

Person	Angular stomatitis	Occupation
1	−	P
2	+	U
3	+	U
4	−	S
.	.	.
.	.	.
.	.	.
186	+	S
187	−	U
188	−	P

These data can be presented in a cross tabulation of the two variables: angular stomatitis (present/absent) and occupation (professional/skilled/unskilled) as in Table 4.3.

Table 4.3 ***Distribution of 188 people by occupational classification and angular stomatitis***

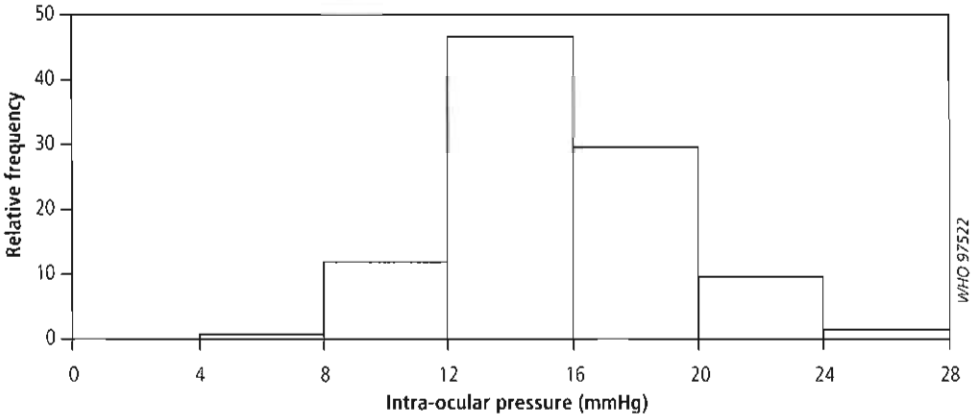
	Angular stomatitis			Percentage
Occupation	Present	Absent	Total	with disease
Professional	5	20	25	20.0
Skilled	13	30	43	30.2
Unskilled	70	50	120	58.3
Total	**88**	**100**	**188**	**46.8**

Table 4.3 shows the relative frequencies of angular stomatitis in the various occupational categories.

Example 3

The data on right intra-ocular pressure in Example 1 may be presented as a histogram (Figure 4.1).

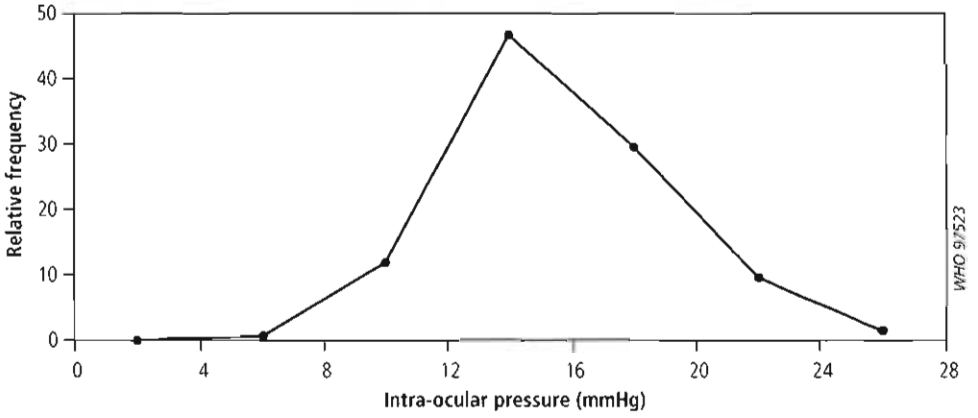
Figure 4.1 ***Histogram of right eye intra-ocular pressure data from Example 1***



Example 4

The intra-ocular pressure data from Example I can also be presented as a frequency polygon (Figure 4.2). Each data point represents the frequency of one class.

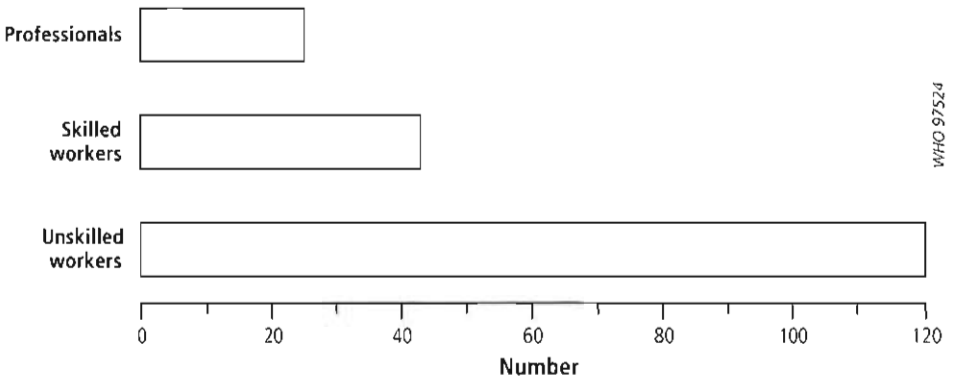
Figure 4.2 ***Frequency polygon of the right eye intra-ocular pressure data from Example 1***



Example 5

The occupational distribution of the 188 people in Example 2 can be presented as a bar chart (Figure 4.3).

Figure 4.3 ***Bar chart of occupation data from Example 2***



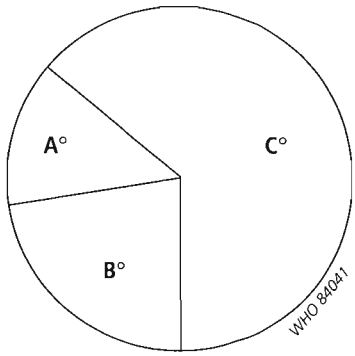
Example 6

A pie chart (Figure 4.4) can also be used to show the distribution pattern of the occupation data in Example 2. The frequencies have to be converted, proportionately, to angles.

Occupation	Frequency	Sectoral angle
Professionals	25	A
Skilled	43	B
Unskilled	120	C
Total	188	360°

$$A = (25/188) \times 360° = 48°;$$
$$B = (43/188) \times 360° = 82°;$$
$$C = (120/188) \times 360° = 230°.$$

Figure 4.4 ***Presentation of the occupation data from Example 2 as a pie chart***



Example 7

Wrong or misleading diagrammatic presentation of data is illustrated in Figures 4.5 to 4.8.

Figures 4.5 and 4.6 show DPT3 vaccination coverage (diphtheria–pertussis–tetanus vaccine, 3 doses) for infants in Nicaragua for the period 1990–1996 (data from Expanded Programme on Immunization, WHO). Figure 4.5 gives a misleading impression of the increase in coverage between 1990 and 1996.

Figure 4.5 ***Inappropriate choice of scale and missing zero point on the vertical axis***

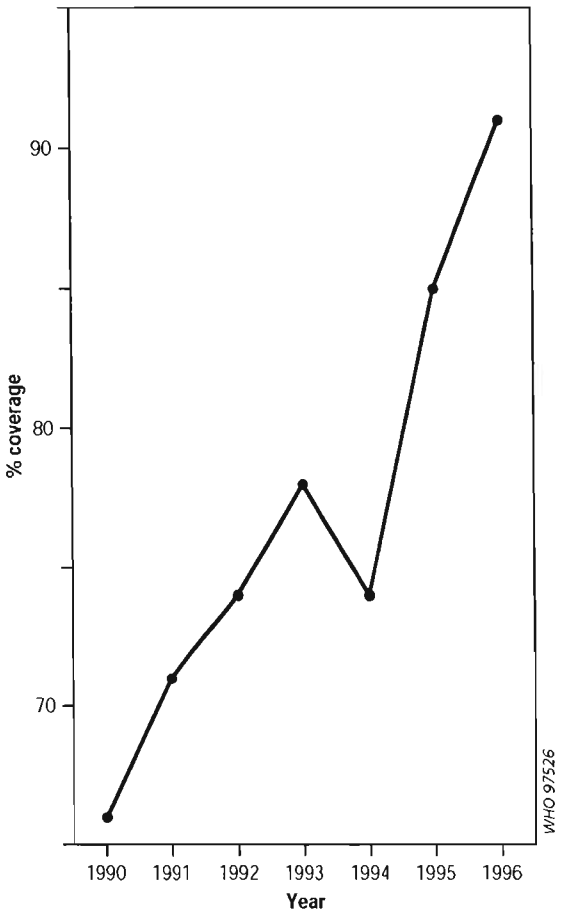
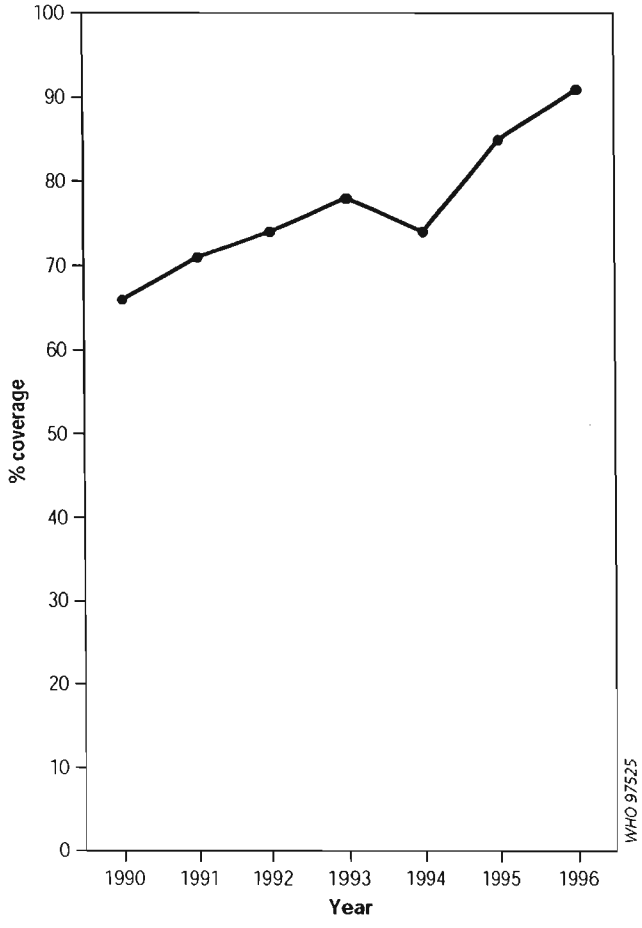


Figure 4.6 ***Zero point included on the vertical axis***



Figures 4.7 and 4.8 present mortality data from Nicaragua for 1991, as reported in *World health statistics annual 1993*. Figure 4.7 shows the number of deaths from infections and parasitic diseases; the data are wrongly presented because identical intervals on the horizontal axis have been used to represent different age ranges (1, 4, 5 and 10 years). Each curve in Figure 4.8, in the form of a frequency polygon, shows the relative frequency of death due to the specified cause in 10 different age groups. The graph is overcrowded and hence difficult to read.

Figure 4.7 ***Equal intervals on the horizontal axis for unequal data intervals***

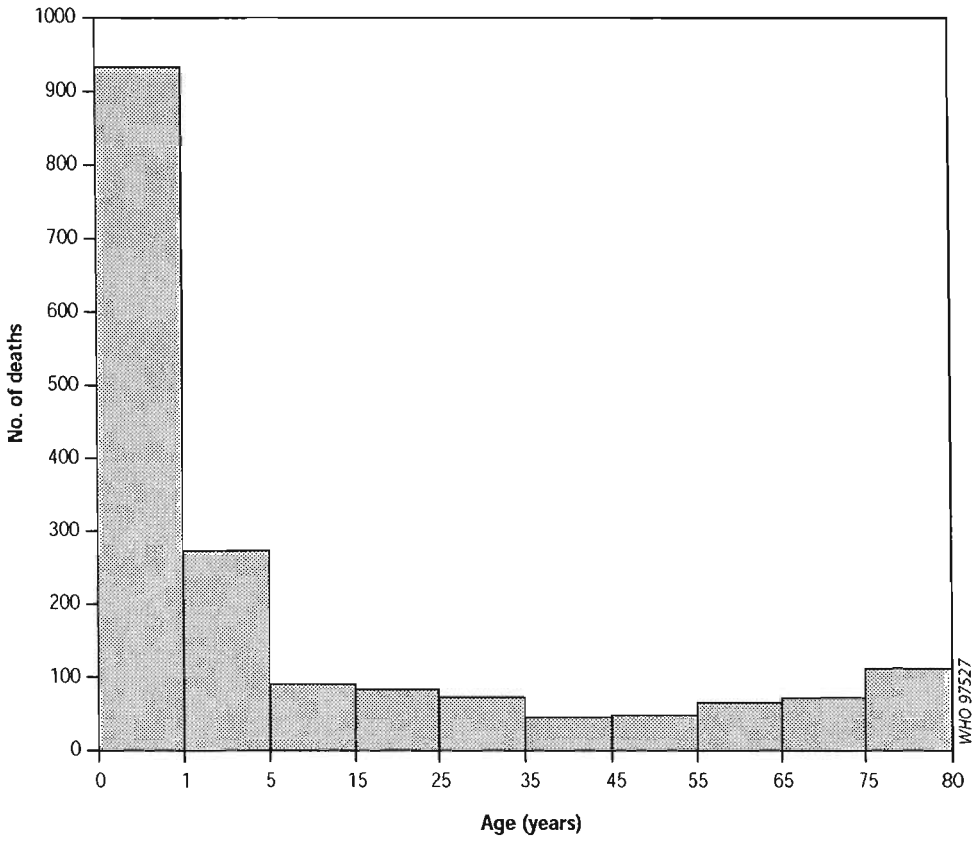
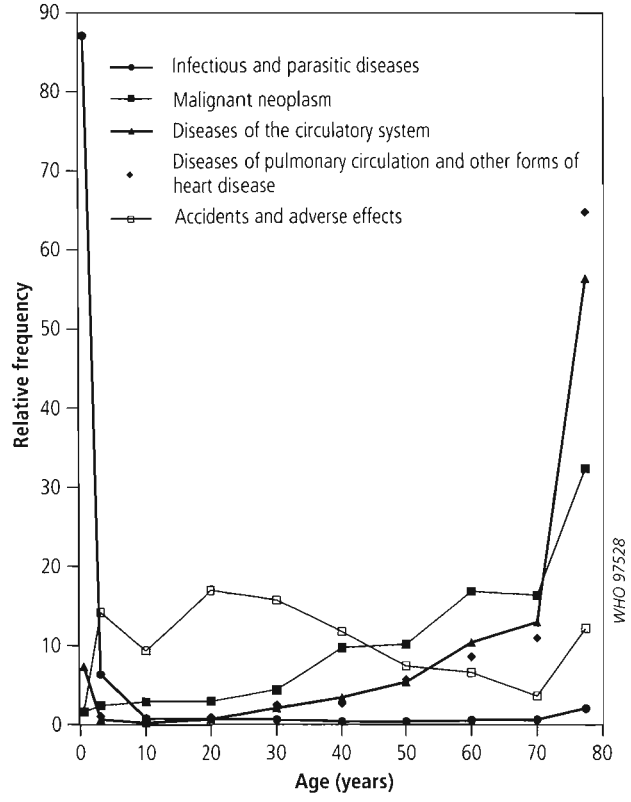


Figure 4.8 ***Crowded graph***



HANDOUT 4.3

Appropriate use of tabular and diagrammatic data presentation

The following is a summary of appropriate methods of data presentation depending on the situation.

Tabular methods

Data situation	Tabular method
Small data set of, for example, less than 20 in number	Ordered array
Individual observations, many in number, involving only one variable	Frequency table
Individual observations involving two or more variables	Cross-tabulation

Diagrammatic methods appropriate to tabular data

Tabular data	Diagrammatic method
Frequency table, quantitative variable, one set of data	Histogram or frequency polygon
Frequency table, quantitative variable, two sets of data	Frequency polygon
Frequency table, categorical data	Bar or pie chart

OUTLINE 5 Measures of central tendency and location

Introduction to the lesson

Sets of measurements cannot be meaningfully and adequately described by the values of all the individual measurements. Appropriate summary indices must therefore be obtained. One type of index describes the "central" point (for example, an average of the values), or the most characteristic value, of the measurements. These are the measures of central tendency and location.

Objective of the lesson

The objective of the lesson is to define, and discuss, the indices of central tendency and other locations (the mean, median, mode and quartiles), their use, interpretation and limitations.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain why summary indices are needed in medicine.

(*b*) Compute the mean, median and mode of a given set of data (grouped and ungrouped).

(*c*) Compute percentages for categorical data.

(*d*) Discuss, with examples, the uses and limitations of the mean, median and mode, and their relative advantages and disadvantages as summary indices of health data.

(*e*) Explain the use of quartiles and percentiles to summarize health data.

(*f*) Select an appropriate measure of central tendency and location for a given application.

(*g*) Differentiate between "average", "normal" and "ideal" values, with reference to health data.

Required previous knowledge

Contents of Outlines 1 to 4 and, if computers are to be used, basic knowledge of their use.

Lesson content

The lesson should cover the definitions, calculation, relative advantages and disadvantages, and appropriate data situations for use of the following:

Measures of central tendency

- Arithmetic mean
- Geometric mean
- Weighted mean

- Median
- Mode

Other measures of location

- Quartiles
- Percentiles
- Proportions

The teacher should be able to construct an outline of this lesson content with reference to the material in the proposed handouts. The following are illustrative examples of the computations of some of these descriptive statistics.

Examples (such as those given below or in Handout 5.2) should be used throughout the lesson. Examples based on real data, and on topics familiar to the students, would be preferable.

Example 1: Arithmetic mean, median, mode, quartiles and 50th percentile

Prior to an extensive health survey of a region in a certain country, the sampling procedure required some knowledge of the household sizes of the survey region. A (random) sample of 31 households was therefore selected and details of the number of residents in each household were as follows:

5 5 6 3 8 2 3 1 6 2

3 1 9 9 8 6 6 8 8 10

5 4 1 9 7 8 5 1 1 11

4

Calculate the arithmetic mean, median, mode, quartiles and 50th percentile of the number of residents per household.

Arithmetic mean

To calculate the arithmetic mean, there are two steps:

First step: add all values to obtain the total number of people in the households:

$5 + 5 + 6 + 3 + \ldots + 4 = 165.$

Second step: divide this total (165 people) by the number of households (31).

Thus the arithmetic mean is 165/31 = 5.32 persons per household.

Median

To determine the median household size, there are also two steps:

First step: arrange all values in order of their magnitude (this arrangement is called an array):

1, 1, 1, 1, 1, 2, 2, . . . 9, 9, 9, 10, 11.

Second step: select the value which divides this distribution into two halves (for example, the middle observation if the number of observations is

odd or the arithmetic mean of the two middle observations if the number of observations is even).

Thus the median value for this distribution is the 16th observation in this array, with a value of 5 persons.

Mode

This is the observation in an array with the highest frequency of occurrence.

Thus in the array of the household size data, there are two most frequently observed numbers of household residents, each presented by 5 households. These are households with single residents and households with 8 residents. There are, therefore, two modes, of 1 and 8 people per household.

The distribution is therefore described as bimodal. If there are more than two modes, then the distribution is said to be multimodal.

Quartiles

These are the observations in an array that divide the distribution into four equal parts. Therefore:

— the first quartile in the household data is the 8th observation in the array, with a value of 3 persons;

— the second quartile is the 16th observation in the array, with a value of 5 persons;

— the third quartile is the 24th observation in the array, with a value of 8 persons.

50th percentile

The percentiles are values in an array that divide the distribution into a hundred equal parts. Thus the 50th percentile in the household data is the 16th observation in the array, with a value of 5 persons.

Note that the 50th percentile corresponds to the second quartile and the median.

Example 2: Weighted mean

The mean ages (in months) of preschool children in different villages are presented in Table 5.1.

Table 5.1 ***Mean ages of preschool children in different villages***

Village	No. of children	Mean age (months)
1	54	58.6
2	52	59.5
3	49	61.2
4	48	62.5
5	48	64.5

Calculate the weighted mean age of preschool children in all the 5 villages.

Weighted mean

The mean age of all the preschool children is found in two steps:

First step: multiply the mean age for each village by the corresponding number of children in each village (weights), and add up the totals thus obtained:

$$(58.6 \times 54) + (59.5 \times 52) + (61.2 \times 49) + (62.5 \times 48) + (64.5 \times 48)$$
$$= 15353.2 \text{ months.}$$

Second step: divide the total cumulative age of the preschool children (obtained in the first step) by the total number of children in the villages:

15 353.2 months divided by 54 + 52 + 49 + 48 + 48

Thus the weighted mean age = $15353.2/251 = 61.17$ months.

The non-weighted mean ignores the fact that the number of children in each village is not the same (that is, unequal weights). In the above example, the non-weighted mean would be:

$$(58.6 + 59.5 + 61.2 + 62.5 + 64.5)/5 = 61.26 \text{ months.}$$

NEW TERMS AND CONCEPTS (see Handout 5.1)

Array; arithmetic mean; bimodal distributions; measures of central tendency and location; median; mode; multimodal distributions; percentiles; quartiles; summary indices; weighted mean.

Structure of the lesson

The following sequence may be followed for this lesson.

(*a*) Briefly review the relevant areas of data presentation already covered, in particular, frequency distributions, grouping of data and class intervals, and modality of frequency distribution.

(*b*) Explain the need for numerical summary indices. Simple examples on the uses of the indices of central tendency in the health field should be given throughout the lesson. Whenever "normal" values are referred to in medicine, these values are indices (bench-marks) of the variables in question (for example, "normal" temperature, "normal" weight for age, etc.). Discuss the meaning of the terms ideal, common, optimum, typical and usual in relation to the mean, median, and mode. For example, a value of the weights of a group of people (who may be poorly nourished) may be the average weight for the group, yet it may not be normal. Similarly, a normal value may not be ideal for healthy and productive living.

(*c*) Explain the limitations of the indices of central tendency and location, using health-related illustrative examples. Lack of sensitivity of the median and mode to some aspects of data distributions should be pointed out, together with their usefulness in describing skewed distributions. The effect of outliers to the mean should also be explained. Mention the need for other measures of location, such as quartiles or percentiles, in situations when the distribution is asymmetric or skewed.

(*d*) Illustrate the use of percentiles for child growth monitoring, using the standard growth-monitoring chart.

(*e*) When discussing the computation of the indices, emphasize the underlying principles rather than the need to memorize formulae. The role of computers as facilitators of the computations of these indices should be pointed out to the students. While use of computers should be encouraged, the processes of computing the mean, median and mode should be explained in detail.

(*f*) Procedural differences for grouped and non-grouped data should be pointed out. Explain that for non-grouped data, the indices represent directly the sets of data they refer to, whereas if indices are computed from grouped data, they are only approximations. The effect of the level of accuracy of the data on estimated means and median (based on grouped data) should, therefore, be discussed.

Determination of class mid-values, and assumptions concerning open-ended intervals, should be clearly explained.

Handout 5.1, giving definitions of the new terms and concepts introduced in this lesson, should preferably be given to the students before the lesson.

Lesson exercises

The exercises should emphasize the correct choice of the various measures of location and their interpretation. The teacher should, therefore, provide appropriate data to demonstrate the different types of distributions and for the calculation of indices.

■ The following are data of daily attendance at a health centre for the month of November 1992. The health centre is open all day for outpatient services from Monday to Friday and for mornings only on Saturdays, and is closed on Sundays except for emergencies.

Table 5.2 ***Data on the daily attendance at a health centre recorded for the month of November 1992***

Date & day	No. of patients	Date & day	No. of patients	Date & day	No. of patients
1 Sunday	24	11 Wednesday	50	21 Saturday	47
2 Monday	75	12 Thursday	80	22 Sunday	35
3 Tuesday	100	13 Friday	96	23 Monday	84
4 Wednesday	112	14 Saturday	58	24 Tuesday	90
5 Thursday	77	15 Sunday	22	25 Wednesday	87
6 Friday	74	16 Monday	98	26 Thursday	91
7 Saturday	50	17 Tuesday	76	27 Friday	86
8 Sunday	38	18 Wednesday	82	28 Saturday	49
9 Monday	103	19 Thursday	69	29 Sunday	30
10 Tuesday	110	20 Friday	79	30 Monday	94

(*a*) Calculate the mean, median and mode for daily attendance.

(*b*) Comment on the distribution on the basis of the values obtained in (*a*).

(*c*) Using a class-interval of 5, construct a frequency table of the daily attendance.

(*d*) From the table obtained in (*c*), calculate the mean and median.

(*e*) Compare and comment on the values of mean and median obtained in (*a*) and (*d*).

(*f*) Calculate the first quartile and the 75th percentile for the attendance.

(*g*) By which day of the month had the clinic seen 50% of the patient-load?

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HANDOUT 5.1

Definitions of new terms and concepts

Arithmetic mean: The sum of all values of a set of observations divided by the number of observations.

Geometric mean: A mean derived by multiplying together the n individual values in a series of observations and calculating the n^{th} root. The logarithm of the geometric mean is thus the arithmetic mean of the logarithm of individual values.

Measures of central tendency and location: Summary indices describing the "central" point, or the most characteristic value, of a set of measurements.

Median: Value that divides a distribution into two equal halves; central or middle value of a series of observations when the observed values are listed in order of magnitude.

Mode: The most frequently occurring value in a series of observations.

Multimodal distributions: Data distributions with more than one mode. Distributions with two modes are **bimodal**.

Percentiles: Those values in a series of observations, arranged in ascending order of magnitude, which divide the distribution into 100 equal parts (thus the median is the 50th percentile).

Quartiles: The values which divide a series of observations, arranged in ascending order, into four equal parts. Thus the second quartile is the median.

Summary indices: Values summarizing a set of observations.

Weighted mean: A mean for which individual values in the set are weighted, very often by their respective frequencies.

Examples of computation of mean and median for grouped data

Table 5.3 ***Systolic blood pressure for 240 men***[a]

Systolic blood pressure in mmHg (class interval)	Frequency (f)	Mid-value of the class (x)	Product (fx)	Cumulative frequency
Under 100	4	95[b]	380	4
100–	16	105	1680	20
110–	18	115	2070	38
120–	40	125	5000	78
130–	66	135	8910	144
140–	56	145	8120	200
150–	34	155	5270	234
160– and over	6	165[b]	990	240
Total	**240**	—	**32420**	—

[a] Data are given in mmHg, but may also be expressed in kPa (1 mmHg ≈ 0.133 kPa).
[b] These are assumed mid-values, with the lowest value being 90 and the highest value 170.

Mean

The approximate mean is the weighted average of the class mid-values:

i.e. 32 420/240 = 135.1 mmHg.

Median

The median blood pressure lies in the interval between 130 and 140 mmHg. It is the average of the 120th and 121st observations. Their estimated values are respectively:

$$130 + \left(120 - 78\right) \times 10/66 = 136.36$$

and $130 + \left(121 - 78\right) \times 10/66 = 136.52$

Therefore the median is 136.4 mmHg.

OUTLINE 6 Measures of variability

Introduction to the lesson

Knowledge of a single summary figure (such as any of the measures of central tendency discussed in Outline 5), for describing the characteristics of a population, is not enough without a measure of the extent of variability or spread of the measurements around this summary index. Health workers often have to decide whether to classify an individual as healthy or sick, suffering from a particular disease or not, needing treatment or not, etc. For this task, the so-called "normal" values of certain clinical, laboratory or radiological measurements provide the necessary yardstick. But the word "normal" value is a statistical concept and depends, to a great extent, on the distribution of the classifying attribute in the population. Measures of spread or dispersion or variability are, therefore, essential for understanding, using and interpreting this concept of "normal" values, and for a complete description of a given health data set. No description of any health data by summary indices is complete without the measures of variability.

Objective of the lesson

The objective of this lesson is to define and discuss the sources of variation in health data, and the various measures of variability, their use, interpretation and limitations.

Enabling objectives

At the end of this lesson, the students should be able to:

(*a*) Explain the meaning of a measure of variability or dispersion and its place in descriptive statistics.

(*b*) Explain the uses of the terms: range, inter-quartile range, variance, standard deviation and coefficient of variation, as measures of variability of health data.

(*c*) Compute the following, given either grouped or non-grouped data, with the aid of reference material:

- range;
- inter-quartile range;
- variance;
- standard deviation;
- coefficient of variation.

(*d*) Describe the relative advantages and disadvantages of the five indices listed above.

(*e*) Select an appropriate measure of variability for a given data situation.

(*f*) Discuss the concept of normality of health data in terms of mean, standard deviation and percentiles.

Required previous knowledge

All materials in the previous lessons in this series, particularly the meaning and interpretation of measures of central tendency, and other methods for data reduction and presentation, including patterns of distributions.

Lesson content

Need for measures of variability

(*a*) Inherent biological variations, as well as variations from a number of other sources, that lead to systematic or non-random variations in health measurements.

(*b*) The concept of summarizing variability in a single number, in order to facilitate comparison of variability between different groups.

(*c*) Uses of "normal values" and "normal range" in medical practice. Examples: systolic and diastolic blood pressure, pulse rate, heart rate, height, weight, serum cholesterol, haemoglobin levels.

(*d*) The concept of using variability as an indicator of homogeneity or heterogeneity of data.

Measures of variability (for definitions see Handout 6.1)

- Range
- Standard deviation
- Variance
- Coefficient of variation

Advantages, disadvantages, properties and uses of the measures of variation

Range

— Simple to calculate.

— Easy to understand.

— Extreme values are dependent on sample size.

— Not based on all observations, that is, takes no account of the variability of observations between the two extreme values.

— Not readily amenable to further mathematical treatment.

— Should be used in conjunction with other measures of variability; otherwise full frequency distributions, means, etc. should be given.

Variance, standard deviation, standard error

— Based on all observations.

— Deviations are taken from mean, that is, the measure of central tendency.

— Most widely used because of the properties of the theoretical normal curve, and because of the importance of variance in inductive statistics (see Outline 7).

— For standard deviation and standard error, the unit is same as the mean.

Coefficient of variation

— Used for the comparison of relative variability of two distributions.

— Measures level of variability in the data relative to the average value.

— It is independent of any unit of measurement, and thus useful for comparison of variability in two distributions having variables expressed in different units (for example, height expressed in centimetres for one distribution and weight in kilograms for the other).

— Takes into account each value of the distribution.

Establishing "normal" values for health data

The establishment of "normal" values permits the selection of appropriate actions in medical practice.

Variability is inherent in all biomedical measurements upon which decisions on individual patient care or community health programmes are based. It is therefore necessary to have established standards on which decisions can be based. These standards are often referred to as "normal values", and are generally based on measurements made on population groups categorized as "healthy". In statistical reasoning, what occurs most frequently is considered as "normal" and the problem is often where to draw a cut-off line between "normal" and "abnormal".

Two types of "normal" values are usually required for medical decisions: the "point normal" values and the "normal ranges". Point normal values are estimated by measures of central tendency (refer to Handout 5.1 for definitions of measures of central tendency and location). Normal ranges give the general level (in terms of an interval) of a characteristic for healthy population groups. Some people in the population will have exceptionally high or low values of a particular characteristic and yet apparently be perfectly healthy. These are called "outliers". Such exceptional values cannot be regarded as typical of the population group. Hence sometimes a few very extreme measurements are excluded from the computation of normal values.

Most biomedical normal ranges have been adopted to ensure that 95% of randomly selected healthy people would fall within the limits. Where a variable follows a unimodal and symmetrical distribution, it is easy to compute the normal range in terms of the mean and standard deviation (SD), by using the properties of the theoretical normal distribution. For example, for the normal distribution, the range, mean plus or minus 1 SD, covers approximately 68%, and mean plus or minus 1.96 SD includes approximately 95%, of the sampled population. For multimodal or asymmetrical distributions, the computation of the normal range can be quite involved, although the same principles apply.

Very often, normal values differ between geographical areas or between sexes or age groups. For example, "normal" blood pressure differs between sexes, and also varies with age, and its pattern is not the same in all human populations. A statement of normal values must therefore indicate the population referred to.

NEW TERMS AND CONCEPTS (see Handout 6.1)

Coefficient of variation; dispersion; normal values; range; standard deviation; standard error; theoretical normal (Gaussian) distribution; variance.

Structure of the lesson

The lesson may proceed in the following sequence.

(*a*) Recapitulate the various sources of variation as presented in Outline 1, and illustrate their cumulative effect on the validity and reliability of measurements in health data. Distinguish between random and systematic variations.

(*b*) Describe the nature of measures of variability or dispersion and their place in descriptive statistics. Differentiate between a summary index of central tendency and a summary index of dispersion, and explain their complementary roles in the study of any characteristic among a group of subjects (for example, as indicators of homogeneity and heterogeneity), and for comparison between different groups of subjects. Explain how variability may or may not be related to the magnitude of the variable, and hence differentiate between indices of absolute dispersion and of relative dispersion.

(*c*) Give the definitions and methods of computation of the different summary indices of absolute dispersion commonly encountered in the literature. These should include:

- index based on distributional positions (range);
- indices summarizing the squares of differences of individual values from the mean (sum of squares, variance or mean square, standard deviation);
- handling open-ended intervals for grouped data.

(*d*) Draw attention to the concept of a range of "normal" values, often determined arbitrarily as the interval spanning the central 95% of values in the frequency distribution (that is, the range from the 2.5 percentile to the 97.5 percentile), and explain how the standard deviation is often used to estimate this normal range in the form $\bar{x} \pm 1.96$ SD.

(*e*) Give special attention to this use of the standard deviation, which derives from the properties of the theoretical normal distribution or normal curve. Explain the concept of the standard normal deviate z (distance from the mean expressed in standard deviation units), and illustrate how percentiles of the normal distribution are related to values of z. Mention how the proportions of the normal distribution that lie within or outside various multiples of z below or above the mean (for example, $\bar{x} \pm$ SE, $\bar{x} \pm 1.96$ SE) can be used to determine the "normal" range of values. Discuss when and why the standard deviation may or may not be used in this way for empirical data (observed frequency distributions).

(*f*) Summarize the uses and limitations of the different measures of variability or dispersion.

Lesson exercises

The teacher should obtain data that can demonstrate variation in an attribute, such as a continuous variable, and ask the students to calculate the various measures of variation and to describe how they can compare variation in variables measured in different units.

■ The following data show duration of illness (in days) for 23 cases of pneumonia:

8, 10, 11, 11, 11, 8, 10, 10, 10, 12, 12, 14, 14, 15, 15, 17, 18, 6, 5, 4

Calculate the range, variance, standard deviation, and coefficient of variation for the above data.

Comment, with reference to the above data, on the advantages and disadvantages of the variance, standard deviation and coefficient of variation, as measures of variation.

■ Table 6.1 presents data on annual income, in US$, in 300 households, given in the form of a frequency distribution.

Table 6.1 ***Distribution of household annual income***

Household annual income (US$)	Frequency
Under 100	2
100–	4
200–	9
300–	10
400–	22
500–	68
600–	85
700–	58
800–	25
900–	8
1000–	6
1100–	2
1200 and over	1

Calculate the variance, standard deviation and coefficient of variation.

Comment on the distribution of household income.

Calculate within what income range the central 95% of the household annual income is likely to fall.

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Definitions of new terms and concepts

Coefficient of variation: Standard deviation expressed as a percentage of the mean (this is independent of the scale/unit of measurement).

Normal (or Gaussian) distribution: The continuous frequency distribution of infinite range with the following properties: it is bell-shaped; its mean, median and mode are identical; and it is completely defined by the mean and standard deviation.

Normal values: Values regarded as being within the usual range of variation in a given population or population subgroup. The range of such values is called the **normal range**.

Range: Difference between largest and smallest value in a series of observations. Calculated by: $R = x_{max} - x_{min}$, where x_{max} and x_{min} denote the largest and smallest values, respectively, in a series of observations.

Standard deviation (SD): Root mean square deviation, where deviations have been taken from the mean. This equals the square root of the variance, expressed in the units of the original observations.

Standard error (SE): Standard deviation of a statistic. For example, the standard error of the mean is the standard deviation divided by the square root of the sample size.

Variance: Sum of squared deviations, taken from the mean, divided by the number of observations n (or $n - 1$ for an unbiased sample variance), expressed in squares of the unit of the original observations.

OUTLINE 7 Introduction to probability and probability distributions

Introduction to the lesson

Health workers, particularly clinicians and health managers, often need to take specific decisions on individuals or communities based on available data. However, outcomes and responses to treatments or situations can rarely be predicted with certainty. Medicine, as an inexact science, is "probabilistic" as opposed to being "deterministic". Mathematical models are therefore often used to describe observed situations in the health field. Probability theory allows us to quantify the degree of "uncertainty" in our deductions. Hence the theory of probability underlies the methods for drawing statistical inferences in medicine.

Objective of the lesson

The objective of this lesson is to provide an understanding of the basic concepts of probability, that is sufficient to serve as background for the subsequent development of its uses in the interpretation of the results of medical studies and in decision-making.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain the meaning and definitions of technical terms used in the study of probabilities and probability distributions.

(*b*) Explain the terms: mutually exclusive, independent and dependent events.

(*c*) Explain and illustrate the operation of the addition and multiplication laws of probability, and their elementary uses in medicine.

(*d*) Differentiate between discrete and continuous probability distributions.

(*e*) Describe the data situations that lead to a binomial distribution.

(*f*) Describe the normal distribution and its properties.

(*g*) Apply values in probability tables (at this stage, tables of normal and binomial probabilities) to solve simple health problems (for example, setting up a "normal" range of values).

Required previous knowledge

Presentation of absolute and relative frequencies and distributions, frequency histograms and polygons, and curves representing distributional patterns.

Common summary indices used in descriptive statistics, including proportions, percentages, percentiles, means and standard deviations.

Lesson content

Concept of probability

- Definition of probability (subjective definition and the frequency concept).
- Definitions of technical terms (trials, experiments, outcomes, events, chance, odds; see Handout 7.1).
- Scale of measurement of probability and its interpretations.

Laws of probability

- Explanations of simple and compound events.
- Mutually exclusive and independent events.
- The addition and multiplication rules.
- Dependent events and definition of conditional probability.

Probability distributions

- Discrete probability distributions (binomial).
- Continuous probability distributions (normal).
- Properties and uses of the distributions.

NEW TERMS AND CONCEPTS (see Handout 7.1)

Additive law of probability; binomial coefficients; binomial distribution; conditional probability; dichotomous independent events; inductive statistics; multiplication law of probability; mutually exclusive events; population; probability; probability distribution; relative frequency; statistical inference.

Structure of the lesson

The students do not need to know probability theory in detail, but should be acquainted with some of its basic concepts, principles, rules and applications.

The lesson content may be presented in the following sequence.

(*a*) Introduce the idea of subjective probability in everyday life, which is not usually quantified.

(*b*) Explain the range of values for probabilities (0–1) and the interchangeable use of the terms "chance" and "probability".

(*c*) Briefly review the uses of the descriptive statistical methods already learned, and introduce the concept and meaning of inductive statistics, illustrating with medical data (for example, how criteria of abnormality used in diagnosis are based on descriptive information but applied to new patients).

(*d*) Explain the meaning of such terms as trials, outcomes, events, experiments.

(*e*) Explain the relationship between probability and observed proportions in data on a dichotomous attribute.

Example: what is the chance of finding a person with Type A blood, or the chance of an unborn child being male?

Explain the concepts of independent and of mutually exclusive events, and illustrate how the additive and multiplication laws of probability operate.

Example: if two diseases are "independent" what is the probability of finding a person with both diseases? What is the chance that a patient with fever has malaria or typhoid? (See Handout 7.1 for a definition of independent events.)

Introduce the concept of a dichotomous population and the data situation for the binomial probability distribution of a discrete random variable.

With reference to dichotomous medical data, discuss the possible outcomes, and their probabilities, in a small sample of n observations.

Example: if treatment of a given disease is effective in 70% of cases, and you have treated 5 cases of this disease (that is, $p = 0.7$ and $n = 5$), what are the chances that the treatment was effective in none of them, one of them, two of them, etc.? (Refer to the worked example in Handout 7.2.)

From the table of computed values of probabilities (Table 7.1, Handout 7.2) for each of the possible outcomes, obtain the cumulative probabilities (upwards and downwards), and give the probabilities of finding less than or more than a specified number of "successes".

Example: from the data in Table 7.1, Handout 7.2, what are the chances of having more than 3 treatment successes among 5 patients?

Explain the derivation of these "binomial probabilities" using the binomial equation with reference to the material in Handouts 7.1 and 7.2.

Give other medical examples involving dichotomous attributes to which the binomial probability distribution can be applied. (Prepare worked examples for other values of n and p if needed.)

(*f*) Explain the general concept of continuous probability distributions and cumulative probability distributions. Review the properties of the normal distribution and discuss the standardized normal distribution (mean = 0, variance = 1). Using a table of "areas under the normal curve" (refer to Annex B, table B.1), explain how to determine the probability of finding values less than or greater than various specified values of z, with reference to medical examples. (Even if this has previously been done, for example, after the lessons on the mean and the standard deviation, it should be recalled at this stage to reinforce and demonstrate the application. Link this to the setting up of a normal range of values.)

(*g*) It is recommended that three handouts be given to the students for use during the lesson:

- Handout 7.1, covering probability and probability distributions, two basic rules of probability, and the binomial probability distribution.
- Handout 7.2, giving worked examples of binomial probability distributions:

  for $n = 5$ and $p = 0.7$ for reference during the lesson;

  for $n = 10$ and $p = 0.5$ (or other values of n and p) for reference during practical work.
- Table B.1 in Annex B, presenting a table of areas under the normal curve.

Lesson exercises

The teacher should prepare exercises that test the students' ability to apply the frequency distribution definitions to calculate probability of events; and demonstrate the application of the

laws of probability and the binomial probability distribution with particular reference to health problems.

To demonstrate and reinforce the concept of a sampling distribution and to show how it is governed by laws of probability, let the students generate an empirical (observed) sampling distribution and compare it with the theoretical (expected binomial) distribution. One way of doing this is to use coloured beads to represent persons with different attributes in a population. Give examples of dichotomous medical attributes that can be represented by beads of two colours, say black and white, for example, genetic traits (sickle cell anaemia, blood grouping, etc.).

■ From a box containing a large number of beads of two colours (for example, black and white), let each student take a random sample of a given size n (for example 5); tabulate the number of black (or white) beads seen in each sample. This gives an observed sampling distribution.

Given the actual proportion of black (or white) beads in the box, calculate the binomial probability distribution for sample size n. Hence calculate the expected sampling distribution for the observed number of samples.

Compare and comment on the observed and expected sampling distributions.

The goodness-of-fit will be tested later when the students have learned about the chi-squared test.

The following exercise is designed to demonstrate the application of the laws of probability and the binomial probability distribution.

■ Give data on prevalence of various attributes (for example, diseases) in a population, and ask questions on the probability of a person having or not having various combinations, or all, or none, of these attributes.

Ask questions about the expected number of 2- or 3-child families that have various numbers of sons or daughters.

Give an exercise to show the role of probability statements in the context of a diagnostic test, for example, concerning its specificity, sensitivity or predictive value.

■ Supposing that a midwife delivering babies at a maternity home does not know the sex of the baby until it is delivered, how can one determine the probability of delivering a male baby, using data from the maternity home?

■ For a couple desiring to have a baby boy following three female births, if it is known that the chance of a pregnancy resulting in a male baby is 0.5, what is the chance that the fourth pregnancy will result in a male birth?

■ If in a hospital, over a period of three years, 27 out of 30 babies with neonatal tetanus have died, what is the probability that a neonate with tetanus will survive if there has not been any change in how tetanus is managed?

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Definitions of new terms and concepts

Concepts in probability and inductive statistics

Conditional probability: The chance of a particular event happening depends on the outcome of some other event. $P(B/A)$ = the probability that event B occurs, given that event A has already occurred.

Descriptive statistics: Statistical methods that deal with description of characteristic(s) about a finite study group.

Dichotomous attribute: A characteristic classified into only two categories, usually the presence or absence of a defined condition (for example, sick or not sick; improved or not improved). Some characteristics are inherently dichotomous by nature (for example, male/female, alive/dead), but all characteristics, whether or not inherently so, can be "dichotomized" by defining and identifying one subgroup and putting all other observations into a second (residual) subgroup.

Dichotomy: Division into two mutually exclusive subclasses.

Event: One of the outcomes of a trial or an experiment.

Simple event: Event that cannot be broken down into any other components.

Compound event: Consists of at least two events.

Independent events: Two events are said to be independent if the presence or absence of one does not alter the chances of the other being present, or if the occurrence of one does not alter the chance of occurrence of the other.

Mutually exclusive events: Events that cannot occur simultaneously or be present at the same time.

Odds: The ratio of the probability and its complement (i.e. $p/(1 - p)$).

Outcome: The results of a trial (experiment).

Probability: An event's long-run relative frequency in repeated trials under similar conditions.

Scale of probability measurement: Probability can be measured on a continuous scale of values between 0 and 1 (inclusive). An event that is impossible is said to have a probability of occurrence of 0, and an event that is certain to occur has a probability of occurrence equal to 1. An event with a probability greater than 0.5 is more likely to occur than not. The notation $P(A)$ represents the probability of occurrence of the event A.

Trials: Experiments in which results cannot be predicted in advance.

Two basic rules of probability

Addition rule: If an event is satisfied by any one of a group of mutually exclusive outcomes, the probability of the event is the sum of the probabilities of the outcomes in the group, that is,

$$P(\text{A or B}) = P(\text{A}) + P(\text{B})$$

Multiplication rule: In a series of independent trials, the probability that each of a specified series of events happens is the product of the probabilities of the individual events, that is,

$$P(\text{A and B}) = P(\text{A}) \cdot P(\text{B})$$

Binomial distribution

The binomial distribution is formed by the terms of the expansion of the binomial expression:

$$(p+q)^n,$$

where n = sample size, p = the probability of a "success", q = the probability of a "failure", and $p + q = 1$.

Examples:

When $n = 2$, the terms of the expansion of $(p+q)^2$ are p^2, $2pq$ and q^2.

When $n = 4$, the terms of the expansion of $(p+q)^4$ are p^4, $4p^3q$, $6p^2q^2$, $4pq^3$, and q^4.

Worked example of a binomial probability distribution

The binomial equation for the probability of specified outcomes of an event

The probability of observing r successes in n independent repeated trials, given that the probability of a success in each trial (p) and the probability of a failure (1-p) is the same from each trial, can be obtained from the equation:

$$P(r \text{ successes}) = \left[n! \Big/ \left((n-r)!\, r!\right)\right] \cdot p^r \cdot (1-p)^{n-r}$$

where $n!$ is n factorial $= n(n-1)(n-2)\ldots(2)(1)$

and $0! = 1$ by definition.

At the height of the drought in a given region, it was estimated that 70% of the children under 10 years old were severely malnourished. If five children, under 10 years old, were selected at random from the region, what is the probability that: all, 4, 3, 2, 1, 0, are severely malnourished?

Table 7.1 ***Binomial probabilities***

Number malnourished	Terms of binomial expansion	Probability
5 (all)	p^5	0.16807
4	$5p^4q$	0.36015
3	$10p^3q^2$	0.30870
2	$10p^2q^3$	0.13230
1	$5pq^4$	0.02835
0 (none)	q^5	0.00243

In this table we have: $n = 5$; $p = 0.7$; $q = 0.3$.

Applying the binomial equation:

- When all children are malnourished, then $r = 5$;

$$\text{hence } P(r=5) = \left[5! \Big/ (5-5)!\, 5!\right] \times 0.7^5 \times (1-0.7)^{5-5}$$
$$= 0.7^5$$
$$= 0.16807.$$

- When 3 children are malnourished, then $r = 3$;

$$\text{hence } P(r=3) = \left[5! \Big/ (5-3)!\, 3!\right] \times 0.7^3 \times (1-0.7)^{5-3}$$
$$= 5 \times 2 \times 0.7^3 \times 0.3^2$$
$$= 0.30870.$$

OUTLINE 8 Sampling and estimating population values

Introduction to the lesson

Whenever we infer the characteristics of other persons in the population at large from those of a finite group which we have studied, we are making use of information about samples to draw conclusions or make inductive inferences. Such information has some limitations regarding reliability, precision and validity. Information based on limited samples constitutes most, if not all, of the medical knowledge that we have of human populations.

Objective of the lesson

The objective of this lesson is to enable the students to understand the concepts of population, samples, sampling methods, sampling errors and estimation problems, and drawing inferences on the basis of probability.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) State the reasons for sampling with the different sampling methods.

(*b*) Distinguish between probability and non-probability sampling.

(*c*) Differentiate between sampling and non-sampling errors.

(*d*) Differentiate between statistics and parameters.

(*e*) List possible advantages and disadvantages of collecting health information through samples.

(*f*) Discuss the relative advantages and disadvantages of each of the following sampling methods, as applied to the design of a health survey:

- probability (random) sample;
- simple random sample;
- stratified random sample;
- systematic sample;
- cluster sample;
- multistage sample.

(*g*) Calculate the standard error of the sample mean or proportion, given the relevant data and formulae.

(*h*) Differentiate between point and interval estimates of health indices.

(*i*) Explain the concept of the central limit theorem.

(*j*) Explain the meaning and application of confidence limits of an estimate of health indices.

(*k*) Explain how sampling error is related to sample size and to variability of the characteristic under study.

(*l*) State the information needed to estimate the minimum sample size for a health survey.

Required previous knowledge

Concept of probability, measures of central tendency and variability.

Lesson content

The concept of sampling

- Population (universe)
- Sample
- Sampling
- Reasons for sampling
- Sampling unit
- Sampling frame
- Sampling fraction
- Unit of inquiry
- Probability and non-probability sampling

Sampling and non-sampling errors

- Sampling variation
- Concept of bias
- Methods for minimizing sampling errors
- Methods for controlling non-sampling errors

Sampling distributions

- Meaning of parameters and statistics
- The central limit theorem

Advantages and disadvantages of using sampling methods to collect health data

Sampling methods and their advantages and disadvantages

- Simple random
- Stratified random
- Systematic
- Cluster
- Multistage

Estimation

- Concept of standard error
- Point and interval estimation (mean and proportion)

- Precision
- Determination of minimum sample size

NEW TERMS AND CONCEPTS (see Handout 8.1)

Bias and selection in sampling; cluster sampling; confidence limits; confidence range; difference between sampling and non-sampling error; dummy tables; estimation of a population mean; estimation of a population proportion; health survey; level of confidence; method of sampling; multistage sampling; point and interval estimates; population (universe); population parameter; precision of estimates; pre-coded data; probability sampling; quality of sample; representativeness of a sample; sample statistic; sampling error; sampling fraction; sampling frame; sampling unit; self-coding record forms; self-selected or natural samples; standard error; statistical estimation; stratified random sampling; survey questionnaire; systematic sampling; validity of estimates; unit of inquiry.

Structure of the lesson

The lesson content may be presented in the following sequence:

Concept of sampling

Explain the concept of population, sample and sampling, giving the reasons for sampling: limited resources available for estimation, lack of access to total population, or sampling may be the only feasible method of collecting the information.

Also explain the following terms: sampling frame, sampling unit, sampling fraction.

Explain the characteristics of a good sample (the sample must be selected at random to reduce bias, be representative to improve validity, and be large enough to increase precision).

Distinguish between random sampling and non-random (purposive) sampling.

Sampling and non-sampling errors

Explain sample statistics and population parameters.

Describe the use of sample statistics as estimates of population parameters. Owing to chance, different samples give different results, a phenomenon called sampling variation. Sampling errors and the concept of bias must be explained.

Explain the concept of sampling error: the unavoidable difference between the value of a sample statistic and the corresponding population parameter. An increase in sample size results in a reduction in the sampling error. Non-sampling errors are systematic errors during estimation. Give examples of non-sampling errors and how they can be reduced.

Sampling distributions

Explain the concept of a sampling distribution using simple examples, without invoking mathematical statistics. Explain the differences between a parameter and a statistic, and that every sample statistic belongs to a sampling distribution.

Describe the principles and applications of the central limit theorem which states that, for all variables, whether normally distributed or not, the sample mean will tend to be normally distributed.

Advantages and disadvantages of sampling

Give examples to demonstrate that, by using a well chosen and reasonably large sample, the estimates will be close to the expected values and the sample will cover the study population adequately. The advantages and disadvantages set out in Handout 8.2 should also be discussed.

Methods of sampling, their advantages and disadvantages

The various methods of sampling must be explained and their relative advantages and disadvantages should be discussed (see Handout 8.2).

Simple random sampling is useful when the sampling frame is well described and not too large. Systematic sampling requires a list of the sampling units or that sampling units are in an ordered sequence. Cluster sampling is useful when sampling units form logical groupings and when the sample frame is difficult to obtain.

Estimation

Explain the concepts of statistical estimation. The following should be covered:

- The context of statistical estimation: the need to estimate population parameters from sample statistics; the problem posed by sampling error for making reliable estimates; the concepts of point and interval estimation; validity and precision of a statistical estimate.
- The concepts of confidence limits and level of confidence: the connection between sampling distributions, confidence limits and levels of confidence. Interval estimation: estimation of a population parameter in terms of an interval that has a specified probability of containing the true value. The interval is the confidence interval, and the limits are the confidence limits.
- The estimation of normal anthropometric values for a population, with examples; estimation of mean birth weight from hospital births; and estimation of disease prevalence in morbidity surveys.

Determination of minimum sample size[1]

Discuss the various factors that determine minimum sample size. Describe the use of the equations given in Handout 8.3 to estimate the sample size required to achieve a desired precision for an estimate, expressed in terms of a confidence range. The following should also be covered:

- The relation between confidence limits and standard error: the meaning of standard error; the basis for derivation and distribution of confidence limits in terms of the standard error.
- Computation of the standard error of the mean and proportion, with examples from the literature to illustrate their computation and use in statistical estimation.

Lesson exercises

The exercises for this lesson should focus on helping the students crystallize the concepts of sampling and estimation of population values covered in the lesson. The emphasis should not be on correct memorization of formulae but on their appropriate use and interpretation of the results. The exercises should, in particular, cover all the major points indicated in the enabling objectives of the lesson (reasons for sampling, the advantages and disadvantages of the different sampling methods, interpretation of confidence interval, etc.).

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[1] See Lwanga SK, Lemeshow S. *Sample size determination in health studies: a practical manual*, Geneva, World Health Organization, 1991.

■ What sampling method would you recommend in the following instances?

- Determining the proportion of undernourished five-year-olds in a village.
- Investigating nutritional status of preschool children.
- Selecting maternity records for the study of previous abortions or duration of postnatal stay.

■ In the estimation of immunization coverage in a province, data on seven children aged 12–23 months in 30 clusters are used to determine the proportion of fully immunized children in the province.

- Give three reasons why the cluster sampling method is used in such a survey.
- Give two sources of systematic error and two sources of random error that may be associated with an immunization coverage survey.
- In the immunization coverage survey, the 30 villages are selected by systematic sampling. If the investigator uses 30 clusters that are easy to reach, what is the type of sampling method in this case, and what possible sampling errors would be associated with the method?

■ If the results obtained from an immunization survey indicate that 48% of the children were fully immunized (standard error 3%), calculate the 95% interval estimate of fully immunized children in the study.

■ In a family planning clinic, there are 2500 clients. Suppose the anticipated prevalence of HIV infection is 3% and the investigator is willing to accept an absolute error of 1%. What is the minimum sample size required to estimate the prevalence of HIV with 95% confidence?

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HANDOUT 8.1

Definitions of new terms and concepts

Confidence limits: The upper and lower limits of the interval in interval estimation. The interval itself is called the confidence interval or confidence range. Confidence limits are so-called because they are determined in accordance with a specified or conventional level of confidence or probability that these limits will in fact include the population parameter being estimated. Thus, 95% confidence limits are values between which we are 95% confident that the population parameter being estimated will lie. Confidence limits can often be derived from the **standard error**.

Interval estimation: Providing an estimate of a population parameter in terms of an interval or range of values within which it is likely to lie.

Level of confidence: Conventionally 95% or 0.95, but may be set higher or lower as desired.

Point estimation: Providing an estimate of a population parameter in terms of a single value that it is most likely to have. A point estimate is usually provided by a sample statistic. By itself, point estimation ignores sampling error.

Population: Any specified group (usually large) of persons, things, or measurement values.

Population parameter: A descriptive index whose value refers to the population at large, as opposed to a sample of the population (for example, a population mean or population proportion).

Precision of an estimate: The inverse of the standard error of the estimate. The less the sampling error that is likely to occur, the greater the precision; that is, the smaller the confidence range, the greater the precision. Hence, precision can be specified in terms of the confidence range or the standard error.

Sample: A subset of a population, whose properties have been, or are to be, generalized to the population.

Sample statistic: A descriptive index, the value of which is obtained from observations in a sample (for example, a sample mean or a sample proportion).

Sampling: The process of selecting a sample from a population.

Sampling distribution: The distribution of probabilities with which sampling error of different magnitudes can occur purely by chance for a particular sample statistic and sample size. It can be demonstrated experimentally by tabulating the values of the same sample statistic obtained from repeated samples of the same size taken randomly from the same population. It can also be calculated theoretically (for example, using the binomial or the normal sampling distribution). Every sample statistic is a member of a sampling distribution, that is, the distribution of values of that statistic that can be expected to occur in different samples of the same size drawn randomly from the same universe.

Sampling error: A difference that occurs purely by chance between the value of a sample statistic and that of the corresponding population parameter (for example, the difference between the value of the mean of a random sample and that of the universe). Sampling error cannot be avoided or totally eliminated, and must always be allowed for when making inferences or drawing conclusions from sample statistics. It can be reduced by increasing sample size or using a more appropriate sampling method.

Sampling fraction: The proportion of sampling units to be selected from a specified sampling frame for inclusion in the sample.

Sampling frame: The set of sampling units from which a sample is to be selected. For example, a list of names, or places, or other items to be used as sampling units.

Sampling unit: The unit of selection in the sampling process. For example, a person, a household or a district. It is not necessarily the unit of observation or study.

Standard error (SE): The standard deviation of a statistic.

Unit of inquiry: Smallest unit on which data are collected.

Universe (of a sample): The population of values, of which the values observed in the sample are a random sample, and to which the properties of the sample can validly be generalized. The universe of a sample may be an abstract or a real population of values, and it may be finite or infinite, depending on the type of sample and the nature of the information under study.

Validity of an estimate: The extent to which an estimate corresponds to the parameter it is estimating. It depends, not on the size of the sample, but on the representativeness of the sample. Hence it depends on the type or nature of the sample, how it was selected, and on the accuracy of the information from which it was calculated and of the calculation itself.

Methods of sampling, and their advantages and disadvantages

Sampling

Advantages	Disadvantages
• Sampling reduces demands on resources such as finance, personnel and materials. • Results are obtained more quickly. • Sampling may lead to better accuracy of collected data; a smaller sample allows more effort to be made to reduce non-sampling errors and non-response biases. • Precise allowance can be made for sampling error (which can be found by calculation), although not for non-sampling errors.	• There is always a sampling error. • Sampling may create a feeling of discrimination within the population. • Sampling may be inadvisable where every unit in the population is legally required to have a record. • For rare events, small samples may not yield sufficient cases for study.

Probability sampling

- All individuals (elements) in the population have a known chance (probability) of selection. The chance of selection need not be the same for each individual or element.
- The knowledge of the selection probability is in contrast with the situation for non-probability sampling techniques, such as quota and chunk sampling.
- There must be an identified sampling frame, whether of individual elements or clusters of elements, from which the sample is to be drawn.

Simple random sampling

- Every sample of the same size has the same chance of being selected.
- Every sampling unit in the sampling frame has the same chance of being selected.
- Random selection from the sampling frame can be done by balloting, using a table of random numbers, or employing a computer.

Advantages	Disadvantages
• Because every unit in the population has an equal chance of being included in the sample, the sample is assured of being representative and subject only to sampling error. • Estimates are easy to calculate.	• If the sampling frame is large, this method may be impracticable because of the difficulty and expense of constructing or updating it in large-scale surveys. • Minority subgroups of interest in the population may not be present in the sample in sufficient numbers for study.

Stratified random sampling

- The population is first divided into groups or strata according to a characteristic of interest (for example, sex, age, geographical location).
- A simple random sample is then selected from each stratum using the same sampling fraction, unless otherwise prescribed for special reasons.

Advantages	Disadvantages
• Every unit in a stratum has the same chance of being selected. • Using the same sampling fraction for all strata ensures proportionate representation in the sample of the characteristic being stratified. • Adequate representation of minority subgroups of interest can be ensured by stratification and by varying the sampling fraction between strata as required.	• The sampling frame of the entire population has to be prepared separately for each stratum. • Varying the sampling fraction between strata, to ensure selection of sufficient numbers in minority subgroups for study, affects the proportional representativeness of the subgroups in the sample as a whole.

Systematic sampling

- Involves the selection of every k^{th} unit in the population or the sampling frame, where $1/k$ is the sampling fraction.
- The first unit to be selected is selected at random from among the first k units.

Advantages	Disadvantages
• The sample is easy to select. • A suitable sampling frame can be identified more easily. • The sample is evenly spread over the entire reference population.	• The sample may be biased if a hidden periodicity in the population coincides with that of the selection. • It is difficult to assess the precision of the estimate from one survey.

Cluster sampling

- The population is first divided into clusters of homogeneous units, usually based on geographical contiguity.
- A sample of such clusters is then selected.
- All the units in the selected clusters are then examined or studied.

Advantages	Disadvantages
• Cuts down on the cost of preparing a sampling frame. • Cuts down on the cost of travelling between selected units. • Eliminates the problem of "packing" (in health surveys, especially those involving case finding and treatment, it is not unusual for neighbouring houses not included in the sample to transfer their households temporarily to a selected house).	• Sampling error is usually higher than for a simple random sample of the same size.

Multistage sampling

- Selection is done in stages until the final sampling units (for example, households or persons) are arrived at.
- In the first stage, a list of large-sized sampling units is prepared. These may be towns, or villages or schools.
- A sample of these is selected at random, with probability of selection proportional to size.
- For each of the selected first-stage units, a list of smaller sampling units is prepared. (For example, if the first-stage units are towns, then second-stage units may be houses or households.)
- A sample of these second-stage units is then randomly selected from each of the selected first-stage units. These are then studied.
- The procedure may contain three or more stages.

Advantage	Disadvantage
• Cuts down the cost of preparing a sampling frame.	• Sampling error is increased compared with a simple random sample of the same size.

Examples of sample size determination

Determination of minimum sample size

The minimum sample size (n) depends on the:

- objective;
- design of the study;
- plan for statistical analysis;
- accuracy of the measurements to be made (d);
- degree of precision required for generalization;
- degree of confidence with which to conclude.

With simple random sampling, for a given magnitude of confidence interval, the precision (z) can be measured by:

$$z = d/\text{SE}.$$

If we want a 95% confidence interval, z must be 1.96 (see Table B.1, Annex B). Since the SE depends on n, we can calculate the value of n required to achieve the chosen level of confidence.

If s is the sample estimate of the population standard deviation (see Outline 6), then the standard error (SE) of the mean, for a sample of size n, is $s/\sqrt{n}$.

For estimating a population mean, with $\text{SE} = s/\sqrt{n}$, the minimum required sample size, in general, is:

$$n = s^2/\text{SE}^2 = z^2s^2/d^2.$$

For a population of size n, involving a binomial distribution with probability p (see Outline 7), let a individuals be observed with the relevant characteristics. Then the standard error of the estimate of p (that is, a/n) is $\sqrt{(pq/n)}$, where $q = 1 - p$.

Since $\text{SE} = \sqrt{(pq/n)}$,

$$n = pq/\text{SE}^2 = z^2pq/d^2.$$

These results apply only if sampling is from a very large (theoretically *infinite*) population, where the ratio of the sample size to the population size is very small.

If sampling is from a finite population of size N, then the minimum sample sizes are:

$$n = z^2s^2/\left(d^2 + z^2s^2/N\right),$$

for estimating the mean, and:

$$n = z^2pq/\left(d^2 + z^2pq/N\right),$$

for estimating p in the binomial distribution.

If n_0 is the sample from an infinite population, the finite population sample size is:

$$n = n_0/(1 + n_0/N).$$

Sampling for a quantitative characteristic

When sampling for a quantitative characteristic (for example, the mean level of haemoglobin in a population), one needs to state:

— how precisely one wishes to estimate this mean level; that is, the amount of sampling error that can be tolerated (d), in either absolute or relative terms;

— the standard deviation (s) of the distribution of haemoglobin in the population;

— the chance the experimenter is willing to take to get an unlucky sample giving a sampling error greater than d; a 5% chance of error (that is, a 95% confidence interval) is conventional.

This means that $x \pm d$ are the required 95% confidence limits, so that $d = 1.96$ SE, where SE $= s/\sqrt{n}$. Hence, $d/1.96 = s/\sqrt{n}$, and therefore the required (minimum) sample size for a very large population is given by:

$$n = (1.96)^2 s^2/d^2.$$

Example 1

A health officer wishes to estimate the mean haemoglobin level in a defined community. Preliminary information is that this mean is about 150 mg/l with a standard deviation of 32 mg/l. If a sampling error of up to 5 mg/l in the estimate is to be tolerated, how many subjects should be included in the study?

Here, $s = 32$ mg/l, and $d = 5$ mg/l.

If the population is assumed to be very large, the required minimum sample size would be:

$$n = \left[(1.96)^2 \times (32)^2\right]/(5)^2 = 157.4.$$

Thus, the study needs at least 158 persons.

If the community to be sampled has 1000 people, the required minimum sample size would be:

$$n = (1.96)^2 \times (32)^2/\left[(5)^2 + (1.96)^2 \times (32)^2/1000\right] = 136.0.$$

Therefore at least 136 people would have to be studied. For a larger community with, for example, $N = 3000$ people, the required sample size would be:

$$n = (1.96)^2 \times (32)^2/\left[(5)^2 + (1.96)^2 \times (32)^2/3000\right] = 149.5.$$

At least approximately 150 people would have to be studied.

Sampling for an attribute

When sampling for an attribute (to estimate the proportion of persons with a certain characteristic in a population) one needs to state:

— a rough approximation to the proportion (p);

— the sampling error that can be tolerated (d) in either absolute or relative terms;

— the acceptable chance of an unlucky sample (conventionally 5%).

The minimum sample required, for a very large population, is then:

$$n = (1.96)^2 p(1 - p)/d^2.$$

Example 2

If $p = 0.26$, and $d = 0.03$, then, for a very large population:

$$n = (1.96)^2 \times 0.26 \times 0.74/(0.03)^2 = 821.2.$$

Thus, the study should include at least 822 persons.

If the sample were from a relatively small population of, for example, 3000 people, the required minimum sample could be obtained from the above estimate by adjustment as:

$$821.2/(1 + 821.2/3000) = 644.7.$$

Thus the study should include at least 645 people.

OUTLINE 9 Tests of statistical significance

Introduction to the lesson

Tests of significance are standard statistical procedures for drawing inferences from sample estimates about unknown population parameters. Sample estimates are never exact, being subject to sampling errors. In the design of any medical research, attempts are made to reduce these sampling errors. Tests of significance allow us to decide whether the sample estimates, or the differences between estimates, are within their normal biological variation, commonly called variability due to chance.

Chance variation can give rise to differences between samples being studied, and so every time a difference is observed the question arises as to its statistical significance, that is, whether the difference is unlikely to have occurred purely by chance alone.

Objective of the lesson

The objective of this lesson is to enable the students to understand the meaning and application of tests of significance and their role in statistical inference. Emphasis is placed on their uses and interpretation rather than on the theory and methodology of the tests.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain the context and meaning of statistical hypothesis.

(*b*) Explain when, and why, a test of significance needs to be carried out.

(*c*) Explain the procedures for carrying out tests of significance.

(*d*) Differentiate between type 1 and type 2 errors in hypothesis testing.

(*e*) Explain the possible outcomes of a test of statistical significance and their respective interpretations in relation to the context of the test.

(*f*) Differentiate between statistical and medical significance.

(*g*) Select an appropriate test statistic for the comparison of two means, for independent and dependent samples.

(*h*) Select an appropriate test statistic for the comparison of two proportions.

(*i*) Carry out an appropriate test of statistical significance for the difference between two means, for independent and dependent samples.

(*j*) Carry out an appropriate test of statistical significance for the difference between two proportions.

Required previous knowledge

The students should have covered the material in all preceding lessons. It is desirable, at the beginning of this lesson, to stress and check that the students have attained the enabling

objectives of Outlines 6 and 7 and, in particular, that they have understood the concepts of sampling error and sampling distributions (Outline 8).

Lesson content

Construct an outline of the lesson with reference to the definitions and explanations of new terms and concepts in Handout 9.1, with the following content.

Nature of statistical hypothesis

- The null and alternative hypothesis
- Need to test the null hypothesis
- The meaning of a test of significance

Situations for tests of significance

- Comparison of sample estimates against a specified standard
- Comparison between two sample estimates

Procedure for testing statistical hypothesis

- State the null hypothesis
- State the alternative hypothesis (indicate 1-tail or 2-tail)
- State the level of significance (explain type 1 and type 2 errors)
- Choose the test statistic (explain parametric and non-parametric tests)
- Compute the numerical value of the test statistic from the observed data
- Compare the calculated value of test statistic with tabulated values in appropriate standard distribution tables at a specified probability level of significance
- Decide whether or not to reject the null hypothesis according to the p-value

Interpretation of results of p-values

- Statistical significance versus medical importance or significance
- Role of sample size in determining statistical significance

Comparison of two mean values

- Independent versus dependent samples (give practical examples)
- The t-test for each statistical design
- The standard errors of the difference between two independent sample means for data situations when equal or unequal variances are assumed

Comparison of two sample proportions

- Use of z for large sample sizes
- Use of t-test for small sample sizes

- Pooled or non-pooled estimate of variance for standard error of a difference
- The use of the χ^2 (chi-squared) test to test for association between two categorical variables when data are presented in 2×2 contingency tables
- Yates' correction for continuity
- Fisher's Exact Probability Test

NEW TERMS AND CONCEPTS (see Handout 9.1)

Alternative hypothesis; degrees of freedom; hypothesis testing; level of significance; null hypothesis; 1-tailed and 2-tailed tests; *p*-value; probability of a difference occurring purely by chance; rejection of a hypothesis; statistical significance; test statistic (z, t, χ^2); type 1 and type 2 errors.

Structure of the lesson

During the lesson, liberal use should be made of examples taken from the literature to illustrate the role of statistical significance in the interpretation of data and drawn conclusions.

Worked examples of how a test of significance is actually carried out should be given to the students. Examples of the z-test, the χ^2 test and the t-test are suggested in Handouts 9.2 and 9.3. The lesson content may be presented in the following sequence.

(*a*) Outline the context and concept of a statistical test of significance. Make reference to:

- differences, for example, between the means of certain biochemical, physiological, demographic or any health measurements in different samples, or between the proportions with certain attributes in different samples, or between the observed and expected number of occurrences of certain events;
- formulation and testing of the null hypothesis;
- the probability that a difference of a given magnitude or greater magnitude can occur purely by chance; illustrate this in relation to the theoretical sampling distribution;
- the direction of difference and the implications for 1-tailed or 2-tailed tests;
- the probability of being wrong in rejecting or not rejecting a hypothesis; type 1 and type 2 errors.

(*b*) Introduce the concept of level of significance

- The lowest value p (the probability) must have for an event to be considered "unlikely", and hence for the null hypothesis to be rejected and the difference to be described as being statistically significant.
- Describe the conventional levels of significance, i.e. "significant" for $p < 0.05$; "highly significant" for $p < 0.01$; "not significant" for $p > 0.05$ or $p = 0.05$.

(*c*) Describe the role of significance testing and the implications of the outcome

- Discuss the possible causes of the observed difference:
  - — chance (the null hypothesis);
  - — the factor under study;
  - — other "real" factors;
  - — "spurious" factors, such as bias and non-comparability.

- The test of significance only takes care of the factor of chance; discuss how the other possible causes of observed difference are dealt with. Emphasize the difference between statistical and medical significance. For example:
  - — a statistically significant difference but of no clinical importance;
  - — a non-statistically significant observation but with the results pointing to a possible clinical or medical importance.
- Discuss possible follow-up as a result of a statistical test of significance, for example, repeat of study with an enlarged sample size.

(*d*) Outline the methodology of the various tests of significance

There are many types of tests of significance, catering to different types of data and differences being dealt with. The most commonly encountered are the *z*-test, the *t*-test and the χ^2 test. Mention only the usefulness of the χ^2 test and indicate that detailed treatment of this test statistic will follow in the next lesson. At least one type of test should be carried out by the students to learn the concepts and principles involved; that is, how to:

- select the appropriate test to be used;
- differentiate between parametric and non-parametric tests;
- calculate the test statistic;
- evaluate its magnitude in relation to its theoretical sampling distribution, in terms of the probability that this magnitude could have arisen purely by chance (if the null hypothesis were true);
- decide whether the difference is significant and, if so, at what level of significance.

Refer to the worked examples given in Handouts 9.2 and 9.3.

Lesson exercises

The class exercises should emphasize the proper selection of the test to be used in each specific situation and how to interpret the results obtained. The teacher should obtain a data set which has both categorical and continuous variables that can be used for the various tests on means in dependent and independent situations and in the case of proportions for small and large data sets.

Class exercises are given to provide practice in carrying out tests of significance, and interpreting the results in the context of the study objectives.

■ For each of the following comparisons, name the appropriate test of significance:

- mean weight for preschool boys and girls;
- mean family size for urban and rural families;
- serum albumin values for women using an intrauterine contraceptive device and for women not using such a device;
- number of sexual partners of HIV-positive men before and after two years of counselling;
- temperature of children with fever taken before treatment and one hour after treatment.

■ The average clinic utilization rate for 1152 infants who reported to Kasangati Health Clinic from 1961 and 1979 is provided in Table 9.1. (Kasangati Health Clinic is the field station for Makerere Medical School, Institute of Public Health, Kampala, Uganda.) The study was reported in the *East African medical journal* (March, 1994).

Table 9.1 ***Average clinic utilization rate, Kasangati Health Clinic, Uganda***

Year	Number of infants	Mean utilization rate
1961	3	1.7
1962	9	2.7
1963	55	2.5
1964	88	1.9
1965	102	3.1
1966	164	3.1
1967	147	2.8
1968	67	2.0
1969	60	1.6
		Mean = 2.6
		SD = 1.9

Year	Number of infants	Mean utilization rate
1970	16	1.6
1971	90	3.5
1972	80	4.0
1973	71	3.9
1974	65	3.4
1975	43	3.0
1976	42	3.2
1977	33	2.9
1978	11	2.1
1979	6	1.2
		Mean = 3.4
		SD = 2.3

Source: Biritwum RB. Record keeping on early childhood diseases in two decades, at the health centre level in Uganda. *East African medical journal*, 1994, 71: 199–203. Reproduced by permission.

- Determine whether the average utilization rate per child in the 1960s is statistically different from the rate in the 1970s.
- Comment on the distribution of the data for the test selected.

■ Table 9.2 gives the summary of the data on immunization of children in Yemen, as reported in the Demographic and Maternal and Child Health Survey, 1991/1992 (source: Demographic and Health Surveys, 1991–92, Macro International Inc., Calverton, MD, USA).

Table 9.2 ***Summary of data on immunization of children, Yemen***

Characteristics	Percentage of children who received										Number of children
		DPT			Polio						
	BCG	1	2	3+	1	2	3+	Measles	All[a]	None	
Child's age (months)											
<6	29.2	28.9	18.6	9.6	28.9	18.6	9.6	13.5	7.6	68.0	718
6–11	47.3	48.6	42.8	30.9	48.6	42.8	30.9	34.8	25.1	49.6	802
12–17	58.8	60.3	56.3	48.7	60.3	56.3	48.7	51.4	45.9	37.3	627
18–23	61.9	62.4	54.6	45.8	62.4	54.6	45.8	51.6	44.0	35.8	628
24–59	66.6	65.8	61.3	53.3	65.9	61.3	53.3	58.5	50.8	30.4	3939
Sex of child											
Male	61.3	61.1	55.8	46.7	61.1	55.8	46.7	51.8	43.7	35.6	3427
Female	56.8	56.7	50.9	42.9	56.8	51.0	42.9	47.2	40.3	40.2	3288
Residence											
Urban	81.3	81.1	76.5	68.1	81.2	76.6	68.1	70.3	63.0	14.9	1113
Rural	54.7	54.6	48.8	40.2	54.6	48.8	40.2	45.4	37.9	42.4	5602
Region											
North-west	55.8	56.4	50.6	42.0	56.4	50.6	42.0	46.9	39.3	41.0	5793
South-east	79.6	75.4	71.1	62.4	75.4	71.1	62.4	66.5	59.4	18.3	922
Mother's education											
No education	56.5	56.6	51.0	42.5	56.6	51.0	42.5	47.1	39.8	40.4	5836
Primary	84.2	81.8	77.8	69.2	81.8	77.8	69.2	73.4	65.1	14.6	383
More than primary	89.1	87.3	83.8	75.2	87.3	83.8	75.2	80.5	72.2	7.9	211
Information not collected	59.3	57.3	49.8	37.1	57.3	49.8	37.1	47.6	35.0	36.6	202
Total	59.1	59.0	53.4	44.8	59.0	53.4	44.8	49.6	42.0	37.9	6715[b]

BCG, bacille Calmette–Guérin; DPT, diphtheria–pertussis–tetanus.

Source: Macro International Inc. *Demographic and health surveys, 1991–92.* Reproduced by permission.

[a] Children who are fully vaccinated (that is, those who have received BCG, measles and three doses of DPT and polio vaccines).

Note: The DPT coverage rate for children without a written record is assumed to be the same as that for polio vaccine, since mothers were specifically asked whether the child had received polio vaccine. For children whose information was based on the mother's report, the proportion of vaccinations given during the first year of life was assumed to be the same as for children with a written record of vaccination.

[b] *Editors' note*: Differences between the total numbers of children accounted for under the different "Characteristics" headings are not explained in the original source.

- Which tests should be used to determine whether the proportion of males who are fully vaccinated is different from the proportion of females who are fully vaccinated?
- Identify which of the variables show significant differences in the proportions of fully vaccinated children.
- Give three reasons why your conclusions may not be correct either medically or statistically.

■ Explain the different errors that can be made in a statistical test of a hypothesis.

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Definitions of new terms and concepts

1-tailed and 2-tailed tests: When the difference being tested for significance is not specified in direction (that is, takes no account of whether $X_1 < X_2$ or $X_1 > X_2$), then the probabilities in both tails of the sampling distribution are used in the test: a 2-tailed test is required. When the difference being tested is directionally specified beforehand (when $X_1 < X_2$, but not $X_1 > X_2$, is being tested against the null hypothesis $X_1 = X_2$), then a 1-tailed test is appropriate because we are only concerned with the probability $P(X_1 < X_2)$ and not $P(X_1 > X_2)$.

Level of significance: The probability of a difference arising purely by chance, below which it is considered sufficiently "unlikely" for the difference to be considered statistically significant (conventionally 0.05). The probability of wrongfully rejecting the null hypothesis.

Null hypothesis: The hypothesis of "no difference" or, more correctly, the hypothesis that the observed difference is entirely due to sampling error, that is, that it occurred purely by chance. In a test of significance, the "null hypothesis" is postulated to establish the basis for calculating the probability that the difference occurred purely by chance. When the difference is not significant, the null hypothesis is not rejected; when the difference is significant, the null hypothesis is rejected in favour of other hypotheses about the causes of the difference. Note that the null hypothesis is never proved completely right or wrong, or true or false, but is only rejected or not rejected at the probability level of significance concerned, for example, 0.05 or 0.01.

***p*-value:** The probability of obtaining the results or more extreme results than those observed in the study under the null hypothesis.

Statistical significance: The concept by which results are judged as due to chance or not.

Type 1 and 2 errors: Type 1 error is the risk of erroneously rejecting a null hypothesis that is really true. Type 2 error is the chance of erroneously failing to reject a null hypothesis that is, in fact, false.

Worked example of the *z*-test for comparing two proportions

Data situation

A rural health survey investigated 124 households in a village and recorded their sources of water supply. By reviewing the village's health centre morbidity records for a period of three months prior to the survey, it was possible to identify household members with a history of diarrhoeal episodes. A total of 88 used the river for water supply and 49 of them had episodes of diarrhoea, as against 10 from the 36 households using the well. There was no piped water in this village. Is there a statistically significant difference in the proportions with episodes of diarrhoea between the households using river and well water supplies?

Solution

Null hypothesis: there is no difference in the proportion with episodes of diarrhoea between household members using river or well water supplies.

Alternative hypothesis: there is a difference in the proportion of diarrhoea episodes as a result of different sources of water supply. (Note that this is a 2-tailed test as no direction is indicated for the difference in episodes of diarrhoea.)

Level of significance: 0.05.

Test statistic: The *z*-test for proportion is chosen as appropriate here:

$$z = (p_1 - p_2)/\mathrm{SE}(p_1 - p_2)$$

$\mathrm{SE}(p_1 - p_2)$ = standard error of difference in proportion

$$\mathrm{SE}(p_1 - p_2) = \sqrt{\{p_1(1-p_1)/n_1 + p_2(1-p_2)/n_2\}} \quad \text{(if we assume unequal variances)}$$

$$\text{or } \mathrm{SE}(p_1 - p_2) = \sqrt{\{p(1-p)(1/n_1 + 1/n_2)\}}$$

$$\text{where } p = (r_1 + r_2)/(n_1 + n_2)$$

r_1 and r_2 are the numbers with attributes (in this case episodes of diarrhoea) in each group;

n_1 and n_2 are the sample sizes in each group.

In our data situation,

$r_1 = 49$

$n_1 = 88$

$r_2 = 10$

$n_2 = 36$

$p_1 = 49/88 = 0.5568$

$p_2 = 10/36 = 0.2778$

$1 - p_1 = 39/88 = 0.4432$

$1 - p_2 = 26/36 = 0.7222$

$$z = \left(0.5568 - 0.2778\right) \Big/ \sqrt{\left\{\left(0.5568 \times 0.4432\right)/88 + \left(0.2778 \times 0.7222\right)/36\right\}}$$

$z = 3.044.$

Conclusion

Checking with the table of the normal distribution shows that the value of z at the 5% level is 1.96; therefore we reject the null hypothesis that the proportion with diarrhoeal episodes is the same in the two groups of households using the different sources of water supply. The difference in the proportion with episodes of diarrhoea is unlikely to be due to chance, $p < 0.05$. In fact, it appears that the household members using the river have statistically significantly more episodes of diarrhoea than those using the well. However, to establish a causal relationship, further investigations would have to be done.

Note: These data can also be tested by the χ^2 test, but the results have to be presented in a 2×2 contingency table, as shown below.

Table 9.3 ***Three-month history of diarrhoeal episodes***

	Number of households according to water supply		
Status	**River**	**Well**	**Total**
No diarrhoea	39	26	65
Diarrhoea	49	10	59
Total	88	36	124
Percentage with diarrhoea	56.7	27.8	47.6

The hypothesis to be tested will now be that of *no* association between diarrhoeal episodes and source of water supply. The data in fact indicate that an association exists between diarrhoeal episodes and source of water in the village (with diarrhoeal episodes in 56.7% and 27.8% of households using river and well water, respectively).

Worked example of the *t*-test

The following data are from a study to compare the mean concentration of lead (in mg/100 g) in the blood of a group of workers in a battery plant (exposed) with that of a group of workers in a textile factory (not exposed).

Table 9.4 ***Mean concentration of lead (in mg/100 g) in the blood of workers in a battery plant and a textile factory***

Battery workers (X_1)	Textile factory workers (X_2)
0.082	0.040
0.080	0.035
0.079	0.036
0.069	0.039
0.085	0.040
0.090	0.046
0.086	0.040

Battery workers	Textile factory workers
$\Sigma X_1 = 0.571$	$\Sigma X_2 = 0.276$
$\Sigma X_1^2 = 0.046847$	$\Sigma X_2^2 = 0.010957$
$\Sigma x_1^2 = 0.0002697143$	$\Sigma x_2^2 = 0.0000757143$
$s_1^2 = 0.0000449524$	$s_2^2 = 0.0000126190$
$s_1 = 0.0067047$	$s_2 = 0.0035523$
$\bar{X}_1 = 0.08157$	$\bar{X}_2 = 0.03943$
$n_1 = 7$	$n_2 = 7$

where $x_1 = X_1 - \bar{X}_1$

and $x_2 = X_2 - \bar{X}_2$

We find

s^2 (pooled) = 0.000028786

and $SE_d = s\sqrt{(1/n_1 + 1/n_2)} = 0.002868$

where the suffixes 1 and 2 refer to battery workers and textile factory workers, respectively, and SE_d is the standard error of the difference in mean lead concentrations between the two groups.

The null hypothesis (H_0) is that there is no difference in the mean lead concentration in the blood of the workers of the two industries. This implies a 2-tailed test. We have

$$d = \bar{X}_1 - \bar{X}_2 = 0.042414.$$

The difference is tested against zero, with

$$t = d/SE_d, \text{ with } (n_1 + n_2 - 2) \text{ degrees of freedom}$$
$$= 14.7, \text{ with 12 degrees of freedom; } p < 0.001 \text{ (see Table B.2 of Annex B).}$$

The null hypothesis is therefore rejected. There is evidence of a significant difference in the mean lead concentration in the blood of the workers of the two industries.

OUTLINE 10 Association, correlation and regression

Introduction to the lesson

The idea of causal relationships lies behind much medical decision-making, in both the preventive and therapeutic fields. As much of the evidence for relationships in medical science is of a statistical nature, students need to understand the statistical basis of such information or knowledge about relationships, in order to be able not only to appreciate the limitations of conclusions that they read about in the literature, but also to evaluate their own experiences more rationally, quantitatively and objectively.

Objective of the lesson

The objective of this lesson is to give the students an understanding of the nature of statistical evidence for relationships between different characteristics or events in a population, and to enable them to use and interpret the statistical methods and indices employed to describe and measure such relationships.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Give examples of types of questions concerning health or medicine that are answered by analysis of statistical association or correlation.

(*b*) Explain the concept of association between two categorical variables.

(*c*) Describe a contingency table.

(*d*) Carry out the χ^2 test when required, with the help of reference material.

(*e*) Explain the concept of relationship between two quantitative variables presented in a scatter diagram.

(*f*) Distinguish between linear and non-linear relationships.

(*g*) Interpret the value of a coefficient of correlation.

(*h*) Assess the statistical significance of the sample correlation coefficient.

(*i*) Explain the concept and application of linear regression.

(*j*) Plot a regression line when the equation is given.

(*k*) Use linear regression for interpolation and prediction.

(*l*) Differentiate between statistical and causal relationships.

Required previous knowledge

The contents of all previous lessons.

Lesson content

Situations in which analysis of statistical association or correlation can provide answers

- Studies of two or more variables measured on the same subject (or unit of inquiry) where the interest is in their relationship

Association between two categorical variables

- Cross-tabulation and contingency tables
- Distinction between contingency tables and other statistical tables
- Calculation of expected cell frequencies under the null hypothesis
- Importance of testing statistical significance of the association

The χ^2 test

Procedure

- The null hypothesis
- Calculation of expected frequencies (E) for each cell under the null hypothesis
- The concept of degrees of freedom
- Calculation of the χ^2 statistic
- Correction for continuity, for 2×2 tables

Limitations

- Effect of small expected frequencies
- Applicability only to categorical data

Interpretation

- Use of the table of the theoretical distribution of χ^2 to determine significance

Relationship between two quantitative variables

(refer to Figures 10.1–10.7 in Handout 10.2)

Pearson coefficient of correlation (r)

- Scatter diagram and its use in indicating the nature and strength of the relationship
- Linear (Figures 10.1, 10.3, 10.4 and 10.7) and non-linear (Figures 10.2 and 10.6) relationships
- Difference in scatter in the case of strong (Figures 10.1 and 10.3) and weak (Figures 10.4 and 10.7) relationships
- Positive (Figures 10.3 and 10.4) and negative (Figures 10.1 and 10.7)
- Pearson correlation coefficient as a measure of strength and direction of linear relationship

Properties

- Unit free (the coefficient r is an absolute number)
- Independent of change of origin and scale
- Lies between -1 and $+1$

Magnitude, sign and interpretation

- Meaning of a particular value of r
- Interpretation of the magnitude and sign of r for a linear relationship

Uses

- Measure of the strength of association between two quantitative variables

Misuses

- Concluding no relationship from zero correlation, while in fact a strong non-linear relationship may exist
- Unwarranted conclusion from spurious correlation
- Concluding a cause–effect relationship from a correlation, while it might just be an indirect relationship
- Concluding an agreement between pairs of measurements, while they may not have the same values at all points

Computation of the correlation coefficient

Using the formula available in text books or using programmable calculators or computers. Different books may give different versions of the formula. The teacher should decide which version would be the easiest for the students to use.

Assessing the statistical significance of a coefficient of correlation

- Procedure
- Limitations
- Degrees of freedom
- Interpretation

Linear regression

A regression estimates the nature of the relationship. The concept and applications of linear regression should be covered, with explanation of the terms dependent and independent variables. A description of the regression line should be given.

Definition and characteristics of the linear regression

- The equation $Y = bX + c$
- The regression coefficient or slope b, given by $\Sigma(X - \bar{X})(Y - \bar{Y})/\Sigma(X - \bar{X})^2$
- The intercept c, given by $\bar{Y} - b\bar{X}$

Computation of the linear regression

- The computation of b and c
- Plotting the line on the scatter diagram

Uses

- Measure of linear association
- Interpolation
- Prediction

Misuses

- Extrapolation without assurance that the trend remains the same
- Using a regression relationship whose slope has been shown to be not significantly different from zero
- Forgetting that the predicted values are subject to sampling error
- Concluding that a cause–effect relationship exists, whereas the relationship may just be statistical
- Applying a relationship established in one group of subjects to another group, without the assurance that it is applicable to all groups

NEW TERMS AND CONCEPTS (see Handout 10.1)

Association; bivariate relationship; multi-factorial relationship; net effect; cross-tabulation; χ^2; contingency table; cell frequency; row total; column total; grand total; expected frequency; independent and dependent variables; linear and non-linear relationships; spurious correlation; agreement; slope and intercept; regression coefficient; extrapolation and interpolation.

Structure of the lesson

(*a*) Introduce the topic by describing the general purpose of correlation and regression analyses. Give examples from the current literature on topics of local interest. Illustrate the statistical nature of the relationships and the importance of studying those relationships.

For example:

- smoking and lung cancer;
- intake of iron and folic acid in diet or as supplement and haemoglobin level;
- mother's education and size of family;
- quality of drinking-water and diarrhoea;
- height of a person and height of his or her father;
- energy intake by a woman during pregnancy and birth weight of her child;
- severity of disease and cure rate.

(*b*) Differentiate between the nature of relationships among categorical and quantitative variables. Explain the need to have different procedures for the two types of variables.

(*c*) Recapitulate the basic principles of hypothesis testing. For the χ^2 statistic as a means for testing the statistical significance of the association between two categorical variables, give a heuristic explanation of the formula of χ^2 so that the students realize that $(O - E)^2/E$ is a measure of deviation from independence. Emphasize that E is the cell frequency expected under the null hypothesis of independence (that is, of no association).

(*d*) Explain the concept of degrees of freedom by giving actual examples of, say, 2×2 and 2×3 tables illustrating the "freedom" to choose frequencies in one and two cells, respectively, under the constraint of fixed marginal totals. Stress the interpretation of a significant χ^2 as mere presence of association, with no implication for the strength of the association. Point out that the magnitude of χ^2 is severely affected by n. Indicate what further calculations are required to measure the strength of the association.

(*e*) Distinguish between linear and non-linear relationships between two quantitative variables by giving examples, as shown in Handout 10.2. Emphasize that the coefficient of correlation measures only the linear component of the relationship, which may not exist in some cases, despite the presence of a strong non-linear relationship. Make liberal use of diagrams to illustrate the magnitude and direction of correlation coefficients.

(*f*) Use scatter plots to explain the fluctuations around a line, even in the case of a linear relationship. In the case of high fluctuations, the predictive value of the relationship can be reduced substantially.

(*g*) Briefly explain the statistic $[r\sqrt{(n-2)}]/[\sqrt{(1-r^2)}]$ following Student's t distribution with $n - 2$ degrees of freedom, subject to the normality of either X or Y. This is just to test the hypothesis that the correlation is zero in the population. For testing other values of correlation, tests based on Fisher's z transformation are required. Explain the role of the sample size in placing confidence on the value of a coefficient of correlation.

(*h*) Briefly explain the use of the t-test for the hypothesis of no correlation. This test does not provide any clue to the magnitude of the correlation. A better indication of the magnitude of correlation can be obtained by computing $100 \times (1 - r^2)$, as the percentage of the variation in the dependent variable is explained by its association with the independent variable. Also mention that the t-test requires normality of Y, particularly for small samples, and that this test should not be used indiscriminately.

(*i*) Discuss the need to obtain the nature of the relationship in the form of an equation. Restrict the lesson to linear relationships only.

(*j*) Come back to the scatter plots used earlier in the context of correlation and illustrate various types of regression lines. Use the illustrations in Handout 10.2 to explain the meaning of the slope measured by the regression coefficient and of the intercept. Show the equivalence of the use of r and b to indicate association. Give examples of situations for preferring one over the other.

(*k*) Superimpose scatters of different variability and explain how variability affects the reliability of predictions — whether extrapolated or interpolated.

(*l*) Discuss the uses and misuses of regression lines on the basis of the examples chosen from published literature.

Lesson exercises

The teacher should give two different kinds of health-related data to the students: one set for 2×2 cross-tabulated data of two discrete variables, and the other for two quantitative variables measured on the same individuals. The exercise should focus on enabling the students to produce a scatter diagram and to carry out appropriate procedures to test association between the

variables in each of the two situations. The students should also be tested on their ability to interpret the results of the tests.

■ Give students a 2 × 2 table with relatively small frequencies, so that the χ^2 is not significant. Multiply each frequency by 10 so that the proportion remains the same. Compute χ^2 again and see how dramatically the value and, consequently, the significance change. An example could be as follows:

	Favouring sex education		
	Yes	**No**	**Total**
Male	8	5	13
Female	5	7	12
Total	13	12	25

$\chi^2 = 0.987$, $df = 1$, $p > 0.25$. When each frequency is multiplied by 10, then $\chi^2 = 9.87$, $df = 1$ but now $p < 0.001$.

■ Give some scatter plots of known data and ask the students to make an educated guess of the magnitude and direction of the coefficient of correlation. Include among the scatter plots at least one random plot (no correlation) as well as at least one with a non-linear relationship. Let the students calculate r to check how good their guesses were.

■ Give some regression lines with different slopes and ask the students to interpret each of them. Superimpose scatter plots on them with different variability and let the students describe the impact of variability on the reliability of the conclusions based on the regression equation.

■ Use the data on age, height and weight of a male preschool child, followed up from the age of six months, to draw a scatter diagram and find the best regression line for age and weight.

Age (months)	Height (cm)	Weight (kg)
6	66.9	7.1
7	68.5	7.2
12	72.0	7.8
16	77.0	8.3
18	79.0	8.9
22	82.1	9.2
24	82.7	9.5
26	84.2	10.4
30	86.0	11.0
32	86.5	10.8
34	89.5	11.4
35	89.7	11.8
43	95.0	13.0

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Colton T. *Statistics in medicine*. Boston, Little, Brown, 1995.

Edwards AL. *An introduction to linear regression and correlation*, 2nd ed. New York, WH Freeman, 1984 (first six chapters only).

Kirkwood BR. *Essentials of medical statistics*. Oxford, Blackwell, 1988.

Last JM, ed. *A dictionary of epidemiology*, 3rd ed. New York, Oxford University Press, 1995.

Wang C. *Sense and nonsense of statistical inference: controversy, misuse and subtlety*. New York, Marcel Dekker, 1993.

Definitions of new terms and concepts

Association:[1] The degree of statistical dependence between two or more events or variables.

Bivariate relationship: Association (or relationship) between two variables.

Cell frequency: The number of observations in a cell of a contingency table.

Column total: The total number of observations in a column of a contingency table.

Contingency table:[1] A tabular cross-classification of data such that subcategories of one characteristic are indicated horizontally (in rows) and subcategories of another characteristic are indicated vertically (in columns).

Dependent variable: In a regression analysis, this is the variable of which the value is thought to be predictable from another variable.

Expected frequency: The number of observations to be expected in a class or cell if the null hypothesis is true.

Extrapolation: The use of the regression line to predict a value of the dependent variable from that of the independent variable outside the range of values actually observed.

Grand total: The total number of observations cross-classified in a contingency table.

Independent variable: The variable, in a regression analysis, of which the value is thought to be predictive of another variable.

Interpolation: The use of a regression line to estimate a value of the dependent variable from that of the independent variable within the range of values actually observed.

Linear relationship: In a regression analysis, when the mathematical model describing the dependent variable in terms of the independent variable is in the form of a straight line.

Multi-factorial relationship: Association (or relationship) between several factors or variables.

Non-linear relationship: When the form of the model describing y in terms of x is not a straight line.

Regression analysis:[1] Given data on a dependent variable y and an independent variable x, regression analysis involves finding the "best" mathematical model (within some restricted form) to describe y as a function of x or to predict y from x.

Regression coefficient(s): For a linear regression, these are the estimated slope and the intercept of the straight line describing the dependent variable as a function of the independent variable.

Row total: The total number of observations in a row of a contingency table.

Spurious correlation:[1] An association between two variables that may be artefactual, fortuitous, false or due to all kinds of non-causal associations resulting from chance or bias.

[1] From Last JM (ed.) *A dictionary of epidemiology*, (3rd ed.) New York, Oxford University Press, 1995.

Diagrammatic presentation of different types of correlations

Figure 10.1 ***Strong negative correlation (r = −1)***

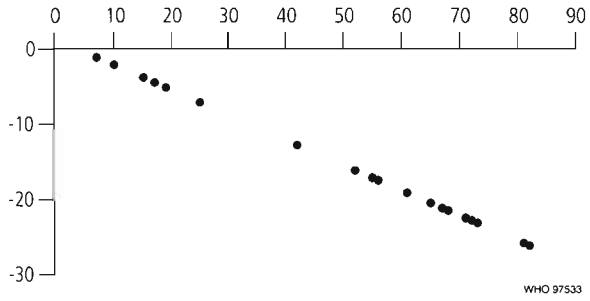


Figure 10.2 ***Non-linear***

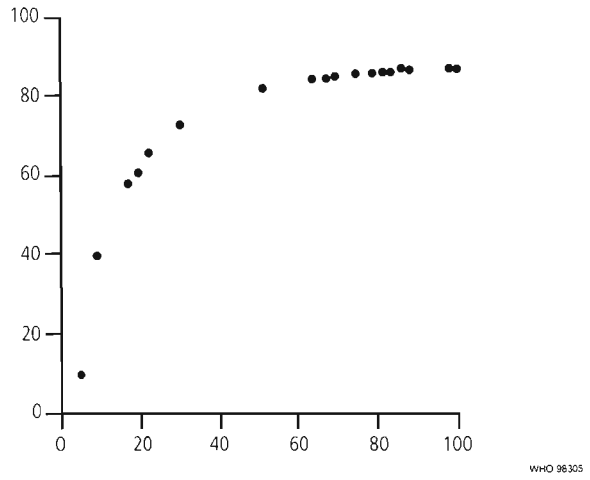


Figure 10.3 ***Strong positive correlation (r = 1)***

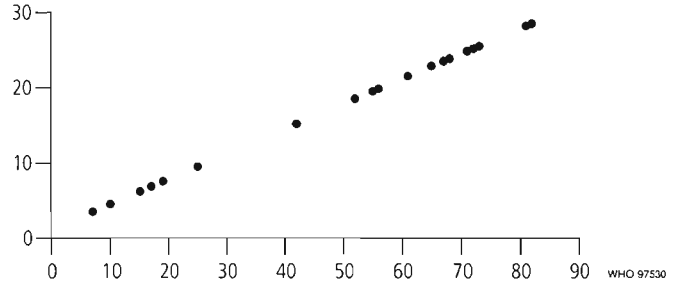


Figure 10.4 ***Positive correlation (0 < r < 1)***

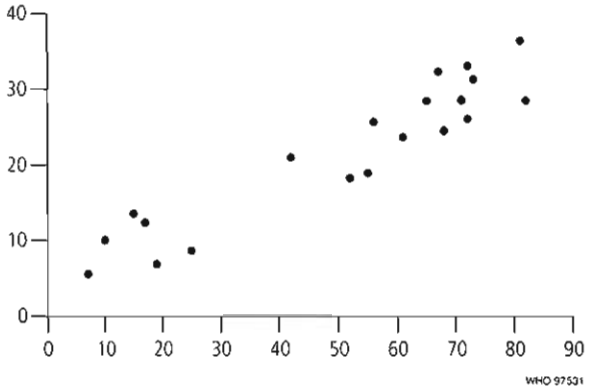


Figure 10.5 ***No correlation (r = 0)***

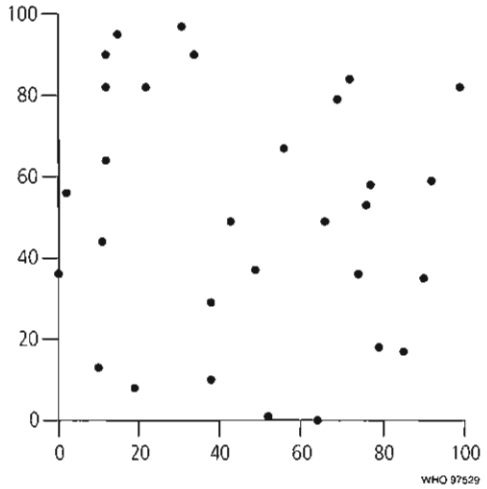


Figure 10.6 ***Non-linear***

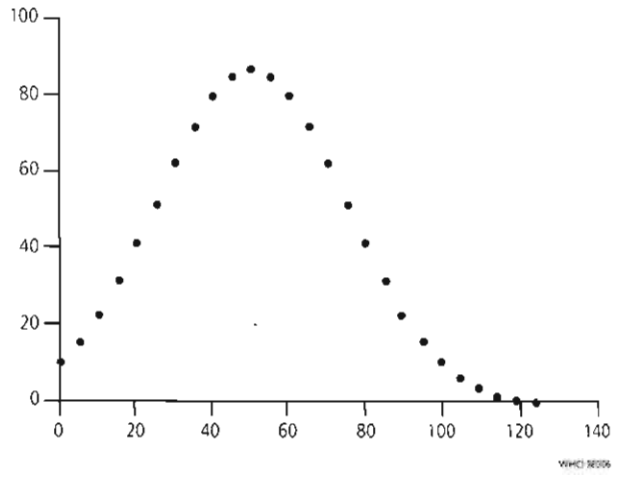
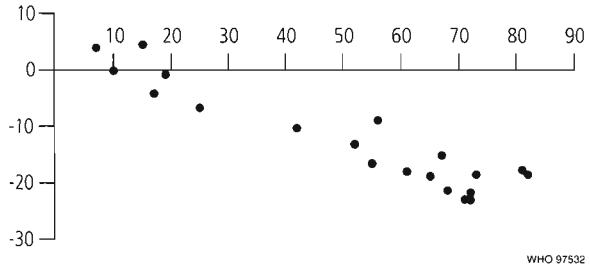


Figure 10.7 ***Negative correlation (−1 < r < 0)***



PART II

Health statistics, including demography and vital statistics

OUTLINE 11 Censuses and vital registration

Introduction to the lesson

Before we can assess the magnitude of the public health problem posed by a specific disease, or the impact of an intervention programme, we must have an idea of the size of the community we are dealing with, its composition with respect to various demographic characteristics, and the magnitude of changes in relation to vital events (births and deaths).

Objective of the lesson

The objective of this lesson is to familiarize the student with the sources of data on the size of the population and its composition.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain the concept of population size, and how it is possible to define the population of a specified geographical area at a specified time in different ways.

(*b*) Give a brief history of censuses in the country.

(*c*) Summarize the steps in the organization of local population censuses (with reference to a field research project) necessary to achieve complete coverage without overlapping information.

(*d*) List the items of information obtainable from the latest census that are relevant to the medical field.

(*e*) State and elaborate on the uses of these items with examples from the latest national population census.

(*f*) Discuss the reliability and the limitations of census data.

(*g*) Define vital events, vital statistics.

(*h*) Describe the vital registration system.

(*i*) State the reasons for recording, reporting and registering of births and deaths.

(*j*) Discuss the role doctors and other health workers should play in the system of recording, reporting and registering births, deaths and fetal deaths, as it operates in the country.

(*k*) Discuss the reliability of, and reasons for shortcomings in, birth and mortality data.

(*l*) Suggest improvements in the vital registration system.

Required previous knowledge

Lesson content of Outlines 2 and 3.

Lesson content

Census of population

Reasons for census taking

A census provides an indication of population size, that is, the total number of persons in a given area. It can be used to demonstrate variation in population sizes between countries, and between geographical and administrative subdivisions of a country. Reasons for census taking are:

- to provide data for use in planning various services, including health services;
- to determine denominators of indices of health;
- for administrative and political purposes.

Types of population

De facto population: the actual population present in the census area on census day; also known as the "present-in-area" or "enumerated" population. Features of this measure of population are:

- it avoids a distinction between temporary and permanent residence;
- people in transit present problems for enumeration and may be missed;
- it is not easily open to conscious manipulation;
- it may give a false impression of size for areas with high migration or high seasonal mobility; hence, the choice of date of the census is critical.

De jure population: all permanent residents who habitually live in the census area; also known as the "resident" population. Features of this measure are:

- it requires a definition of "permanent residence", which may be difficult in a population of high mobility, to differentiate it from "temporary" residence; there may be confusion with "usual" or "legal" residence, or place of domicile;
- residents temporarily away present problems for enumeration and can easily be missed;
- it is subject to possible biases in implementation of residential criteria;
- it is technically free from the influence of short-term or seasonal mobility or migration, but hence may not reflect the size of the population actually present in the area at a given time.

History of population censuses in the country

Organizational steps for national and local population censuses (including the actual enumeration)

The following steps should be carried out:

- statement of the reasons for the census;
- choice of questions to be asked;

- design of the census form;
- recruitment of census staff;
- training of recruited staff;
- testing of the census form;
- dealing with financial and legal aspects;
- enumeration area demarcation, including numbering of houses;
- population enumeration (preliminary and final).

Data organization leading to publication of results

The following steps should be taken:

- coding and checking;
- producing computer data files;
- preliminary tabulations and interim publications;
- consolidation of results and detailed publications.

Characteristics of the population

In a population census, information may be collected about the following characteristics: age, sex, marital status, area (place) of residence (address), literacy, occupation, economic activity, relationship within a household, etc.

Problems in definition of characteristics

Problems may arise in defining the following demographic characteristics:

- age: concept of "completed" years of age, whether stated without proof, stated with proof (for example, birth certificate), estimated on the basis of growth milestones, estimated on the basis of a calendar of events, guessed;
- place of residence: permanent residence, temporary residence;
- occupation: multiplicity of possible occupations, multiple occupations;
- relationships and marital status: may raise difficulties in some cultures.

Census reports

Consider the information available from a census, and the limitations of censuses as sources of health statistics.

Uses of census data in the health field

Census data may be used:

- for planning health services;
- as a source of denominators for health indicators.

Reliability and limitations of census data

It should be remembered that results are estimates of the actual situation (even for the point in time of enumeration).

Registration of births and deaths

Vital statistics: data on various vital events of human life, such as births, stillbirths, deaths, marriages, divorces

Definitions of technical terms

Reasons for recording, reporting and registering births and deaths

These reasons are:

- for individual (personal) documentation;
- for legal and civic purposes (for example, establishing citizenship, evidence of which may be needed for social and welfare services);
- to maintain a "balance sheet" of the population.

The role of the health worker in the registration system

The health worker may take the role of:

- an attendant at births and deaths;
- a certifying official for death;
- a user of the information on births and deaths;
- a citizen.

Reliability and shortcomings

There may be problems with registration of births and deaths:

- in applying the definition of a live birth (especially in connection with severe congenital malformations);
- in applying the definition of a late fetal death (especially in connection with determining correctly the period of gestation);
- births followed by early neonatal deaths may not be reported to be *registered* as births (although they may be *recorded* as births and deaths if they occur in a health facility);
- there may be a lack of motivation among the general public to register an event;
- registration system may not exist or it may be incomplete or unreliable.

Systems

Systems existing in the country for recording, reporting and registering deaths and fetal deaths should be discussed from several points of view. For example, consideration may be given to:

- the system for registration of deaths and stillbirths in the country;
- possible differences in methods used for recording, reporting and registering deaths, from country to country or region to region;
- the agencies responsible for registering death, according to the legal provisions of the country (in Turkey, for example, reporting of deaths to the office of population registration is the responsibility of the head of the district).

It should be emphasized that a uniform system of registering deaths is necessary for national and international comparisons.

Shortcomings in the registration system

Shortcomings in the recording, reporting and registration of deaths and fetal deaths may occur through:

- incomplete data;
- lack of uniformity in collection or reporting of such data;
- lack of uniformity in definitions of events and criteria for reporting;
- lack of accuracy, particularly with respect to age at, and cause of, death.

Improvement of the registration system

The following are a number of suggestions for possible improvement of the system (the discussions should be focused on ways of improving the existing system of the country):

- compulsory registration of deaths;
- establishment of a uniform system throughout the country;
- health education by the primary reporting agency to promote recognition of the significance and usefulness of such data;
- use of special sample surveys to check the extent and accuracy of registration of deaths by regular agencies;
- training of persons certifying deaths.

NEW TERMS AND CONCEPTS (see Handouts 11.1 & 11.2)

Census; census area; census unit; enumerator; intercensal period; population census; *de facto* census; *de jure* census; population size; household; characteristics of population; reticulation; fetal death (early, intermediate, late); live birth; stillbirth; vital events.

Structure of the lesson

Explain the importance of population data for planning and organizing health services, and how the population structure affects the need for, and utilization of, the various medical and health services.

(*a*) Give a brief history of census taking in the country, mentioning when the first census took place, the population groups covered, what the census results were used for and the subsequent developments.

(*b*) Discuss the methods of obtaining reliable census and registration data, and the associated problems. Also discuss the use of population data.

(*c*) Discuss the types of sources of population data, their advantages and disadvantages.

(*d*) Arrange for census publications from the Census Office to be made available to students as a source of further information on national censuses.

(*e*) Discuss why standardization of definitions of census characteristics and vital events is important for studies of patterns, trends and differentials.

(*f*) Discuss international recommendations on the definitions of census characteristics and vital events, pointing out whether they differ from those used in the country.

Lesson exercises

Class exercises should test the students' grasp of the various sources of population data, their limitations and associated problems. Questions should also examine their knowledge and understanding of the various terms used in connection with population censuses and vital registration systems. Exercises should furthermore test their ability to identify appropriate sources of data needed to solve particular health problems.

Population census

■ What is the concept of the population of a country, in terms of population size and types?

■ What is:

- a census?
- a census area?

■ What are the relative advantages and disadvantages of taking a census of *de facto* and *de jure* populations?

■ What are the necessary steps in the organization of a local population census, with special regard to completeness of coverage and non-duplication of information?

■ Describe the system of birth and death registration in your country, pointing out any strong and weak areas of the system.

Registration of births and deaths

■ What is meant by registration of births and deaths, and what do you understand by the terms "live birth", "stillbirth", "fetal death" and "death"?

■ Why should births and deaths be reported, recorded and registered?

■ What is the system for reporting, recording and registering births and deaths in the country?

■ What role should health workers play in the system?

■ What are the limitations of the data on births and deaths?

■ Describe how information on population and the registration of vital events is used.

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HANDOUT 11.1

Definitions of new terms and concepts: population censuses

Census: Count (enumeration) of items.

Census area: The defined area in which the census is to be done.

Census unit: The smallest area into which the census area is divided for administrative and data collection purposes.

***De facto* census:** The method of counting the actual population present in the census area on census day.

***De jure* census:** The method of counting all permanent residents who habitually live in the census area.

Enumerator: The person who carries out the enumeration.

Household: A group of persons living together in a house and sharing common food arrangements.

Intercensal period: Time between two censuses; usually 10 years for national population censuses.

Local population census: A population census covering small defined areas.

National population census: A population census covering the whole country.

Population census: The total process of collecting, compiling and publishing demographic, economic and social data pertaining, at a specified time or times, to all persons in a country or delimited territory.[1]

Population characteristics: The socio-economic-cultural structure of the population in an area.

Population size: The total number of persons who make up the defined population in a specified area at a specified time.

Reticulation: The determination of boundaries of census areas, units, and other subdivisions in the country.

[1] United Nations Statistical Office. *Handbook of population census methods, Vols I–III.* New York, 1958–59 (Studies in Methods, Series F, No. 7).

Definitions of new terms and concepts: registration of births and deaths

The definitions given here are abstracted from the WHO Technical Report Series, No. 25, 1950, and the tenth revision of the ICD.[1] (The definitions used in the particular country concerned, if different from these, should also be included here.)

Fetal death: Death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy. The death is indicated by the fact that after such separation the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

Fetal deaths are subdivided by period of gestation (measured from the beginning of the last menstruation) as follows: early fetal death, intermediate fetal death, late fetal death.

Early fetal death: A fetal death that occurs before 20 completed weeks of gestation.

Intermediate fetal death: A fetal death that occurs at or after 20 completed weeks of gestation but before 28 weeks.

Late fetal death: A fetal death that occurs at 28 completed weeks of gestation and over.

Live birth: The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Each product of such a birth is considered live born.

Stillbirth: A late fetal death, that is, a fetal death that occurs at or after 28 completed weeks of gestation.

[1] *International Statistical Classification of Diseases and Related Health Problems, Tenth revision (ICD-10). Vol. 2.* Geneva, World Health Organization, 1993.

OUTLINE 12 Measurement of morbidity

Introduction to the lesson

The role of medicine is to improve the health status of individuals, through either clinical medicine or public health. Planning for health services should be based on the health needs of defined populations, which can be determined in part by morbidity and mortality levels. Monitoring of changes in the health patterns of populations, and evaluation of health services and programmes, are based largely on morbidity data.

Objective of the lesson

This lesson aims at enabling the students to identify the sources of information on morbidity and disability in the country, and to summarize these data using appropriate indices.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain the difficulties inherent in attempting to define and measure health, morbidity and disability.

(*b*) List the sources of local and national morbidity and disability data.

(*c*) Indicate the types of data obtainable from each listed source.

(*d*) Indicate the completeness and accuracy of the data from each listed source.

(*e*) Suggest briefly how the stated completeness and accuracy could be improved.

(*f*) Define disease prevalence and incidence, differentiating between point and period prevalence, and between persons and episodes.

(*g*) Differentiate between and use the indices: proportion, ratio and rate.

(*h*) Identify the correct numerators and denominators (population at risk) for incidence and prevalence, for a given set of morbidity data.

(*i*) Compute and interpret crude and specific morbidity proportions, ratios and rates, for a given set of appropriate data.

Required previous knowledge

Lesson content of Outlines 2, 3 and 11, and some knowledge of the organization of the country's health service.

Lesson content

Definition and measurement of health, morbidity and disability

- Definition of health, morbidity and disability (see Handout 12.1)

- Measurement of health, morbidity and disability through personal statements, observation of performance and activity, physical examination, and laboratory examination

Difficulties of defining and measuring health, morbidity and disability

- Problems of case definition
- Variation in perception of sickness among individuals, cultures and over age
- Inconsistencies in diagnostic procedures
- Reporting inadequacies and constraints
- Inadequacies of health care workers

Sources of local and national morbidity and disability data

- Routine health service records (including periodic school health examinations) provide, for example, general morbidity and disability data, by diagnosis or symptomatology, in accordance with the sophistication of the institution
- Routine data collection and notification systems of government and private institutions provide data on new cases of communicable diseases, etc.
- Occupational health institutions provide occupation-related morbidity and disability data
- Patients' groups (for example, people with diabetes) provide detailed disease-specific or condition-specific data on individual patients
- Disease registries (for example, for cancer or mental disorders) provide detailed information on the group of disease or conditions covered by the registry
- Surveillance records of selected diseases (primarily for detection of outbreaks) provide, for example, information on the time course of diseases under surveillance
- Reports from volunteer workers contain secondary and generally crude data on morbidity and disability
- Reports to ministries of health and international organizations contain summary data on morbidity and disability, usually also with demographic data on the reference populations

Completeness and accuracy of data

Data may be incomplete or inaccurate for the following reasons.

- Routine health service records:
  - — data are only available on those seeking the services of the health institutions;
  - — the reference population is undefined.

- Health institutions:
  - — the health institutions are not primarily data collection centres, but are service units; hence there are likely to be undetected imperfections in the collected data.
- Occupational health institutions:
  - — there may be differential coverage of the population served by the occupational health institutions (for example, data at entry into service will most likely be available on employees only, and not on their dependents);
  - — some industries may have an unstable (mobile) population (for example, agricultural industries).
- Patients' groups and registries:
  - — data are only available if these patients use any health services; coverage of the registries may be unsatisfactory.
- Disease registries:
  - — most registries have data only from areas or health centres with special facilities relevant to the diagnosis of the diseases covered by the registry.
- Surveillance systems:
  - — data from notification reports usually do not refer to a specific reference population, and their accuracy depends on the conditions prevailing at the time of notification;
  - — data from special surveys are usually available for a single point in time; hence they may not be useful for study of morbidity and disability patterns over time;
  - — these systems tend to pick up chronic diseases rather than acute conditions.
- Reports:
  - — data from reports do not provide information on individuals;
  - — being summary data, reports are generalizations of what was observed.

The usefulness of the data obtained is likely to decrease as one moves up the hierarchy of health services and reporting agencies.

Suggestions to improve data

- Strengthen hospital medical records departments through training programmes
- Create awareness among primary health data generators of their important role as primary data contributors
- Encourage all health workers to use health-related information in support of their activities
- Feed information back to health institutions, so that those involved in generating the data can see the results of their labours

- Make reports more comprehensive, so that the summary information is complete, meaningful and useful
- Data elements should produce a primary benefit at the level of collection

Common disease indices

Define and differentiate between the following disease indices, explaining their particular uses: proportion, ratio and rate.

Examples:

- If 105 male and 115 female babies are born alive with congenital malformations in one year then the *proportion* of malformed male babies among children with malformation is:

  $$\left[105/(105 + 115)\right] \times 100 = 47.7\%.$$

- The *ratio* of male to female congenitally malformed children is:

  105:115 or 1:1.1.

- The average number of children born with congenital malformations per year, for every 1000 live births, is a *rate* of congenital malformations per year.

Numerators and denominators of morbidity indices

The following table gives numerators and denominators of morbidity indices.

Index	Numerator	Denominator
Proportion	People with the disease	All people (with and without the disease)
Ratio	People with the disease	People without the disease
Rate	People with the disease in a given period	All people (with and without the disease)

Prevalence and incidence

Define prevalence (point and period) and incidence, describing their applications. Mention should also be made of their interrelationship, and their dependence on the duration of the disease.

Examples:

- Disease *period prevalence*:
  - — the number of children diagnosed as malnourished in a health centre catchment area during the year 1994 (old cases starting before the study plus new cases starting during the study);
  - — the number of accident cases in the surgical ward of a hospital during the month of January 1995 (one month period: old cases that were present at 1 January 1995 plus new cases admitted during January 1995).
- Disease *point prevalence*:
  - — the number of accident cases in the surgical ward of a hospital on a certain day, for example, on 15 January 1995.

- Disease *incidence*:
  - — the number of children diagnosed as having malnutrition during the year 1995 in the catchment area of the health centre;
  - — the number of new accident cases admitted to the surgical ward of the hospital during the month of January 1995.

NEW TERMS AND CONCEPTS (see Handout 12.1)

Health; morbidity; disability; prevalence (point, period, person, episode); incidence (person, episode); population at risk; proportion; ratio; rate.

Structure of the lesson

(*a*) When presenting the lesson the teacher should use medically (health) oriented examples to illustrate the various points. The selected examples should be relevant and meaningful to the students.

(*b*) The teacher should explain the statistical implications of the definitions of health, morbidity and disability. The presentation should cover problems of incompleteness and inaccuracy of data, with indications as to how these problems could be solved.

(*c*) Discussion of the sources of local and national morbidity and disability data is best done by considering each level of the health system in turn, from the peripheral to the national (central) level. The discussion should include examples, not only of the different data elements collected at each level, but also of the different depths at which data on a characteristic may be collected at the different levels. (Reference may be made to Outline 2.) The teacher should stress that the primary need for morbidity and disability data is for health management at the level at which they are collected.

(*d*) The discussion of indices of health, morbidity and disability should emphasize their uses more than their computation. The distinction between prevalent and incident cases may best be demonstrated graphically (an example is shown in Handout 12.2).

Lesson exercises

The exercises on measurement of morbidity should be as relevant to the students' environment as possible, as they are among the best vehicles for demonstrating the use of statistical principles in future work. A local data source should be used for the exercises. The exercises should focus on the sources of morbidity data, the problems involved in routine data collection and shortcomings of data sources. The exercises should also aim to help the students practise the computation and interpretation of simple indices of morbidity (proportions, prevalence, incidence, ratios and rates).

■ Describe the disease pattern using data from your country.

■ Define the prevalence rate of a disease and describe steps to obtain the data for the calculation of the rate.

■ Calculate the age-specific prevalence rate from the data on disease surveillance in your country.

■ The data obtained on absenteeism due to acute upper respiratory system diseases among the employees in a big carpentry factory during the month of January 1995 are given in Handout 12.2. The estimated total number of employees working in this factory is 250.

— Identify which cases should be used to calculate prevalence and incidence rates, and the number of sickness episodes and sick employees.

— Calculate the point prevalence for 10 January 1995.

— Calculate the period prevalence and incidence rates.

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Definitions of new terms and concepts

Disability: Restriction or lack (resulting from an impairment) of ability to perform an activity in the manner or within the range considered normal for a human being.

Handicap: A disadvantage for a given individual, resulting from an impairment or a disability, that limits or prevents the fulfilment of a role that is normal for that individual.

Health: Defined in the Constitution of the World Health Organization as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".

Impairment: Any loss or abnormality of psychological, physiological or anatomical structure or function.

Incidence: Occurrence of new cases of a specified disease in a specified community during a specified period of time.

Morbidity: Any departure, subjective or objective, from a state of physiological or mental well-being, whether due to disease, injury or impairment.[1]

Population at risk: People who stand a chance of contracting a specified disease (for example, during an epidemic outbreak).

Prevalence: A measure of the total number of existing cases (episodes or events) of a disease or condition at a specified point in time. (If a period of time is specified, then the resulting disease measure is **period prevalence**.)

Proportion: Defined as the fraction $a/(a + b)$ for mutually exclusive groups with elements a and b. (The b elements may belong to more than one group, each mutually exclusive of the group with the a elements.)

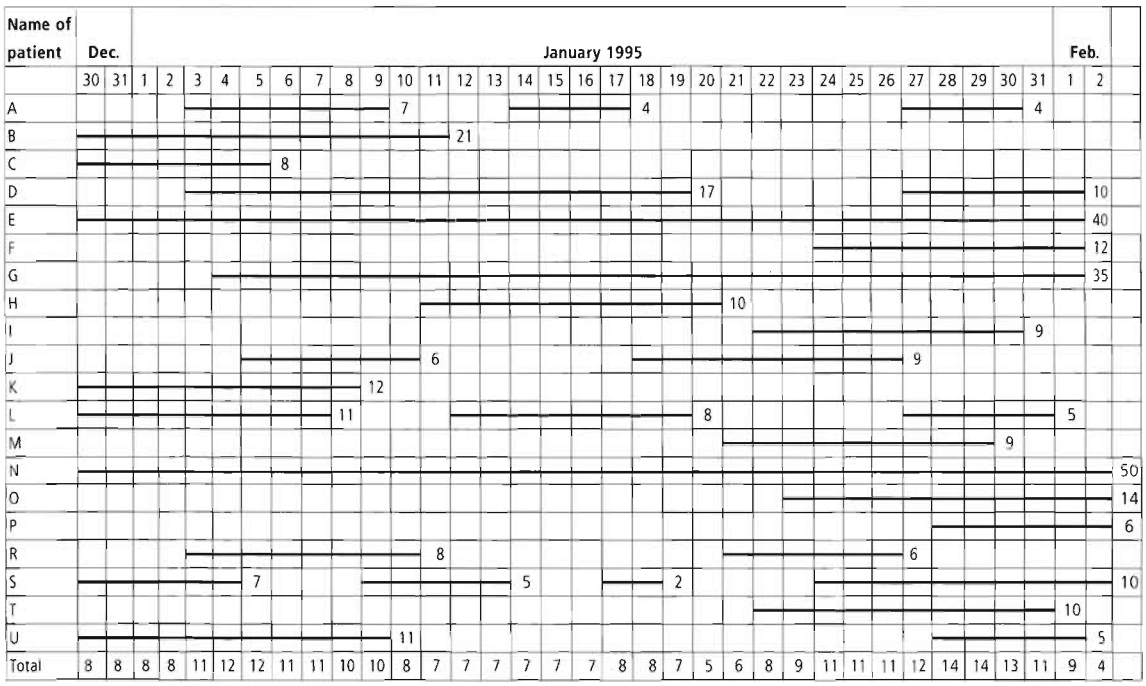
Rate: A measure of the "speed" at which events are occurring (for example, rate of incidence of a specified disease is a measure of the "speed" with which new cases occur in the community).

Ratio: Defined as the fraction a/b for two mutually exclusive groups with elements a and b (conventionally expressed as $1 : b/a$).

[1] *WHO Expert Committee on Health Statistics. Sixth Report.* Geneva, World Health Organization, 1959 (WHO Technical Report Series, No. 164).

Example of data on absenteeism due to acute upper respiratory system diseases, Turkey

The data obtained on absenteeism due to acute upper respiratory system diseases among the employees in a big carpentry factory in Ankara, Turkey, during the month of January 1995 are given below. The estimated total number of employees working in this factory is 250.



Name of patient	Dec.		January 1995																												Feb.		
	30	31	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	1	2	
A												7								4												4			
B														21																					
C								8																											
D																						17													10	
E																																			40	
F																																			12	
G																																			35	
H																							10													
I																																	9			
J													6																9							
K											12																									
L										11												8												5		
M																																9				
N																																				50
O																																				14
P																																				6
R													8																6							
S							7									5						2														10
T																																		10		
U												11																							5	
Total	8	8	8	8	11	12	12	11	11	10	10	8	7	7	7	7	7	7	8	8	7	5	6	8	9	11	11	11	12	14	14	13	11	9	4	

Explanatory notes for the table

(*a*) Each horizontal bar represents an episode of disease, from beginning to end.

(*b*) The length of each bar represents the duration of the disease (or duration of the worker's absence), which is written at the end of the bar.

(*c*) Some of the employees were sick more than once in the study period.

(*d*) The figures in the column totals are the number sick on each day of January. For example, on 20 January 1995, five employees were sick.

OUTLINE 13 Measurement of mortality

Introduction to the lesson

The measurement of the level of health of a community is usually undertaken by studying mortality and morbidity due to different causes. In practice, mortality statistics are easier to come by than morbidity data, and can provide much useful information on the disease patterns in the community.

Objective of the lesson

The objective of this lesson is to discuss the role of mortality statistics in clinical and community medicine, the definitions of various indices, and their uses and interpretations.

Enabling objectives

At the end of the lesson, the students should be able to:

(*a*) Discuss the uses and limitations of mortality statistics in clinical medicine and community health.

(*b*) List the local and national sources of mortality data.

(*c*) Describe the local and national systems of recording, reporting and registering deaths and fetal deaths.

(*d*) Identify the shortcomings in the local and national systems of recording, reporting and registering deaths and fetal deaths in terms of the completeness and reliability of data.

(*e*) Compute the following mortality indices and explain their uses:

- crude death rate;
- age-specific, sex-specific and age/sex-specific death rates;
- stillbirth rate (late fetal death rate);
- perinatal mortality rate;
- neonatal mortality rate;
- post-neonatal mortality rate;
- infant mortality rate;
- maternal mortality rate;
- disease/cause-specific death rate;
- case–fatality rate;
- specific death ratio.

(*f*) Describe the limitations of the crude death rate as a comparative index of total mortality.

(*g*) Explain the meaning and use of a standardized death rate.

(*h*) Compute, from a given set of data and reference material, a standardized death rate (using both direct and indirect methods).

(*i*) Explain the meaning of life expectancy.

Required previous knowledge

Contents of Outlines 2, 11 and 12.

Lesson content

Mortality data

- Mortality statistics:
  - components of mortality data;
  - summaries of mortality data;
  - aggregation, tabulation and presentation of mortality data by categories of special importance for health monitoring (for example, sex, age, occupation).
- The use of mortality and fatality rates in the following contexts:
  - comparative assessment of community health;
  - assessment of health needs of the people and fixing of priorities for action in terms of reducing risks of death;
  - remodelling and strengthening health services;
  - evaluation of health programmes;
  - measurement of the relative importance of specific diseases as causes of death;
  - estimation of the average span of life that an individual of a specified age is likely to attain;
  - assessment of the efficacy of a drug or procedure, in a clinical trial, against a disease, particularly one for which fatality is high.

Limitations of mortality data

Used alone, mortality data do not reveal the levels of health of a group of people who are alive. Detailed cause-specific mortality data are of limited use in the absence of reliable statistics on births, deaths and demographic aspects, preferably by geographical and social subgroups.

Sources of mortality data

Sources of mortality data include:

— vital registration system;

— national sample surveys;

— special health surveys;

— health facility records;

— notification of infectious diseases;

— government health institutions;

— voluntary health institutions;

— revenue agencies;

— police;

— village/community councils;

— reports of national and international organizations;

— census of population;

— registration systems.

Systems for death registration

Refer to Outline 11.

Definitions of mortality rates

Handout 13.1 gives the definitions for the computation of mortality rates. All the rates are usually calculated for one year (but they may be calculated for any other specified period). A one-year period is assumed here.

- The advantages and disadvantages of the *crude death rate* are that:
  - — it measures the average risk of death in the population at large;
  - — it is easy to compute;
  - — it is often used to compare relative mortality in a given area between two periods that are not too far apart;
  - — its level is affected by the age and sex composition of the population; hence it can only be used to compare general mortality levels of two populations if they have a similar age/sex composition;
  - — it takes no account of the fact that the chance of dying varies according to age group, sex, race, occupation, etc.
- The advantages and disadvantages of the *age-specific, sex-specific and age/sex-specific death rate* are that:
  - — it measures the risk of death among persons in a specific age and/or sex group;
  - — it is simple to calculate;
  - — it can be used to compare the mortality of two populations of the same specific age and/or sex group, even when the age and/or sex compositions of these populations are different;
  - — it gives the essential components for constructing life-tables;
  - — it does not summarize total mortality in a single figure;
  - — it takes no account of differences in the population structure in terms of race, occupation, religion, etc.;

— comparison of overall mortality conditions in the two populations is cumbersome, because of the need to compare rates for all the different age groups, and for males and females.

Meaning of life expectancy

Life expectancy is the number of years that a person, at a certain age, is expected to live. The most used indices are expectation of life at birth and at 5 years of age.

Standardization of death rates

Standardized death rates are rates in which allowance has been made for the composition of the population. They are used to compare the mortality experience of two or more populations of different compositions.

Standardized death rates may be computed by:

— direct method;

— indirect method.

NEW TERMS AND CONCEPTS (see Handout 13.1)

Case–fatality rate; crude death rate; death rates (age-specific, sex-specific, age/sex-specific, disease/cause-specific); late fetal death rate; leading causes of deaths; life-table; mortality rate (infant, neonatal, perinatal, post-neonatal, maternal); mortality statistics; specific death ratio (by age and cause); standard population; standardization of death rates; standardized mortality ratio; stillbirth rate and ratio; perinatal mortality rate and ratio.

Structure of the lesson

(*a*) Discuss the relative advantages and disadvantages of defining, collecting, and using mortality data, as compared with morbidity data. Explain the relevance and uses of mortality statistics in clinical and community medicine, giving examples.

(*b*) Discuss the sources of mortality data. Explain the vital registration system in the country and the procedures for reporting, recording and registering deaths and fetal deaths, making reference to the actual record forms involved. Point out the possible sources of error or inaccuracy, and causes of under-reporting or over-reporting; describe the steps that can be taken to evaluate or reduce these errors, and the role of physicians and other health workers in the system.

(*c*) Explain the uses and definitions of the common mortality indices and their applicability and limitations in your country, differentiating where applicable between national practice and international recommendations.

(*d*) Point out that, for monitoring national health development, cause-specific mortality data are less important than gross indicators of mortality (infant mortality, child mortality, maternal mortality, and overall mortality).

(*e*) Explain the purpose of a comparative index of total mortality, the limitations of the crude death rate for this purpose, and hence the need for a standardized death rate. Give examples of crude and standardized rates, and discuss their use and interpretation, as well as their

limitations. Show, with reference to worked examples, how a standardized rate may be computed, differentiating between the direct and the indirect methods. Emphasize the fictitious nature of standardized death rates, which do not depict the true experience of any population. Standardized death rates are derived purely for comparative purposes.

(*f*) Discuss the general principle of standardization and its possible application to comparisons of other parameters besides total mortality, illustrating with examples of disease-specific mortality (for example, comparing cancer mortality between countries) and morbidity (for example, comparing incidence or prevalence of a disease between countries). Stress that a common standard is a prerequisite for valid comparison of standardized indices. Discuss the problem of selecting a standard population, and the acceptability or otherwise of a common standard population for all occasions and all countries.

Lesson exercises

The possible sources of mortality data and the degree of quality of each source should be assessed. National data should be given for calculations of mortality indices. The exercises should test the students' ability to use the indices to describe the health situation of the country, and to compare their results with those for other countries.

■ Table13.1 gives the mid-year population by age and sex, and the number of deaths which occurred in each age and sex group in 1994, in the area covered by one health centre in rural Turkey.

Table 13.1 ***Age and sex distribution of mid-year population and deaths in a rural region of Turkey***

	Population			Deaths		
Age	**Male**	**Female**	**Total**	**Male**	**Female**	**Total**
Under 1	661	676	1337	85	80	165
1–4	2310	2216	4526	19	15	34
5–9	3286	3205	6491	2	2	4
10–14	3506	3431	6937	1	1	2
15–19	3258	3321	6579	3	2	5
20–24	2553	2386	4939	1	3	4
25–29	2542	1607	4149	1	1	2
30–34	1686	1381	3067	0	1	1
35–39	1271	1145	2416	5	1	6
40–44	1288	1313	2601	4	3	7
45–49	1354	1291	2645	3	6	9
50–54	1152	1024	2176	15	8	23
55–59	861	784	1645	20	10	30
60–64	572	494	1066	19	13	32
65–69	589	521	1110	31	19	50
70–74	368	276	644	25	16	41
75–79	175	141	316	20	14	34
80–84	92	103	195	18	16	34
85+	26	24	50	14	7	21
Total	**27550**	**25339**	**52889**	**286**	**218**	**504**

Details of the infant deaths are as follows:

Age (days) at death	Male	Female	Total
0–6	19	13	32
7–27	9	12	21
28–364	57	55	112
Total	**85**	**80**	**165**

The total number of births occurring in this region in 1994 was 1315, with 20 stillbirths. Table 13.2 gives the ten leading causes of death by age and sex, in the same region.

Table 13.2 ***Ten leading causes of deaths by age and sex in a rural region of Turkey (same region as Table 13.1)***

Causes of death	Male	Female	Total
Chronic bronchitis	37	26	63
Senility	30	18	48
Hypertension	19	29	48
Ischaemic heart disease	19	11	30
Pneumonia	17	12	29
Perinatal causes	17	10	27
Intestinal infections	12	10	22
Malignant neoplasm	13	8	21
Nutritional deficiency	11	8	19
Congenital anomalies	9	7	16

Evaluate the mortality situation in this health centre region by using the data given in Tables 13.1 and 13.2, and by using the rates and ratios given in Handout 13.1.

■ Prepare a report to present the findings, giving your interpretation of the mortality data.

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Definition of mortality rates

All the following death rates are usually calculated for one year (but they may be calculated for any other specified period).

Crude death rate (CDR): [Total number of deaths occurring in a year ×1000]/Mid-year population. The adjective "crude" refers to the overall death rate with no compensation for the effect of any associated factor, such as age, sex or race.

Age-specific death rate: [Total number of deaths in a specific age (or age group) in a year ×1000]/Mid-year population of the same age (or age group) of the population.

Sex-specific death rate: [Total number of deaths in a specific sex group in a year ×1000]/Mid-year population of the same sex group.

Age/sex-specific death rate: [Total number of deaths in a specific age and sex group in a year ×1000]/Mid-year population of the same age and sex group.

Stillbirth (or late fetal death) rate: [Number of stillbirths occurring in a year ×1000]/Total number of births in the same year.

Stillbirth (or late fetal death) ratio: [Number of stillbirths occurring in a year ×1000]/Total number of live births in the same year.

Perinatal mortality rate: [(Number of stillbirths) + (number of infant deaths in the first week after birth) in a year ×1000]/Total number of births in the same year.

Perinatal mortality ratio: [(Number of stillbirths) + (number of infant deaths in the first week after birth) in a year ×1000]/Total number of live births in the same year.

Neonatal mortality rate: [Number of deaths of infants under 28 days of age in a year ×1000]/Total number of live births in the same year.

Post-neonatal mortality rate: [Number of deaths among infants aged between 28 and 364 days in a year ×1000]/Total number of live births in the same year.

Infant mortality rate: [Number of deaths under one year of age in a year ×1000]/Total number of live births in the same year.

Maternal mortality rate: [Number of female deaths due to complications of pregnancy, childbirth and the puerperium in a year ×1000]/Total number of live births in the same year.

(In the strict sense, this is a maternal mortality *ratio*. Ideally the denominator should include all deliveries and abortions, but because of lack of data on abortions, only live births are used.)

Disease/cause-specific death rate: [Number of deaths due to a specified disease (cause) occurring in a year ×1000]/Mid-year population.

Case–fatality rate: [Number of deaths due to a given disease or condition occurring in a year ×1000]/Total number of persons who suffered from the same disease or condition in the same year.

Age-specific proportional death ratio: [Number of deaths at a specified age or in a specified age group (usually for 50+) in a year ×100]/Total number of deaths in the same year.

Cause-specific proportional death ratio: [Number of deaths from a specified cause in a year ×100]/Total number of deaths in the same year.

Worked examples on the calculation of standardized death rates

Table 13.3 ***Mid-year population by age and age-specific death rates for three towns in 1990***

Age group (years)	Town A		Town B		Town C	
	Population	Death rate per 1000	Population	Death rate per 1000	Population	Death rate per 1000
0–4	9222	27.11	6473	24.10	15695	26.00
5–14	19576	2.25	13740	1.97	33316	2.01
15–49	39056	3.00	22458	2.89	61514	2.94
50–59	4156	12.03	6164	11.52	10320	11.63
60–69	2688	29.76	4165	32.17	6853	30.06
70–79	1489	76.56	2795	55.10	4284	60.00
80+	334	137.72	972	110.08	1306	123.28
Total	**76521**	**9.16**	**56767**	**12.58**	**133288**	**10.50**

As seen from Table 13.3, the crude death rates of Towns A and B are 9.16 and 12.58 per 1000, respectively. This result may be due to the different age composition of the two towns. The first step should be to check if these two towns are different from the point of view of age composition. If they are different, then we have to calculate the standardized death rate. In this example, the age composition of these two towns is different.

Direct method of standardization

Table 13.4 demonstrates the steps to be followed in the computation of standardized death rates for the two towns, by the direct method. The population of Town C will be used as the standard population. The standard population and death rates are taken from Table 13.3. The expected number of deaths is calculated by multiplication of the standard population by the death rate, for each age group.

Table 13.4 ***Standard population and expected deaths: direct method of standardization***

Age group (years)	Standard population	Town A		Town B	
		Death rate per 1000	Expected deaths	Death rate per 1000	Expected deaths
0–4	15695	27.11	425	24.10	378
5–14	33316	2.25	75	1.97	66
15–49	61514	3.00	185	2.89	178
50–59	10320	12.03	124	11.52	119
60–69	6853	29.76	204	32.17	220
70–79	4284	76.56	328	55.10	236
80+	1306	137.72	180	110.08	144
Total	**133288**		**1521**		**1341**

Calculation of the standardized death rate (SDR):

$$\text{SDR} = \left[\text{Total number of expected deaths} \times 1000\right] / \text{Standard population.}$$

For Town A it is: $\text{SDR}(\text{A}) = (1521/133\,288) \times 1000 = 11.41.$

For Town B it is: $\text{SDR}(\text{B}) = (1341/133\,288) \times 1000 = 10.06.$

Comments

This result shows us that although the crude death rate (CDR) is higher in Town B than in Town A, the standardized death rate for Town B is lower than that for Town A. A careful study of the age compositions of these two towns will show that the proportion of the elderly population in Town B is higher than that in Town A, this being the reason for the higher crude death rate. When we standardized the populations of the two towns by age, we compared the two towns on the basis of similar age compositions, and the effects of age on the crude death rates were, therefore, cancelled.

It may be concluded that the mortality risks in the population of Town A are higher than those in Town B. In other words, from the mortality conditions, it may be inferred that people of Town A have poorer health than those of Town B.

Indirect method of standardization

The death rates of Town C are taken as the standard death rates to be applied to the populations of Town A and Town B in Table 13.3. The calculation process is given in Table 13.5.

Table 13.5 ***Standard death rates and expected deaths: indirect method of computation***

Age group (years)	Standard death rates	Town A		Town B	
		Population	Expected deaths	Population	Expected deaths
0–4	0.0260	9222	240	6473	168
5–14	0.0020	19576	39	13740	28
15–49	0.0029	39056	115	22458	66
50–59	0.0116	4156	48	6164	72
60–69	0.0301	2688	81	4165	125
70–79	0.0600	1489	89	2795	168
80+	0.1233	334	41	972	120
Total	**0.0105**	**76521**	**653**	**56767**	**747**

(*a*) Calculate the expected number of deaths by multiplying the standard death rate by the population of each age group in each town, separately. The results are shown in Table 13.5.

(*b*) Calculate the index death rate by dividing the total expected number of deaths in each town by the total population of the same town, separately:

$$\text{Index death rate} = \left[\text{Total number of expected deaths} \times 1000\right] / \text{Population.}$$

For Town A it is: $(653/76521) \times 1000 = 8.53.$

For Town B it is: $(747/56767) \times 1000 = 13.16.$

Divide the crude death rate of the standard population by the index death rate to obtain the standardizing factor.

For Town A, the standardizing factor is: $10.50/8.53 = 1.231$.

For Town B, the standardizing factor is: $10.50/13.16 = 0.798$.

Multiply the crude death rates of Towns A and B by their standardizing factors to obtain the standardized death rates.

For Town A, the standardized death rate is: $9.16 \times 1.231 = 11.276$.

For Town B, the standardized death rate is: $12.58 \times 0.798 = 10.039$.

Comments

The crude death rates of Towns A and B are 9.16 and 12.58 per 1000, respectively. The standardized death rates are 11.28 for Town A and 10.04 for Town B. The indirect method of standardization gave similar results to the direct method for the same towns.

OUTLINE 14 Measurement of fertility

Introduction to the lesson

Planning of effective and efficient maternal and child health (MCH) and family planning services requires reliable information on fertility and the fertility behaviour of the community, including their determinants. Statistics on population characteristics and on mortality and morbidity are also important. Fertility level indices are essential for the monitoring of such services.

Objective of the lesson

The objective of this lesson is to provide the students with the skill to be able to measure levels of fertility and to appreciate the limitations of these measures.

Enabling objectives

At the end of this lesson, the students should be able to:

(*a*) State the importance of fertility statistics in the planning of health services, especially in MCH and family planning.

(*b*) Describe the sources of data, their advantages, disadvantages and limitations.

(*c*) Discuss the factors affecting fertility behaviour of the community.

(*d*) State and define the main indices for measuring fertility, and discuss their uses and limitations.

(*e*) Describe the net reproduction rate and explain its use for the measurement of population replacement.

(*f*) State and define the main indices for measuring family planning activities.

(*g*) Compute from appropriate data the following rates:

- crude birth rate;
- general fertility rate;
- age-specific fertility rate;
- total fertility rate;
- gross and net reproduction rate;
- rates of family planning activities:
  - — current users' rate;
  - — beginner's rate;
  - — induced abortion rate;
  - — open and closed birth interval.

Required previous knowledge

Contents of Outlines 2, 11 and 13.

Lesson content

This lesson is concerned with the importance of fertility statistics in planning maternal and child health (MCH) and family planning services.

Sources of fertility data

The following are sources of fertility data:

— hospital and maternity records;

— registration of births, stillbirths, abortions (refer to Outline 13);

— population census (refer to Outline 11);

— ad hoc surveys.

Indices of fertility

The five main indices for measuring fertility are: crude birth rate, general fertility rate, age-specific fertility rate, total fertility rate, and gross reproduction rate (for definitions, see Handout 14.1). All these rates are usually calculated for one year (but they may be calculated for any other specified period).

Uses and limitations of fertility indices

Crude birth rate: used to indicate the general magnitude of the fertility level. Limitations include its sensitivity to differences in age structure of the population, and the fact that its denominator includes sections of the population not able to give birth.

General fertility rate: intended mainly as an index of general fertility, relating mainly to those at risk of giving birth. Its value is affected by the age distribution of women in the reproductive age group.

Age-specific fertility rate: used to measure the reproductive performance of women of a given age, thus showing variation in fertility by age. Its use, to indicate variations in fertility level with age, should take into account the fact that the comparison is between different groups of women. It is not a summary index of overall fertility level of the whole population.

Total fertility rate: used as a standardized index for the overall fertility level. It overcomes the limitations of the crude birth rate and the general fertility rate. Its use as an indicator of cohort fertility is limited by the fact that the experiences summarized refer to groups of women at different ages, that is, a synthetic cohort, not a real cohort.

Gross reproduction rate: has the same uses as the total fertility rate, but also purports to give an indication of replacement of females in the population per generation. It has the same limitations as the total fertility rate; in addition, it can distort comparisons of populations with differing sex ratios at birth. Its use as a replacement index does not take mortality into account.

Net reproduction rate: shows the size of a particular generation in relation to the previous generation, that is, the rate of replacement of females in the population per generation, according to present schedules of fertility and mortality. It has long-term implications for population growth. It is calculated by assuming that newborn females are subjected, throughout their lives, to the current observed age-specific mortality rates in the population. It is further assumed that survivors will bear children according to the current age-specific fertility rates. The total number of female offspring divided by the number in the original population is the net reproduction rate. If this rate is less than one, then the reproductive performance of the population is said to be below replacement level.

Measuring the activities of family planning

Useful measures of family-planning activities are the current users' rate, beginners' rate, open birth interval, closed birth interval, and induced abortion rate (for definitions, see Handout 14.1).

NEW TERMS AND CONCEPTS (see Handout 14.1)

Crude birth rate; general fertility rate; age-specific fertility rates; total fertility rate; gross reproduction rate; net reproduction rate; family planning; current users' rate; beginners' rate; induced abortion rate; open birth interval; closed birth interval.

Structure of the lesson

(*a*) Explain the meaning and importance of the study of fertility in health services planning and population growth.

(*b*) Explain the sources of fertility data, their advantages and limitations.

(*c*) Explain the definitions and uses of the common fertility indices. Explain the age patterns of fertility and mortality in terms of cohort survival and reproduction, differentiating between the concepts of synthetic and real birth cohorts involved in the computation and interpretation of the indices concerned.

(*d*) Explain the importance of family planning and indices of the activities of family planning.

Lesson exercises

The teacher should ask the students to list the common indices of fertility and the sources of data for the calculation of the indices. The students should describe the factors which affect trends in fertility. Give national data for the calculation of indices of fertility, and compare the results with other countries or regions.

■ Table 14.1 gives the mid-year population of women in the reproductive age group and the number of births among these women in the area covered by a rural health centre in Turkey in 1994.

Table 14.1 ***Mid-year population of women in the reproductive age group and number of births***

Age	Mid-year population	Number of live births			Number of stillbirths	Total births
		Male	Female	Total		
15–19	3321	109	86	195	1	196
20–24	2386	262	262	524	4	528
25–29	1607	155	165	320	5	325
30–34	1381	64	66	130	4	134
35–39	1145	40	32	72	2	74
40–44	1313	17	24	41	3	44
45–49	1291	18	15	33	1	34
Total	**12444**	**665**	**650**	**1315**	**20**	**1335**

Calculate the crude birth rate and all the fertility rates given in Handout 14.1.

■ Prepare a report on the fertility level of this health centre region.

■ Define the general fertility rate and give the estimate for your country. How is the rate different from that of the total fertility rate?

■ List, and give estimates of, four measures of fertility for your country. Which one is the best indicator of fertility levels?

References

Pressat R. *Demographic analysis.* Chicago, Aldine-Atherton, 1972.

Shryock HS, Siegel JS. *The methods and materials of demography. Vols I & II.* United States Department of Commerce, 1971.

United Nations. *Demographic yearbook.* New York, United Nations [published annually].

Evaluation of the Strategy for Health for All by the Year 2000: seventh report on the world health situation, Vol. 5: European Region. Geneva, World Health Organization, 1986.

HANDOUT 14.1

Definitions of new terms and concepts

All the following fertility rates are usually calculated for one year (but they may be calculated for any other specified period).

Age-specific fertility rate: [Number of live births to women of specified age or age group in a year ×1000]/Mid-year population of the specified age or age group.

Crude birth rate: [Number of live births in a year ×1000]/Mid-year population.

General fertility rate: [Number of live births in a year ×1000]/Mid-year population of women of childbearing age (15–44 years or 15–49 in some countries).

Gross reproduction rate: The total fertility rate restricted to female births only. It is the average number of daughters that a synthetic cohort of women would have at the end of the reproductive period, if there were no mortality among the women.

Net reproduction rate: Rate of replacement of females in the population per generation, with the current schedules of fertility and mortality.

Total fertility rate: Sum of all the age-specific fertility rates for each year of age from 15 to 49 years. It is the average number of children that a synthetic cohort of women would have at the end of the reproductive period, if there were no mortality among the women.

The following rates can be calculated for any period of time, as well as for a year.

Beginners' rate: [Number of new users of any contraceptive method in a specified period ×100]/Total number of non-users.

Current users' rate: [Number of current users of any contraceptive method in a specified period ×100]/Total number of target population. This rate can be calculated specifically, by using several variables, such as method and education.

Induced abortion rate: [Number of induced abortions in a specified period ×100]/Total number of live births in this specified period. Abortions performed for medical purposes and spontaneous abortions are excluded.

Additional definitions:

Closed birth interval: Interval between two successive births.

Open birth interval: Interval between last birth and the date of the study.

Real birth cohort: A group of births occurring at the same time.

Synthetic birth cohort: An artificial birth cohort, composed of a cross-sectional sample of the population.

OUTLINE 15 Population dynamics

Introduction to the lesson

There is a close interaction between population dynamics and medicine. The practice of medicine and the management of health development require an understanding of the current size and composition of the population, and of the determinants of changes in these characteristics. Health planners must also be able to describe such changes quantitatively.

Objective of the lesson

The objective of the lesson is to familiarize the students with the concept of population dynamics, to explain to them the nature of the interaction between the various factors that produce changes in population size and structure, and to teach them how to use appropriate indices to describe population change.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) State the factors determining the age and sex composition of a population and the changes over time.

(*b*) State the determinants of changes in population size.

(*c*) Make population projections using arithmetic and geometric progressions, given the appropriate formulae.

(*d*) State and define the indices for measuring survivorship.

(*e*) Describe and interpret population pyramids.

(*f*) Explain the concept of demographic transition.

Required previous knowledge

Contents of Outlines 2, 11, 13 and 14.

Lesson content

Definition and concept of population dynamics

Population dynamics is the study of changes in population size and structure. The determinants of population growth are the number of births and deaths, and the amount of migration into and out of the area.

Population structure or composition

Population structure refers to the distribution of people by certain categories, variables, or characteristics, for example, age, sex and geographical area:

- the distribution by age shows the number or proportion of persons in each age group;
- the sex distribution shows the number or proportion of persons of each sex;
- the distribution by geographical area shows the number or proportion of persons living in each area.

Population pyramid

Definition: a graphic presentation of the age and sex distribution of a population in the shape of a pyramid.

Uses: to study sex-specific age distribution of a population. A series of population pyramids over time can be used to study ageing patterns of birth cohorts.

Construction: the basic pyramid form consists of bars, usually representing 5-year age groups (or other age combinations) in ascending order, from the lowest to the highest age group. Conventionally, the left side is used for males and the right side is used for females.

Population change with time

Various factors determine the age and sex structure of a population, and the changes over time.

(*a*) The "cause and effect" aspect of population structure:

- the present population structure is the effect of previous structures; for example, a current population with a large number of 5–10-year-olds is the effect of a large number of births 5–10 years ago.
- the present composition is the cause of the future composition.

(*b*) Influence of changing demographic characteristics:

- changes in fertility levels and patterns are the important determinants in modifying population structure: a prolonged decrease in fertility level (for example, as a result of widespread contraceptive practices or increase in age at marriage) will have a marked effect on the structure of the population;
- changes in mortality levels and patterns also modify population structure, but are less important than fertility.

(*c*) Population structure can also be affected by unusual phenomena, such as wars, mass migration, or a pandemic outbreak of a killer disease.

Indices used to describe population growth

(*a*) Type of population growth:

- natural (or reproductive) growth is the balance between births and deaths;
- total growth is the balance between births, deaths and net migration.

(*b*) Measurement of population growth:

- the general measurement of growth is given by intercensal percentage

change in size, that is,

$$\left(P_t - P_0\right)/P_0 \times 100,$$

where P_0 is population size at a given census, and P_t is the population size at a census t years later;

- the rate of population growth is the change in size per unit time;
- the annual rate of growth r is the relative change in population size per year;
- there are two commonly used assumptions concerning the nature of growth, namely:

the arithmetical growth model: $P_t = P_0\left(1 + rt\right)$

the geometric growth model: $P_t = P_0\left(1 + r\right)^t$

where P_0 = baseline population, P_t = population at time t, and r = population rate of change.

Simple population projections

The expressions linking P_t with P_0 and r can be used to make projections of the present population to any time in the future (refer to Handout 15.2).

Hazard of population projection

Accurate projections of the population require a realistic estimate of r (that is, the change in the growth rate itself) during the projection period.

Indices for measuring survival

There are two indices for measuring survival:

Expectation of life at birth is the number of years of life a newborn baby is expected to live under the prevailing mortality conditions in the population.

The *probability of survival* from one age to another is the chance that those attaining a stated age will survive to a given higher age.

Concept of demographic transition

- Stable population
- Stationary population
- Implications of rapid population growth; time for the population to double (the "70/r" rule)

NEW TERMS AND CONCEPTS (see Handout 15.1)

Annual rate of population increase; arithmetic progression; change in population size; change in population structure (age and sex); demographic transition; expectation of life at birth; geometric progression; migration; natural growth; population dynamics; population "explosion"; population pyramid; probability of survival; rate of natural increase; rate of population growth; stable population; stationary population; survival rate; young-old population; zero population growth.

Structure of the lesson

(*a*) Explain the use of the population distributions by sex and age, emphasizing their importance in the calculation of age-specific and sex-specific rates.

(*b*) Explain the meaning and importance of the study of population dynamics, differentiating between changing population size and changing population structure (distribution by age and sex).

(*c*) Illustrate and discuss past trends in population size in the country, and show how these have resulted from trends in the number of births and deaths, as well as from migration. Differentiate between external and internal migration, and between population trends for the country as a whole and for geographical subdivisions (for example, urban/rural areas). Show graphically, and by the trend in growth rates, whether the population size has been changing according to arithmetic or geometric progression, and examine the reasons for this. (The use of semi-log paper to illustrate geometric growth may suitably be demonstrated here.) Explain the possible use of computers to draw population pyramids.

(*d*) Explain the computation of the arithmetic and geometric growth rates, and show that projections based on assumptions of arithmetic growth and of geometric growth produce different estimates of future population size.

(*e*) Illustrate and discuss past trends in the age–sex composition of the population, using population pyramid charts to facilitate comparison. Explain the implications of "young" and "old" populations, the dependence of age structure on fertility, and how changes in fertility and mortality affect population trends in age composition and in size.

(*f*) Remind students of the definitions and uses of the common fertility indices. Explain the age patterns of fertility and mortality in terms of cohort survival and reproduction, differentiating between the concepts of synthetic and real birth cohorts involved in the computation and interpretation of the indices concerned.

(*g*) Explain the concept of the demographic transition. Differentiate between stable and stationary populations. Discuss the implications of rapid population growth ("explosion"), of population decline, and of zero population growth.

Lesson exercises

The teacher should obtain population data from the two latest national population censuses. Using these data, set exercises to test the students' knowledge of the concept of population composition and their ability to describe it using population figures and pyramids. Questions should elicit students' ability to calculate population growth rates and to make simple population projections.

■ Obtain population data for your country similar to those presented for Turkey in Outline 13 (Table 13.1). Construct a population pyramid and describe the typical features of the population structure.

■ Using population estimates at two points in time:

(*a*) Calculate the population growth rates using the arithmetic and geometric methods.

(*b*) Use the rates to make a population projection for 10 years beyond the later date using the arithmetical model and the geometric model of population projection, and discuss the results of the two operations.

References

Pressat R. *Demographic analysis*. Chicago, Aldine-Atherton, 1972.

Shryock HS, Siegel JS. *The methods and materials of demography. Vols I & II*. United States Department of Commerce, 1971.

United Nations. *Demographic yearbook*. New York, United Nations [published annually].

Definitions of new terms and concepts

Annual rate of population change: Relative change in population size (increase or decrease) per annum.

Arithmetic progression: A series of figures is said to be in arithmetic progression when the difference between any two adjacent figures is the same. For example, the series 3, 5, 7, 9, 11, 13, . . . is in arithmetic progression. Population sizes over a period of years are in arithmetic progression if the size changes by a constant amount each year.

Change in population structure (age and sex): Alteration in the age-composition and sex-composition of the population, as a result of births, deaths and migration.

Demographic transition: The process by which, over a number of years, continuous changes in one or more of the fertility, mortality and migratory rates in the population produce alterations in the characteristics and structure of the population.

Expectation of life at birth: Number of years a newborn baby is expected to live, given the prevailing mortality conditions.

Geometric progression: A series of ordered numbers is said to be in geometric progression if the proportion between any two adjacent numbers is the same. For example, the series 3, 9, 27, 81, . . . is in geometric progression. Population size over a period of years is said to follow a geometric pattern of growth if the proportional change is constant in successive years.

Migration: Movement of people from one geographical location to another within the same country or across country borders.

Natural growth: Change in population as a result of births and deaths, and excluding migration.

Population dynamics: The study of changes in population size and structure over time.

Population explosion: Rapid increase in population size.

Population pyramid: A method of graphically depicting the age–sex composition of a population.

Probability of survival: Chance that somebody alive at a particular age will still be alive at a given older age.

Rate of natural increase: Relative change in population size brought about solely by the balance between births and deaths; it is obtained as the difference between the crude birth and death rates.

Rate of population growth: Relative change in population size as a result of births, deaths and net migration.

Stable population: A population that has been growing at a constant rate over a number of years.

Stationary population: A population with no migration and for which the crude birth rate is equal to the crude death rate.

Young and old populations: The median age is usually used as a basis for describing a population as "young" or "old". Populations with medians under 20 years may be described as young, those with medians of 30 years or over as old, and those with medians between 20 and 29 as of intermediate age.

The proportion of elderly persons can also be used as an indicator of young or old population. On this basis, populations with 10% or more people aged 65 years and over may be said to be old.

Zero population growth: Absence of growth in the population.

Computation of population projection

Example

If a country with a population of 10.4 million inhabitants has a constant annual population growth rate of 2.1%, what would be its population in 10 years time?

The present population, P_0, is 10.4; $r = 2.1\% = 0.021$; $t = 10$.

P_{10} is the required population ten years from now.

Using the arithmetical model:

$$P_{10} = 10.4\left(1 + 0.021 \times 10\right) = 10.4 \times 1.21 = 12.6,$$

giving an estimated population in ten years time of 12.6 million.

Using the geometric model:

$$P_{10} = 10.4\left(1 + 0.021\right)^{10} = 10.4 \times 1.2310 = 12.8.$$

Thus the population in ten years time is estimated as 12.8 million.

It is not surprising that the results differ (however slightly), as the two relationships used are based on different assumptions for population growth. The geometric model is usually more realistic, and is to be preferred.

OUTLINE 16 Indicators of levels of health

Introduction to the lesson

In order to evaluate the effectiveness and efficiency of a health treatment, health programme or health service, and the extent to which objectives and targets are being achieved, measurable yardsticks (indicators) are needed. Indicators are used to measure changes and to compare different patient groups, treatment regimens, countries and regions, as well as different periods of time.

Objective of the lesson

The objective of this lesson is to introduce the students to the concept of health indicators, and their uses in health monitoring and surveillance.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain the need for monitoring health activities.

(*b*) Describe a health indicator.

(*c*) State the requirements of a good indicator.

(*d*) Give examples of health indicators used for monitoring health activities.

(*e*) Explain the meaning, advantages and disadvantages of each indicator.

(*f*) Identify the data necessary for calculating each indicator.

Required previous knowledge

Contents of Outlines 1, 4, 5 and 6.

Lesson content

The need for monitoring health activities and levels of health

There is a need to monitor health activities and levels of health:

- to determine the extent to which targets are being reached;
- to assess the impact and effectiveness of health programmes;
- to provide information for the programming and re-programming of health activities.

Indicators of levels of health

Health indicators are indices used to measure change or monitor health activities.

Expected requirements of an indicator

The most important desirable characteristics of an indicator (see Handout 16.1) are:

- feasibility;
- reliability;
- relevance;
- sensitivity;
- specificity;
- validity.

Types of indicators

Types of indicators (see Handout 16.2) include:

- health policy indicators;
- social and economic indicators;
- indicators of the provision of health care;
- health status indicators.

Proxy indicators

Proxy indicators are used in place of more definitive (and possibly more objective) indicators which may be more difficult to measure or compute.

Sources of data for the various health indicators

Data sources include:

- vital events register;
- population censuses;
- routine health services records;
- epidemiological surveillance data;
- sample surveys;
- disease registers.

NEW TERMS AND CONCEPTS (see Handout 16.1)

Completeness of coverage; feasibility; goal of a health programme; health status indicator; indicator; objective of a health programme; process indicator; proxy indicator; relevancy of an indicator; sensitivity of an indicator; specificity of an indicator; target (of a programme); validity of an indicator.

Structure of the lesson

(*a*) When presenting the lesson, the teacher should emphasize the need, use, interpretation, advantages and disadvantages of each indicator, rather than their computation. The use of indicators as tools for health monitoring should also be emphasized (refer to Handout 16.3).

(*b*) Explain, with examples, the different groupings of health indicators shown in Handout 16.2.

(*c*) As far as possible, use real data which are relevant to the country when discussing national indicators. The discussion should concentrate on inter-regional comparisons and comparison of indicators over time, to show trends.

Lesson exercises

Encourage students to draw on all the previous lessons to demonstrate how the knowledge could be used to monitor health care activities. The exercises for this lesson should, therefore, aim at helping the students consolidate their knowledge of the need for health monitoring, the need for health indicators and their use (including the type and source of data needed for their computation).

■ List six important health indicators and briefly describe their use.

■ List and rank five indicators of development used to assess a country.

■ A sample of 5018 inhabitants in three counties of Iganga District, Eastern Region of Uganda, was selected by means of a multistage cluster sampling procedure and all were interviewed. Half the population (50.2%) were under 15 years of age and 4.2% were aged one year or less. The male to female ratio was 1:1.1. Most men above the age of 15 years were subsistence farmers and most women worked at home.

A total of 38% of the people of school age had no education. The male adult literacy rate was 61.5%, and the female adult literacy rate was 40.2%.

The majority of the households (82.9%) used a well or an unprotected spring as their main source of water. A total of 30% of households did not have a pit latrine. The average number of people per sleeping room was 2.4.

Of the people interviewed, 5% had been admitted to hospital over the past one-year period for various conditions, including sleeping sickness and measles and for delivery. Of the people interviewed, 22% had been sick within one week of the interview. The major causes of morbidity were fever, clinical malaria, respiratory conditions and non-specific pains.

Clinic utilization appeared to be high for inhabitants living within 10 kilometres of a health centre. Self-care was widely practised: between 42.1% and 65% of the people had purchased drugs, or had had drugs purchased for them, without prescription, within the six-month period prior to the interview.

The infant mortality rate was estimated to be between 126 and 165 per 1000 live births. Of 78 deaths in children under five years of age, 47 occurred in infants and 17 occurred in children less than one month of age. Measles was the major cause of under-five mortality (38%). The birth rate estimate was 51 per 1000.

Immunization coverage in the preschool population studied was poor. Only 12% of 999 children aged less than 5 years had BCG immunization; 5% had a clinic card; and DPT (diphtheria–pertussis–tetanus), polio and measles immunization was less than 2%.

The nutritional status, as measured by anthropometric parameters of weight and height, showed that 80% of the children had satisfactory to good nutritional status. The estimate of lameness due to polio was 6.6 per 1000 children aged 15 years or below.

(*a*) Identify the indicators in the summary report.

(*b*) Group the indicators into the four categories described in Handout 16.2.

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HANDOUT 16.1

Definitions of new terms and concepts in the context of health indicators

(Health) status indicator: An indicator of the level of the health phenomena of interest.

Example: Average annual number of cases (episodes) of diarrhoea per child under five years of age.

Feasibility: The ability to obtain the data needed to compute the indicator.

Example: An indicator of fetal loss may not be feasible, since not all data on fetal losses are routinely collected.

Goal (of a health programme): The ultimate aim of a health programme.

Example: polio eradication.

Indicator: A variable that helps to measure changes directly or indirectly and is used to assess the extent to which objectives and targets are being attained.

Example: see Handout 16.3.

Objective (of a health programme): A measurable state a health programme is expected to be in, at a given time, as a result of the application of programme activities, procedures and resources.

Example: An objective of an expanded programme of immunization could be effectively to immunize at least 90% of the eligible children by the end of the current 5-year national health programme.

Process indicator: A measure of the extent, efficiency or quality of service performance.

Example: Proportion of pneumonia cases seen who receive standard case management at health facilities.

Proxy indicator: An indicator used in place of a direct indicator which may be more difficult to measure or compute.

Example: School absenteeism may be used as a proxy indicator for general morbidity in school-age children.

Relevance: The extent to which an indicator contributes to the understanding of the phenomena of interest.

Example: The proportion of preschool children (under 5 years of age) more than 2 SD below the median height-for-age of the WHO/National Center for Health Statistics reference population contributes to the understanding of childhood moderate and severe stunting.

Reliability: The indicator should be reproducible if measured by different people under similar circumstances.

Example: Infant mortality is a reliable indicator of early childhood mortality in countries with comprehensive birth and death registration.

Sensitivity: The degree to which an indicator reflects changes in the phenomena of interest.

Examples: The quantity of non-expired drugs by category at a health facility is a sensitive indicator of drug supply at the facility. In many developing countries, outpatient attendance rates at public health facilities are a sensitive (proxy) indicator of the supply of drugs at those facilities.

Specificity: The ability of an indicator to reflect changes in only the specific phenomena of interest.

Example: The amount of drugs dispensed daily at a health facility *is not* a specific indicator of drug supply at the facility.

Target (of a programme): An intermediate result towards an objective that a programme seeks to achieve.

Example: The target of an immunization programme could be the vaccination of 95% of all the children under one year old, this year, according to the national immunization schedule.

Validity: The degree to which an indicator is a true expression of the phenomena of interest.

Example: The proportion of the national health budget spent on drugs *is not* a valid indicator of the existence of drugs in health facilities.

HANDOUT 16.2

Examples of the four groups of indicators for monitoring progress towards achievement of health for all

Health policy indicators

- High-level political commitment to health for all.
- Allocation of adequate resources for primary health care.
- Level of community involvement in attaining health for all.

Social and economic (background) indicators

- Rate of population increase.
- Gross national product (GNP) or gross domestic product (GDP).
- Income distribution.
- Work availability.
- Adult literacy rate.
- Adequacy of housing expressed as number of persons per room.

Indicators of the provision of health care (process indicators)

- Availability.
- Physical accessibility.
- Economic and cultural accessibility.
- Indicators for assessing quality of care.
- Indicators of coverage by primary health care:
  - level of health literacy;
  - availability of safe water in the home or within a short walking distance;
  - birth attendance by trained personnel;
  - availability of essential drugs throughout the year.

Health status indicators

- Percentage of newborn infants with birth weight of at least 2500 g.
- Percentage of children that have a weight-for-age that corresponds to a specified norm.
- Infant mortality rate, child mortality rate, under-5-year mortality rate.
- Life expectancy at a given age.

- Maternal mortality rate.
- Disease-specific mortality rates.
- Disease-specific morbidity rates.
- Disability rates.

HANDOUT 16.3

Some of the indicators for monitoring the goals and targets of the World Summit for Children

Indicators of mortality

- Infant mortality rate: the annual number of deaths of infants under one year of age per 1000 live births.

Indicators of childhood nutrition

- Underweight prevalence: proportion of preschool children (under 5 years of age) more than 2 SD (moderate and severe) or more than 3 SD (severe) below the median weight-for-age of the WHO/National Center for Health Statistics reference population.

Indicators of water and sanitation

- Proportion of the population with access to an adequate amount of safe drinking-water in a dwelling or located within a convenient distance from the user's dwelling.
- Proportion of the population with access to a sanitary facility for human excreta disposal in a dwelling or located within a convenient distance from the user's dwelling.

Indicators of disability

- Disability type-specific prevalence: the total number of persons with disability, specifying the number having serious difficulty in seeing, hearing or speaking, moving, learning or comprehending, or having strange or unusual behaviour, or other disability of duration of at least six months or of an irreversible nature, in the following age groups: 0–4, 5–14, 15–19 and 20 and over.

Indicators of health and nutrition of the female child, and of pregnant and lactating women

- Antenatal care: proportion of women attended at least once during pregnancy by trained health personnel.

Indicators of child spacing

- Contraception: proportion of women of childbearing age (15–49) currently using contraceptive methods (either modern or traditional).
- Fertility: fertility rate of women 15–49 years of age.

Indicators of immunization coverage

- Proportion of children immunized against diphtheria, pertussis, and tetanus (DPT, 3 doses) before their first birthday.
- Proportion of children immunized against measles before their first birthday.
- Proportion of children immunized against poliomyelitis (OPV, 3 doses) before their first birthday.
- Proportion of children immunized against tuberculosis before their first birthday.

PART III

Statistics in medicine, including medical records

OUTLINE 17 Medical records and health facility statistics

Introduction to the lesson

A good medical records and health facility statistics system can contribute effectively towards improved medical care. It plays a prominent role in the evaluation of the quality of care and aids medical research significantly.

Objective of the lesson

The lesson aims to introduce the students to the medical record as an essential source of data, for statistics used to evaluate the quality of patient care and health facility utilization, and also for other activities of the health facility.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Discuss the value of medical records to the patient, to the health facility, to the physician, for medical research and teaching, and as a source of data for health facility statistics.

(*b*) Explain the need for standardized medical records in a health care system.

(*c*) Define the elements of a medical record and the terms used in the context of health facilities.

(*d*) Draw up a set of minimum identification particulars for a medical record, with justifications for each element in the set.

(*e*) Give examples of possible uses for the data elements in a medical record.

(*f*) Explain the process of, and the need for, validation of data sources.

(*g*) Explain the legal status of the medical record with regard to:

- confidentiality of data;
- length of time the medical record is kept after the patient's discharge.

(*h*) State, and elaborate upon, at least three limitations of the medical record as a source of data.

(*i*) Explain, calculate and interpret the indices used for measuring the quality of service rendered by a health facility:

- mortality rates;
- health facility infection rate;
- postoperative infection rate;
- autopsy rate;
- caesarean section rate.

(*j*) Explain other indices needed by administrators of the health facility:

- bed occupancy ratio;
- turnover interval;
- average duration of health facility stay.

Required previous knowledge

The students should have had exposure to clinical medicine and possess a good understanding of the health care delivery system of the country. They should also have a good knowledge of general statistical methods and health statistics.

Lesson content

Definitions of health facility terms and elements of medical records

Definitions related to health facility statistics and medical records are given in Handout 17.1.

Standardization of health facility terms, statistics and medical records

In order to have comparable statistics, internally or externally, all health facilities should use the same terminology. The use of different names for identical statistics is as confusing within a health facility as it is among a group of health facilities. A lack of uniformity in defining health facility terms may lead to mistaken or inequitable interpretations, comparisons and judgements.

Identification data and their uses

Health care institutions are complex organizations with medical, nursing, technical, clerical and other staff caring for the patients. It is essential that the right treatment be given to the right person by the appropriate member of the treatment team. To help ensure this, identification data for each patient should include, as a minimum:

- document reference number (when appropriate);
- family name or surname;
- given name (first name);
- any other names by which known (aliases);
- sex;
- date of birth (day, month and year);
- place of birth (if known);
- home address.

Validation of data

Data validation is the process by which the information in a medical record is checked for accuracy.

It is necessary to validate data because incorrect information in medical records could lead to false conclusions when it is used. The information may be incor-

rect, either because it was incorrectly recorded or because it was incorrectly coded, either by mistake or through lack of knowledge.

Diagnoses may be validated by other health workers reviewing a random sample of medical records without reference to the reported final diagnoses and making their own diagnoses based on the data in the record. Similarly, a coding clerk from another institution might code the diagnoses given without referring to the codes already allotted.

Confidentiality of medical data

Patients should be assured that personal and private information given to the health worker will remain confidential. It is desirable, therefore, for each country to have laws that enforce this right of the patients.

It is recognized that, because of the complexity and the hierarchical organization of health care, records of information given in confidence will inevitably be seen by staff other than those to whom the information was given.

If a patient's personal data need to be published in a report, the identifying information should be given in coded format, unless permission is granted by the patient to publish detailed identification data.

Utilization of medical records and health facility data

Limitations of medical records

The limitations of the medical record as a source of health management data are as follows:

(*a*) The information does not cover all episodes of illness that occur in the community. For many illnesses, people do not seek medical care. Ambulatory services often have no appropriate health record system, and general practitioners in most countries have not yet been encouraged to keep patient records in such a way that they can be used for epidemiological purposes.

(*b*) As sources of morbidity data, medical records understate the level of morbidity due to conditions that are difficult to diagnose and categorize.

(*c*) The patient-related data are subject to vagaries in recall. This applies to all situations where a person is asked to recall previous events but particularly so in the health facility situation where the person providing the information is usually apprehensive at being in a strange environment.

Data needed for health management

A primary purpose of statistical data is to provide information to guide internal operational management. The kind of statistical data needed may vary considerably from one management to another, depending upon individual methods and problems.

Regardless of the primary concerns and individual problems of health facility administrators, correct and complete statistical data are needed to:

- establish administrative control over functional activities;
- provide a basis for preparing operating budgets;

- render reports to governing bodies and outside agencies;
- provide a basis for the distribution of expenses when computing the cost of operations;
- provide a basis for the calculation of average income and costs per unit of service rendered.

The data elements from the medical record required for national, regional and local records, include:

- sex;
- age;
- marital status;
- separation (final or discharge) diagnoses (ICD codes);[1] if the patient dies earlier than 48 hours after admission, the length of stay should also be indicated, in hours;
- accident cause (ICD code);[1]
- operations (ICPM code);[2]
- length of stay in health facility (for inpatients).

Other data required for administrators include:

- health facility infections;
- outpatient records;
- records of other departments (sections), such as laboratories, emergency services, ambulance, accounting.

Indices of quality of patient care and their uses

Formulae for the following indices of quality of care provided by the health facility to the patient are given in Handout 17.2.

(*a*) Mortality rates (for health facility):

- gross death rate;
- net death rate;
- anaesthesia death rate;
- postoperative death rate;
- death rate in maternity unit;
- infant death rate;
- fetal death rate.

(*b*) Health facility infection rates:

- gross infection rate;
- net infection rate;
- postoperative infection rate.

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[1] See Outline 18.

[2] See *International classification of procedures in medicine*. Geneva, World Health Organization, 1978.

(*c*) Other rates:

- autopsy rate;
- caesarean section ratio;
- unnecessary surgery rate.

Indices of utilization of health facility services and their uses

Methods of calculating the following health facility indices are given in Handout 17.3.

(*a*) Average duration of stay in health facility;

(*b*) Bed occupancy ratio;

(*c*) Turnover interval.

NEW TERMS AND CONCEPTS (see Handout 17.1)

Admission; data elements; follow-up care; International Classification of Diseases (ICD); International Classification of Procedures in Medicine (ICPM); inpatient; medical record; outpatient; patient identification data; separation; separation diagnosis; separation summary; health facility beds; bed capacity; health facility deaths; patient day; length of stay; percentage of occupancy; health facility infections and infection rates (gross, net, postoperative); health facility death rates (gross, net, maternal, infant, postoperative, anaesthesia); autopsy rate; caesarean section rate; average length of stay; bed occupancy; turnover interval.

Structure of the lesson

(*a*) Explain the need for evaluation of health facility services from the point of view of quality of care of the patient, health facility utilization and other administrative activities.

(*b*) Explain the need for medical records for producing health facility statistics, and the value of medical records to the patient, health facility, physician, medical researcher and teacher.

(*c*) Explain the role of health workers as essential contributors to, and users of, the medical record systems.

(*d*) Discuss the need to record accurate data for each patient or reporting centre, and explain how checks on the accuracy of the data can be made.

(*e*) Discuss the most common problems that a medical record department may encounter. (A medical record officer may be invited to carry out this discussion, giving real examples from the medical records department.)

(*f*) Discuss the legal requirements for medical records.

(*g*) Discuss the indices for quality of care and utilization of health facility services, and their uses.

Lesson exercises

The teacher should obtain information on the utilization of the hospital services from the medical records department of a hospital. The students should calculate some of the indices of quality of patient care and utilization of health facility services.

If there is a large group of students, they may be divided into small working groups for the purpose of the exercises. Each group may then be asked to carry out the following exercises.

■ Collect the data needed for the calculation of the indices of quality of patient care and utilization of health facility services (listed above) from the medical records department of a hospital.

■ From the data on bed status of the hospital, calculate:

- bed occupancy rate;
- turnover rate;
- average duration of stay.

References

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Definitions of new terms and concepts

Admission: Formal acceptance, by a health facility, of a patient who is to receive medical or paramedical care while occupying a health facility bed.

Data elements: Those items of information extracted for statistical purposes (for example, sex and age).

Health facility deaths: Deaths occurring after lodging a patient in an inpatient bed. Detailed records should be maintained for the deaths occurring within or beyond 48 hours after lodging.

If a patient dies earlier than 48 hours after admission, length of stay should also be indicated in hours (for calculation of the net death rate).

Deaths occurring before lodging (for example, in the emergency room, the ambulance or the lift) are not classified as health facility deaths. Separate records must be kept for these events.

Fetal deaths (stillbirths) should be recorded separately.

International Classification of Procedures in Medicine (ICPM): Published by the World Health Organization, it classifies the procedures used in the different branches of medicine (such as surgical, radiological, laboratory and preventive).

Inpatient: A patient occupying a bed in a health care institution for the purposes of receiving medical or paramedical treatment (that is, an admitted patient).

Inpatient bed: A bed regularly maintained for use by inpatients who are receiving continual physician or dentist services and are lodged in a continuous nursing service area of the health facility.

Inpatient bed capacity: The number of beds regularly maintained for inpatients in a health facility.

Inpatient census: The number of inpatients occupying beds in the health facility at a given time.

Length of stay: Number of days an inpatient has stayed in the health facility. It is computed by subtracting the admission date from the separation date (the admission day is counted but the separation day is not counted). Admission and separation on the same day is counted as one day.

Medical record: A cumulative narrative of the history of a patient, the treatment given, final diagnosis, and continuing care following separation.

Outpatient: A patient whose visit to a health care institution is confined to only a few hours and who is not accommodated overnight.

Patient day: The unit of measure denoting lodging facilities provided and services rendered to one inpatient between the census-taking hour on two successive days.

Patient identification data: The information required for the unique data identification of an individual patient.

Percentage of occupancy: The ratio of actual patient days to the maximum patient days as determined by bed capacity, during any given period of time.

Separation: The termination of the occupation of a health facility bed by a patient either through discharge, transfer to another health care institution, or death.

Separation diagnosis: The final diagnosis made at, or following, the patient's separation. (The diagnosis made on admission is usually a provisional one.)

Separation summary: A summary written, or dictated, by a doctor about the case, setting out the essential facts from the record: symptoms, previous history, diagnosis, laboratory and X-ray findings, treatment given, operations performed, information given to the patient, and further treatment arranged or prescribed.

Transfer of inpatient: The movement of the patient from one type of accommodation to another. Transfer is not new admission.

Turnover interval: The mean number of days a bed is not occupied between two admissions.

Indices of quality of care

Health facility mortality rates (death rates)

Deaths occurring in the emergency room of the health facility or in the ambulance on the way to the health facility or anywhere before a patient is lodged in an inpatient bed are not included in the computation of health facility death rates.

Health facility death rates are usually calculated for one year. Because of this, the period is not specified in the formulae. The term separation in the denominator includes discharges, deaths and transfers to other health institutions during the time specified in the numerator.

Gross death rate

The gross death rate includes all deaths occurring among inpatients.

$$\text{Gross death rate} = \frac{\left[\text{Total number of health facility deaths}\right] \times 100}{\text{Total number of separations}}$$

This is a very rough indicator of the quality of patient care, since it does not include the exact time of the occurrence of the deaths. If, for example, the majority of the deaths occur in the first 48 hours after lodging of the patients in the clinics, not much can be said about the quality of patient care. If, however, the majority of the deaths occur after 48 hours of admission to the clinics, then a detailed study of the deaths can provide useful information on the quality of patient care. Because of this disadvantage, the gross death rate is not a good indicator for measuring the level of death in a health facility. Net death rate is a better indicator.

Net death rate

The net death rate includes only the deaths occurring 48 hours after admission to a health facility.

$$\text{Net death rate} = \frac{\left[\text{Number of deaths occurring 48 hours or more after admission}\right] \times 100}{\text{Total number of separations } \left(\text{minus deaths occurring within 48 hours after lodging}\right)}$$

This is a good indicator of the quality of patient care in a health facility. A 48-hour period is regarded as sufficient for a health facility to diagnose a patient's illness and start curative measures. If this rate is higher than expected (according to the standards of the country), then the records of all the deaths should be studied in detail.

Anaesthesia death rate

Deaths occurring on the operating table and caused by anaesthetic agents (but not surgical complications) are included in this rate.

$$\text{Anaesthesia death rate} = \frac{\left[\text{Number of deaths due to anaesthetic agents}\right] \times 100}{\text{Total number of anaesthetics administered}}$$

Postoperative death rate

Deaths occurring within the 10 days immediately following a surgical operation are included in this rate.

$$\text{Postoperative death rate} = \frac{[\text{Number of deaths within 10 days of surgical operation}] \times 100}{\text{Total number of surgical operations}}$$

Maternity-unit death rate

Deaths occurring among inpatients due to pregnancy, delivery and postpartum complications make up the calculation of this rate.

$$\text{Maternity-unit death rate} = \frac{[\text{Number of deaths due to pregnancy, delivery and postpartum complications}] \times 100}{\text{Total number of obstetric patients separated}}$$

Infant death rate

Only the infants who were born and who died in the health facility are included in the calculation of this rate.

$$\text{Infant death rate} = \frac{[\text{Number of infant deaths among infants born in the health facility}] \times 100}{\text{Total number of infants separated}}$$

Fetal death rate

Deaths of fetuses occurring in the health facility after 20 or more weeks of gestation are included in this rate.

$$\text{Fetal death rate} = \frac{[\text{Number of fetal deaths occurring in the health facility after 20 or more weeks of gestation}] \times 100}{\text{Total number of births in the health facility}}$$

Health facility infection rates

Infections which occur following clean wounds, operations or births, or develop in patients after admission to the health facility, are classified as nosocomial or non-nosocomial according to the health facility's guidelines.

Health facility infection rates are normally calculated for one year. The term separations in the denominator includes discharges, deaths and transfers to other health institutions during the time specified in the numerator.

Gross infection rate

The gross infection rate includes all infections occurring after admission to the health facility.

$$\text{Gross infection rate} = \frac{[\text{Number of infections recorded}] \times 100}{\text{Total number of separations}}$$

This is a very rough indicator of the quality of patient care, as it does not differentiate between health facility (nosocomial) and non-health facility (non-nosocomial) infections. Net infection rate is a better indicator than gross infection rate.

Net infection rate

The net infection rate includes health facility infections only.

$$\text{Net infection rate} = \frac{[\text{Number of infections attributed to the health facility}] \times 100}{\text{Total number of separations}}$$

Postoperative infection rate

All infections among clean surgical cases before separation are included in this rate.

$$\text{Postoperative infection rate} = \frac{[\text{Number of infections in clean surgical cases}] \times 100}{\text{Total number of operations}}$$

Other rates

Autopsy rate

The autopsy rate includes only the autopsies performed on inpatients who have died (autopsies on stillborn babies, patients dead on arrival and patients who die in the emergency room and cases released to legal authorities are not included).

$$\text{Autopsy rate} = \frac{[\text{Number of autopsies}] \times 100}{\text{Total number of deaths}}$$

Caesarean section rate

This is the ratio of caesarean sections performed to total deliveries.

$$\text{Caesarean section rate} = \frac{[\text{Number of caesarean sections performed}] \times 100}{\text{Total number of deliveries}}$$

Unnecessary surgery rate

This is the ratio of unnecessarily performed operations to the total number of operations performed.

$$\text{Unnecessary surgery rate} = \frac{[\text{Number of biopsy materials reported as normal tissue by pathologist}] \times 100}{\text{Total number of operations}}$$

Indices of utilization of health facility services

Average duration of stay in health facility

The average duration of stay in a health facility is the total number of inpatient days of care provided to separated patients (exclusive of newborn babies) in a period divided by the total number of separated patients (exclusive of newborn babies). In computing the length of stay, the day of admission is counted but the day of discharge is not counted. Admission and separation on the same day is counted as one day. The formula for computing the average length of stay of inpatients is:

$$\text{Average duration of stay in health facility} = \frac{\text{Total number of inpatient days of care provided to separated patients}}{\text{Total number of separations}}$$

In order to have more detailed information, the average length of stay should be calculated separately for each service, for each disease and for other variables.

This index may be used to plan a waiting list.

Bed occupancy ratio

This is the ratio of occupied bed-days to the available bed-days as determined by bed capacity, during any given period of time. The formula is:

$$\text{Bed occupancy ratio} = \frac{\left[\text{Actual number of occupied bed-days}\right] \times 100}{\text{Available bed-days}}$$

The index should be calculated for all groups of inpatients who are normally assigned to beds specifically maintained for such groups. It should also be calculated for each service separately.

The bed occupancy ratio is used to measure the utilization of health facility beds.

Turnover interval

This is the mean number of days that a bed is not occupied between two admissions. The formula is:

$$\text{Turnover interval} = \frac{\text{Number of vacant bed-days}}{\text{Total number of separations}}$$

The turnover interval is used to measure the demand for, or pressure on, beds.

OUTLINE 18 International Classification of Diseases (ICD) and certification of causes of death

Introduction to the lesson

The development of public health, especially in the fields of health management, health care and research, brought about the need and opportunity to collect and compare large amounts of data of high quality. The use of the International Classification of Diseases (ICD) as the basic format has contributed to the comparability between data collection systems. The ICD also provides a basis that can be adapted for use in other fields, for example, dentistry, oncology and ophthalmology.

Determination of disease-specific death rates depends on accurate completion of death certificates. It is, therefore, essential that doctors complete the certification of death correctly.

Objective of the lesson

The objective of this lesson is to introduce the students to the principles of the ICD, its application, and the completion of death certificates.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain the purpose of classifying diseases and causes of death, and discuss the problems encountered in doing so.

(*b*) Explain the structure of the ICD and its uses.

(*c*) Discuss the problems in defining cause of death, give the definition of underlying cause of death, and explain its use and application.

(*d*) Correctly complete a certification of cause of death on a prescribed form, on the basis of a patient's medical file.

Required previous knowledge

Concepts of the etiology of diseases; concept of the natural history of a disease process, and of associated signs and symptoms; disease-specific morbidity and mortality indices.

Lesson content

Most of the materials in this section are taken from *International Statistical Classification of Diseases and Related Health Problems, Tenth revision (ICD-10). Vols 1–3.* Geneva, World Health Organization, 1992–1994.

General principles

A classification of diseases may be defined as a system of categories to which morbid entities are assigned according to some established criteria. There are

many possible choices for these criteria. The anatomist, for example, may desire a classification based on the part of the body affected, whereas the pathologist is primarily interested in the nature of the disease process. The public health practitioner would be more interested in the disease etiology, and the clinician in the particular manifestations requiring care. There are therefore many axes of classification, and the particular axis selected will depend on the interest of the investigator.

A statistical classification of disease and injury will depend, therefore, on the use to be made of the statistics to be compiled. Adjustments must be made to meet the varied requirements of vital statistics offices, hospitals of different types, medical services of the armed forces, social insurance organizations, sickness surveys, and numerous other agencies. While no single classification will fit all the specialized needs, it should provide a common basis of classification for general statistical use: that is, storage, retrieval and tabulation of data.

A statistical classification of disease must be confined to a limited number of categories that encompass the entire range of morbid conditions. The categories should be chosen so that they will facilitate the statistical study of disease phenomena.

It is the element of grouping in a statistical classification that distinguishes it from a nomenclature (a list or catalogue of approved names for morbid conditions), which must be extensive in order to accommodate all pathological conditions. The concepts of classification and nomenclature are, nevertheless, closely related in the sense that some classifications, for example in zoology, are so detailed that they become nomenclatures. Such classifications, however, are generally unsuitable for statistical analysis.

In order to make accurate comparisons of morbidity or mortality data, specified for various diseases or causes of death, it is essential that a uniform classification is used throughout the world. Such a classification was introduced many years ago and is known as the International Classification of Diseases (ICD). Since its inception, it has been revised about once every 10 years; the latest revision (ICD-10) was adopted by the Forty-third World Health Assembly in 1989.

The International Classification of Diseases, tenth revision (ICD-10)[1]

ICD-10 is presented in three volumes: Volume 1 contains the main classification; Volume 2 provides guidance to users of the ICD; and Volume 3 contains the index to the classification. The previous revisions, ICD-8 and 9, had been presented in two volumes, comprising the main classification and alphabetical index.

Volume 1: main classification

Most of Volume 1 is taken up with the main classification, composed of the list of three-character categories, and the tabular list of inclusion and four-character

[1] This part of the lesson content is abstracted from *International Statistical Classification of Diseases and Related Health Problems, Tenth revision (ICD-10). Vol. 2: Instruction manual*. Geneva, World Health Organization, 1993.

sub-categories. The "core" classification, comprising the list of three-character categories (Volume 1, pp. 29–104), is the mandatory level for reporting to the WHO mortality database and for general international comparisons. This core classification also lists chapter and block titles. The tabular list, giving the full detail of the four-character level, is divided into 21 chapters (pp. 105–1175).

Volume 1 also covers the morphology of neoplasms. The classification of morphology of neoplasms (pp. 1177–1204) may be used, if desired, as an additional code to classify the morphological type of neoplasms which, with a few exceptions, are classified in Chapter II only according to behaviour and site (topography). The morphology codes are the same as those used in the special adaptation of ICD for oncology (ICD-O).

Special tabulation lists

Because the full four-character list of the ICD, and even the three-character list, are too long to be presented in every statistical table, most routine statistics use a tabulation list that emphasizes certain single conditions and groups others.

Four special lists for the tabulation of mortality and one list for the tabulation of morbidity were adopted by the World Health Assembly for ICD-10 in 1990. These lists are as follows:

- List 1 General mortality — condensed list (103 causes);
- List 2 General mortality — selected list (80 causes);
- List 3 Infant and child mortality — condensed list (67 causes);
- List 4 Infant and child mortality — selected list (51 causes);
- Tabulation list for morbidity (298 causes).

For mortality, the list number is used as a prefix to the item numbers to prevent confusion over which special tabulation list was used for coding. For example, if cause of death is "tetanus", coding of this cause by using different lists of mortality is as follows:

- If list 1 is used: 1-008;
- If list 2 is used: 2-007;
- If list 3 is used: 3-005;
- If list 4 is used: 4-004.

For the national display of mortality and morbidity data, countries are free to use any lists constructed from the items of the basic list, but to ensure a minimum of international comparability, any tabulation lists used for these purposes should contain the headings used in the mortality and morbidity lists of ICD-10.

Definitions

The definitions on pp. 1233–1238 of Volume 1 have been adopted by the World Health Assembly and are included to facilitate the international comparability of data.

Nomenclature regulations

The regulations adopted by the World Health Assembly set out the formal responsibilities of WHO Member States regarding the classification of diseases and causes of death, and the compilation and publication of statistics. They are set out on pp. 1239–1243 of Volume 1.

Volume 2: instruction manual

This brings together the notes on certification and classification formerly included in Volume 1 with a good deal of new background and instructional matter and guidance on the use of Volume 1, on tabulations, and on planning for the use of ICD, which was seen as lacking in earlier revisions. It also includes the historical material formerly presented in the introduction to Volume 1.

Volume 3: alphabetical index

This presents the index itself, with an introduction and expanded instructions on its use.

Chapters and coding system of ICD-10

ICD-10 consists of 21 chapters and uses an alphanumeric code with a letter in the first position and numbers in the second, third and fourth positions. The fourth character follows a decimal point. Possible code numbers, therefore, range from A00.0 to Z99.9.

Examples:

- K35 acute appendicitis;
- K35.0 acute appendicitis with generalized peritonitis;
- K35.1 acute appendicitis with peritoneal abscess;
- K35.9 acute appendicitis, unspecified.

The letter U is not used. It was left for coding the provisional assignment of new diseases of uncertain etiology (codes U00–U49) and for use in research (codes U50–U99), for example when testing an alternative sub-classification for a special project.

Each letter is associated with a particular chapter, except for the letter D, which is used in both Chapter II, Neoplasms, and Chapter III, Diseases of blood and blood-forming organs and certain disorders involving the immune mechanism, and the letter H, which is used in both Chapter VII, Disease of the eye and adnexa and Chapter VIII, Diseases of the ear and mastoid process. Four chapters (Chapters I, II, XIX, and XX) use more than one letter in the first position of their codes.

Chapters I to XVII relate to diseases and other morbid conditions, and Chapter XIX to injuries, poisoning and certain other consequences of external causes. The remaining chapters complete the range of subject matter nowadays included in diagnostic data. Chapter XVIII covers symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified. Chapter XX, External causes of morbidity and mortality, was traditionally used to classify causes of injury and poisoning, but, since the ninth revision, has also provided for any recorded

external cause of diseases and other morbid conditions. Finally, Chapter XXI, Factors influencing health status and contact with health services, is intended for the classification of data explaining the reason for contact with health care services of a person not currently sick, or the circumstances in which the patient is receiving care at that particular time or otherwise having some bearing on that person's care.

The list of the chapters of ICD-10 is given in Handout 18.1.

Blocks of categories

The chapters are subdivided into homogeneous blocks of three-character categories. In Chapter I, the block titles reflect two axes of classification: mode of transmission and broad group of infecting organisms. In Chapter II, the first axis is the behaviour of neoplasms. Within behaviour, the axis is mainly by site, although a few three-character categories are provided for important morphological types (for example, leukaemia, lymphomas, melanomas, mesotheliomas, Kaposi sarcoma). The range of categories is given in parentheses after each block title.

Three-character categories

Within each block, some of three-character categories are for single conditions, selected because of their frequency, severity or susceptibility to public health intervention, while others are for groups of diseases with some common characteristics. There is usually provision for "other" conditions to be classified, allowing many different but rarer conditions, as well as "unspecified" conditions, to be included.

Four-character subcategories

Although not mandatory for reporting at the international level, most of the three-character categories are subdivided by means of a fourth, numeric, character after a decimal point, allowing up to ten subcategories. Where a three-character category is not subdivided, it is recommended that the letter X be used to fill the fourth position so that the codes are of a standard length for data processing.

The four-character subcategories are used in whatever way is most appropriate, identifying, for example, different sites or varieties if the three-character category is for a single disease, or individual diseases if the three-character category is for a group of conditions.

The fourth character .8 is generally used for "other" conditions belonging to the three-character category, and .9 is mostly used to convey the same meaning as the three-character category title, without adding any additional information.

When the same fourth-character subdivisions apply to a range of three-character categories, they are listed once only, at the start of the range. A note at each of the relevant categories indicates where the details are to be found. For example, categories O03–O06, for different types of abortion, have common fourth characters relating to associated complications (see Volume 1, p. 724).

Cause of death

The causes of death to be entered on the medical certificate of cause of death are "all those diseases, morbid conditions or injuries which either resulted in or contributed to death and the circumstances of the accident or violence which produced any such injuries". This definition does not include symptoms and modes of dying, such as heart failure or asthenia.

From the standpoint of prevention of deaths, it is important to break the chain of events or to institute the cure at some point. Statistics on the underlying cause of death would be the most useful for this purpose, and it is therefore recommended that the underlying cause, as defined below, be uniformly selected for primary tabulation of causes of deaths.

Underlying cause of death

This is defined as: (a) the disease or injury that initiated the train of morbid events leading directly to death, or (b) the circumstances of the accident or violence that produced the fatal injury.

Certificate of cause of death

In order to secure uniform application of the above principle, it is implicit that the medical certification form recommended by the World Health Assembly should be used (see Figure 18.1). A different certificate is needed for perinatal deaths (this is described in ICD-10, Volume 2, pp. 88–93).

The medical certificate of cause of death is designed to elicit the information that will facilitate the selection of the underlying cause of death when two or more causes are jointly recorded.

Figure 18.1 ***International form of medical certificate of cause of death***

CAUSE OF DEATH		Approximate interval between onset and death
I Disease or condition directly leading to death*	(a).....	.....
	due to (or as a consequence of)	
Antecedent causes Morbid conditions, if any, giving rise to the above cause, stating underlying condition last	(b).....	.....
	due to (or as a consequence of)	
	(c).....	.....
	due to (or as a consequence of)	
	(d).....	.....
II Other significant conditions contributing to the death but not related to the disease or condition causing it	.....	.....
	.....	.....
* This does not mean the mode of dying, for example, heart failure or respiratory failure. It means the disease, injury or complication that caused death.		

The certificate consists of two parts. In Part I, the cause leading directly to death is reported in line (a), and the antecedent conditions that gave rise to the cause reported in line (a) are entered in lines (b) and (c), the underlying cause being stated last in the sequence of events. No entry is necessary in lines (b) and (c) if the disease or condition directly leading to death, stated in line (a), completely describes the train of events.

Any other significant condition that unfavourably influenced the course of the morbid process and thus contributed to the fatal outcome, but that was not related to the disease or condition directly causing death, is entered in Part II.

After the words "due to (or as a consequence of)", which appear on the certificate, should be included not only the direct cause or pathological process, but also indirect causes, for example where an antecedent condition has predisposed to the direct cause by damage to tissues or impairment of function, even after a long interval.

NEW TERMS AND CONCEPTS

Classification; alphanumeric codes; codes (three-digit categories, four-digit subcategories); death certificate; International Classification of Diseases; nomenclature; underlying cause of death; long list; special tabulation lists.

Structure of the lesson

(*a*) Recall the uses of disease-specific morbidity and mortality indices, dealt with in previous lessons, and give examples to illustrate the relative importance of various diseases as causes of ill health and death (for example, show a distribution of the number of deaths by cause, arranged in order of magnitude; discuss the distributions in different age groups).

(*b*) Differentiate between nomenclature and classification of diseases, and discuss the possibility of classifying diseases by various axes or criteria (for example, by anatomical site, etiology, disease process, signs and symptoms). Point out the need for a conventional or standard classification in order to ensure uniformity and comparability of data.

(*c*) Explain the structure of ICD and the history of its development, drawing special attention to the new objectives and features introduced in the sixth revision (1948), that is, combined classification for use in both morbidity and mortality analyses, different levels of grouping, supplementary lists for special applications, definition of underlying cause of death, and introduction of a recording form to facilitate clear and uniform certification and correct identification of the underlying cause. Special attention should be paid to the rationale for selecting the underlying cause of death for the primary tabulation of causes of death. Describe the contents and layout of Volume 1 and Volume 3 of ICD-10.

(*d*) Explain the national and local requirements for procedures and documentation relating to the certification of causes of death (by physicians or other personnel), and discuss the differences, if any, between these and the WHO recommendations. Examine the limitations with regard to reliability and completeness of cause-of-death certification, and their implications for comparability of statistics on causes of death over time and between places (for example, urban/rural) in national and international comparisons. (If a copy of Volume 2 of ICD-10 is

available, it is recommended that the teacher read through the section on "Rules and guidelines for mortality and morbidity coding", pages 30–123).

(*e*) Examples of genuine documents and data should be used liberally to illustrate the problems of obtaining good disease-specific data from morbidity and mortality records, and to indicate the steps that may be taken at the different levels of data recording, collecting and processing to raise the quality of disease-specific morbidity and mortality data in the country.

Lesson exercises

Obtain copies of medical certificates and provide information on the medical history of patients and cause of death from the records department of the local hospital. Ask the students to complete the form and insert the ICD codes. Ask the students to explain the advantages and disadvantages of using ICD codes.

■ Given several case histories leading to death, fill out the death certificate identifying the underlying cause. For example, an eighty-two year old white female who had been receiving treatment for hypertension dies through cerebral haemorrhage. Use the information provided to fill out the medical certificate of death.

■ Determine the ICD codes for the following disease conditions: ischaemic heart disease, malignant neoplasm of the stomach, urinary tract infection, pneumonia and chronic bronchitis.

■ Provide the ICD codes for the top ten causes of morbidity in the country using the three-digit codes.

References

Application of the International Classification of Diseases to Dentistry and Stomatology (ICD-DA), 3rd ed. Geneva, World Health Organization, 1995.

International Classification of Diseases for Oncology (ICD-O), 2nd ed. Geneva, World Health Organization, 1990.

The International Classification of Diseases and health-related classifications. *World health statistics quarterly*, 1990, Vol. 43, No. 4.

**International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10). Vols 1–3*. Geneva, World Health Organization, 1992–1994.

Kupka K. International Classification of Diseases: ninth revision. *WHO chronicle*, 1978,32: 219–225.

Medical certification of cause of death. Geneva, World Health Organization, 1979.

* The most important reference.

Chapters of ICD-10

		CODE
I	Certain infectious and parasitic diseases	A00–B99
II	Neoplasms	C00–D48
III	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	D50–D89
IV	Endocrine, nutritional and metabolic diseases	E00–E90
V	Mental and behavioural disorders	F00–F99
VI	Diseases of the nervous system	G00–G99
VII	Diseases of eye and adnexa	H00–H59
VIII	Diseases of ear and mastoid process	H60–H95
IX	Diseases of the circulatory system	I00–I99
X	Diseases of the respiratory system	J00–J99
XI	Diseases of the digestive system	K00–K93
XII	Diseases of the skin and subcutaneous tissue	L00–L99
XIII	Diseases of the musculoskeletal system and connective tissue	M00–M99
XIV	Diseases of the genitourinary system	N00–N99
XV	Pregnancy, childbirth and the puerperium	O00–O99
XVI	Certain conditions originating in the perinatal period	P00–P96
XVII	Congenital malformations, deformations and chromosomal abnormalities	Q00-Q99
XVIII	Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	R00–R99
XIX	Injury, poisoning and certain other consequences of external causes	S00–T98
XX	External causes of morbidity and mortality	V01–Y98
XXI	Factors influencing health status and contact with health services	Z00–Z99

OUTLINE 19 Design of health investigations: health surveys and clinical trials

Introduction to the lesson

Often, routinely collected data from health service records do not provide a complete description of the current health status of the population suitable for use in health service planning. On such occasions, carefully planned health surveys may be used to collect additional information.

In clinical medicine, the beneficial effects of a great majority of new treatments may not be very obvious. Observations made at the bedside by individual clinicians provide insufficient grounds for deciding whether these new treatments are effective at all, or more effective than the usual treatment. A well-designed scientific trial is the best way to obtain conclusive evidence.

Students are often required, as part of their training, to participate in community health surveys or to undertake individual projects, and may also be involved in clinical trials after qualifying. Moreover, all students read medical journals, most issues of which report the results of trials. If the students are to be able to assess such reports critically, they must have some knowledge of the principles of the design, conduct and uses of such trials.

Objective of the lesson

The objective of this lesson is to describe the design, execution, uses and interpretation of various types of health surveys and clinical trials.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Describe what is meant by a health survey and explain its uses.

(*b*) Describe the steps to be taken in planning a health survey.

(*c*) Describe the main principles of the design of a health questionnaire.

(*d*) Design a simple health questionnaire for use in a particular survey under specific circumstances.

(*e*) Explain the need for, and uses of, clinical trials.

(*f*) Distinguish between the four different phases of clinical trials.

(*g*) Distinguish between therapeutic and prophylactic trials.

(*h*) Explain, with examples, why controlled trials are necessary.

(*i*) State what is meant by historical controls and explain why they are unsatisfactory.

(*j*) Explain the meaning of, and need for, randomization in clinical trials.

(*k*) State what is meant by single-blind and double-blind trials.

(*l*) Explain what is meant by cross-over trials.

(*m*) Explain what is meant by matched controls.

(*n*) State what is meant by a sequential trial.

(*o*) Outline the ethical issues raised by the use of controls and placebos, and by the need to have patients' consent to participate in the trial.

Required previous knowledge

The students should have a clear understanding of the statistical principles and methods covered in Outlines 1–10. Failure to have attained these learning objectives may seriously limit their understanding of the issues covered in this lesson. Previous exposure to epidemiological principles would be an asset.

Lesson content

Health survey

Definition of a health survey

A health survey is a planned study to investigate the health characteristics of a population. The health survey is used to:

- measure the total amount of illness in the population;
- measure the amount of illness caused by a specified disease;
- study the nutritional status of the population;
- examine the utilization of existing health care facilities and the demand for new ones;
- measure the distribution in the population of particular characteristics, for example, haemoglobin level, serum cholesterol level, breastfeeding practice, contraceptive practice;
- examine the role and relationship of one or more factors in the etiology of a disease.

Planning a health survey

Step 1: Preparation of a detailed written statement of the objectives of the survey

The objectives of the survey have to be clearly stated, if possible in measurable terms. Each objective must be examined to ensure that it is achievable given the resources of the survey (time, personnel and money) and the availability of data. A check should be made to determine whether information on some of the objectives is already available.

Step 2: Determination of the items of information required, and specification of definitions, criteria of classification and methods of collection

The survey objectives determine the items of data that need to be collected. Only those items necessary for the survey to achieve its objectives should be included; the inclusion of other items, on such grounds as "it would be interesting to know . . ." or "it won't make any difference to ask just one more question . . ." should be firmly resisted. The questionnaire should not be unduly long.

The use of each item should be elaborated in terms of its intended classification, tabulation and analysis. Dummy tables should be drawn up where relevant, and precoding of classes done where possible.

Each item should be well defined, and the criteria and procedures to be used for its collection laid down. Data collectors should be trained to apply these criteria in a uniform manner throughout the survey.

Step 3: Definition of the reference population on which information is to be sought

The reference population has to be defined both physically and demographically (that is, its location, size, structure, etc.). A clear definition of the reference population is essential for the determination of the appropriate sampling procedures and eventual interpretation of the findings. A complete specification of the population to be sampled is the sampling frame.

Step 4: Decision on whether the reference population is to be studied as a whole or in part (sampled)

In making this decision, the size of the reference population has to be considered in relation to the resources available for the study. The advantages and disadvantages of a sample compared with a comprehensive survey should be considered (see Outline 8 for the advantages and disadvantages of collecting information through sample). A so-called comprehensive survey may, in fact, turn out to be a bad sample survey because of low response rates.

Step 5: Determination of the number of units in the population to be selected for study during the survey

Once it has been decided to take a sample, the optimum sample size must be determined, taking into account the following considerations (see Outline 8):

- sampling error versus non-sampling errors;
- a sample size much larger than the optimum wastes resources;
- a sample size much smaller than the optimum decreases the precision of the estimate and narrows the range of conclusions and generalizations;
- optimum sample size depends on the prevalence or variability of the condition being surveyed, and the desired precision.

Step 6: Decision on how respondents will be selected from the population (sampling method)

If only part of the population is to be examined, it is essential that those selected are a fair representation of the population. There are several scientific methods of selection that ensure fairness (see Outline 8). Some of these methods are more practical than others. It should be remembered that the best of samples can be ruined by low response rates.

Step 7: Design, testing and validation of the questionnaires or forms on which observations will be recorded

A good questionnaire is essential to the success of the survey. Strict principles are involved in the design of a good questionnaire (see main principles of designing a questionnaire in this outline). It is essential that the draft forms be tested and validated before use in the main survey.

Step 8: Selection and training of interviewers

The accuracy and reliability of the data collected depend on the interviewers. They should be carefully selected and properly trained in interview techniques, and should understand fully the prescribed definitions, criteria and methods. It is important to train all interviewers together to ensure uniformity of performance. Trials or dummy runs should be included in the training.

Step 9: Collection of data

The data collection process involves:

- publicity to inform and solicit the cooperation of the population;
- correct identification of selected sampling units (houses, respondents, villages);
- transportation arrangements;
- supervision and monitoring of the interviewers;
- testing and checking of equipment;
- retrieval of completed forms and preliminary editing.

Step 10: Preparation for data analysis

The design of forms should incorporate plans for analysis, precoded questions, coding lists for free texts, etc. Arrangements need to be made for data analysis facilities to be available: the personnel needed may include editing and data entry operators, key punch operators, programmers and statisticians.

Relative advantages and disadvantages of sampling methods in health survey design

Probability sampling: see under individual sampling method (Outline 8).

Estimation of minimum sample size

Certain information is required for the estimation of minimum sample size (n) of a health survey based on simple random sampling (see Outline 8 for details).

Main principles of designing a questionnaire

The questions should be:

- relevant only to the specific objectives of the inquiry;
- set out in suitable order (arranged such that sensitive questions are at the end);
- preclassified and precoded wherever possible;
- clear and unambiguous;
- simple;
- valid.

Clinical trials

Definition of clinical trials

Planned experiments to compare the effectiveness of different regimens or methods of treatment in human subjects.

Need for clinical trials

- Evaluation of safety and efficacy of therapies, for which the results need to be:
  - — non-subjective;
  - — scientifically valid.
- Opportunity to screen new drugs in a drug development programme.
- Carefully designed trials are the only means to detect the usually small differences between drugs or methods of treatment or the advantages of one over another.

Phases of clinical trials

The development of a drug usually undergoes four phases of experimentation:

Phase I

First experiments are carried out on human volunteers (usually after animal experimentation). The objectives of a phase I trial are to demonstrate the safety and non-toxicity of the drug.

Phase II

After success in a phase I trial, phase II trials are carried out to measure, with a stated precision, the effectiveness of the drug in order to decide whether further experimentation is warranted. In a drug development programme, phase II trials are used to screen rapidly drugs with a promising level of effectiveness.

Phase III

Phase III trials are comparative trials of the new agent versus established standards. The objective is to compare the efficacy and safety of the new method with those of the existing standard treatment under the same set of conditions and simultaneously.

Phase IV

Phase IV trials are large-scale studies to demonstrate the efficacy and safety of a drug after its introduction into general practice. Phase IV trials, which are also known as post-marketing surveillance studies, are necessary because of the usually limited scope of phase III trials.

Therapeutic and prophylactic trials

- Therapeutic trials measure the efficacy of drugs or other therapeutic procedures (for example: diet, bed-rest, surgery, physiotherapy, ionizing radiation).
- Prophylactic trials measure the effect of preventive measures on the health of populations (for example, control of pollution of water supplies, immunizations, change of diet, change of smoking habits, fortification of foodstuffs, weight reduction, contraception).

Design of phase III trials

Most of the reports of clinical trials in the general medical journals are of the phase III type. They introduce the new treatment to the practising health care giver.

In the design of a phase III clinical trial, the following considerations should be paramount:

Objectives of the trial

The objectives of the trial should:

- be carefully stated;
- not be too many;
- primarily concern which of the two drugs or methods of treatment is better.

Need for an appropriate statistical design

The goal of an appropriate design should be that the patients receiving the new treatment and those receiving the standard treatment (the controls) are as alike as possible in everything likely to influence the outcome, other than the treatments they receive. One of the main ways of achieving this is to use an appropriate statistical design. The design should be simple, and appropriate for the objectives. A brief description of the basic designs is given in Handout 19.2.

Bias

Bias is a distortion in the perception of the effects of a treatment or in the measurement of differences between the effects of two treatments.

Sources of bias:

- systematic difference between treatment groups at admission into the trial;
- differential practice in the follow-up of treatment groups;
- differential assessment of outcome in treatment groups;
- differential exclusion or withdrawal of subjects from the study.

Methods of reducing bias:

- randomization;
- blinding;
- uniform handling of procedures.

Ethical considerations (see Outline 22)

The following issues are important to ensure ethical acceptability of a clinical trial:

- safety of the drugs or methods of treatment;
- the existence of an honest hypothesis;
- informed consent of the participants;
- the right of participants to withdraw from the study at any time without sanctions;

- confidentiality of information;
- possibility to terminate the trial to prevent continued use of harmful or inferior treatment.

NEW TERMS AND CONCEPTS (see Handout 19.1)

Dummy tables; health survey; precoded data; sampling frame; self-coding record forms; survey questionnaire; systematic sampling; clinical, therapeutic and prophylactic trials; control group; cross-over trial; historical controls; matched controls; informed consent; placebo; placebo effect; randomization; sequential trial; single-blind and double-blind trials.

Structure of the lesson

More than one session may be needed to cover this topic. Give examples of published health surveys and clinical trials throughout the lesson.

(*a*) Recall the limitations of health data available from routine sources, and the important role that ad hoc data collection plays in the health information system. Explain the meaning of a health survey, and illustrate with real examples the different types of objectives that a health survey might have.

(*b*) Throughout the lesson, use references to actual surveys as much as possible to illustrate the applications of the various steps in survey planning, and to emphasize how decisions at each step must be made with the survey objective(s) firmly in mind.

(*c*) Explain that survey planning should seek to ensure that the information yielded by the survey is reliable, valid for the reference population, obtained and processed in the most cost-effective way, and above all, answers the questions posed in the survey objectives. Deficiencies in the information collected cannot be "made up for" or remedied even by the most sophisticated analytical methods or equipment.

(*d*) As each step is dealt with, therefore, demonstrate its importance by discussing the implications or consequences of poor or inadequate planning of that step.

(*e*) Briefly explain the essential features of clinical trials, including the meaning of, and need for, controls. Also explain the differences between the two categories of clinical trials (therapeutic and prophylactic).

(*f*) Explain that scientific testing of the efficacy of therapies is needed because of the rapid growth of laboratory medicine, and because the advantages of new drugs over established treatments are usually small.

(*g*) Explain that the choice of a particular design is determined by the need to attribute observed differences to the test drug. Explain the different types of possible controls and treatment allocations, with examples.

(*h*) Explain the steps which should be taken to control bias, such as randomization, use of single-blind or double-blind studies, and use of uniform handling procedures and calibration of measuring instruments.

(*i*) Explain and discuss the ethical constraints in clinical trials. The discussion should consider whether it is ethical to have controls, or give an inert "treatment" (a placebo) to some patients, and whether patients' consent should always be obtained.

(*j*) Reading the publication on which the class exercise is based is strongly advised. Teachers who want to use other reported clinical trials as class exercises are encouraged to do so.

Lesson exercises

Exercises should test the students' knowledge of the principles of the design and conduct of survey and clinical trials, and their understanding of the terminology. The teacher should use examples of health surveys and clinical trials published in the literature, and set questions that test the students' knowledge of the various aspects and principles taught in class. The class may be divided into groups to present plans to conduct similar investigations on selected topics.

Health surveys

■ List five uses of a health survey.

■ Indicate and discuss an appropriate sampling procedure for use in the following situations:

- to estimate the prevalence of tinea capitis among schoolchildren in a town with 25 primary schools;
- to estimate the regional distribution of patients who attended a big teaching hospital in a 12-month period;
- to select 25% of patients for interview among those attending a physician's clinic in a single day.

Clinical trials

■ This class exercise is based on a clinical trial involving the use of three antimalarial drugs, mefloquine, mefloquine/sulfadoxine/pyrimethamine (MSP) and chloroquine, by Sowunmi and Oduola, of the Department of Pharmacology and Therapeutics and Postgraduate Institute for Medical Research and Training, University of Ibadan, Ibadan, Nigeria, published in the *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 1995, 89:303–305.

Objectives of the study

- To determine the susceptibility of *Plasmodium falciparum* to mefloquine, mefloquine/sulfadoxine/pyrimethamine (MSP) and chloroquine.
- To determine if the combined MSP had any therapeutic advantage over mefloquine alone.

Design of the trial

Source of patients

A total of 150 children, aged between 6 months and 10 years, suffering from acute symptomatic uncomplicated falciparum malaria were enrolled in the study.

Selection criteria

- age 6 months to 10 years;
- history of fever in 24 hours preceding presentation or pyrexia at presentation;
- falciparum asexual parasitaemia;

- no anti-malaria drug administered in the two weeks preceding presentation;
- negative urine test for anti-malarial drug;
- no other causes of fever or concomitant illness or sickle cell disease;
- with approval of parents or guardian.

Allocation of patients to treatment

Table 19.1 provides clinical and laboratory data on enrolment for patients assigned to each of the three treatment groups. Details of dosage regimens are given in Table 19.2.

Table 19.1 ***Clinical and laboratory data for patients with acute non-complicated falciparum malaria on enrolment in the trial***[a]

	Treatment regimens		
	Mefloquine	**MSP**[b]	**Chloroquine**
Number of patients	43	36	36
Age (mean years)	3.5 (SD 2.3)	3.6 (SD 2.0)	3.6 (SD 2.3)
Weight (mean kg)	19 (SD 3.6)	18.9 (SD 2.6)	19.6 (SD 2.8)
Duration of fever (days)	1–4	1–4	1–4
Temperature (mean °C)	38.9 (SD 0.9)	38.8 (SD 1.0)	38.7 (SD 1.1)
Heart rate (mean per min.)	141 (SD 13)	138 (SD 18)	140 (SD 18)
Parasitaemia (per μl)			
Geometric mean	99 121	96 106	83 100
Range	12 132–1 231 115	10 061–1 112 112	10 000–1 000 120
Haematocrit (mean %)	31 (SD 7)	30 (SD 6)	31 (SD 8)

Source: Sowunmi A, Oduola AMJ. Open comparison of mefloquine, mefloquine/sulfadoxine/pyrimethamine and chloroquine in acute uncomplicated falciparum malaria in children. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 1995, 89:303–305. Reproduced by permission.

[a] Of the 150 children enrolled in the study, 35 were excluded from the analysis for various reasons.

[b] Mefloquine/sulfadoxine/pyrimethamine.

Table 19.2 ***Randomization of patients into the three treatment groups***

Treatment group	**Dosage**
Mefloquine	25 mg/kg of body weight as a single oral dose on day 0
Mefloquine, sulfadoxine and pyrimethamine	Tablets containing: 125 mg of mefloquine 250 mg of sulfadoxine 12.5 mg of pyrimethamine given as a single oral dose on day 0 according to body weight. *Body weight (kg)* — *Tablets* 5–10 — 1 11–20 — 2 21–30 — 3 31–45 — 4
Chloroquine	25 mg/kg of body weight base given orally over 3 days: 10 mg/kg on days 0 and 1, 5 mg/kg on day 2

Follow-up

Post-treatment follow-up on day 14.

Outcome

A total of 115 children completed the study, 43 in mefloquine group, 36 each in the MSP and chloroquine groups. Therapeutic responses are shown in Table 19.3.

- Parasite clearance time was calculated as the time from drug administration to the day when a patient's parasitaemia was zero for at least 72 hours.
- Fever clearance time was taken as the time from drug administration till the core temperature fell to, or below, 37.2°C and remained so for at least 48 hours.
- Treatment in all groups was considered a failure if the parasite count on day 3 was over 25% of that on day 0, or if parasitaemia cleared and then reappeared within 14 hours of treatment.

Table 19.3 ***Therapeutic responses of patients with acute uncomplicated falciparum malaria***

	Treatment regimens		
	Mefloquine	**MSP**[a]	**Chloroquine**
No. of patients	43	36	36
Fever clearance time (hours):			
mean	49.9 (SD 12.1)	49.6 (SD 13.1)	56.6 (SD 17.1)
range	48–72	48–72	48–96
Reduction of parasitaemia (%)	67.4 (SD 31.5)[b]	66.5 (SD 30.1)[c]	60.1 (SD 29.6)[d]
Parasite clearance time (hours):			
mean	49.4 (SD 13.8)	46.7 (SD 8.9)	53.6 (SD 8.6)
range	42–96	42–96	42–120[e]
No. with increased parasitaemia at 12 hours	12	10	9
Response (no. of patients)[f]			
Cured	43	35	30
RI	0	1	4
RII	0	0	2
RIII	0	0	0
Cure rate at day 14 (%)	100	97.2	83
Cure rate at day 28 (%)	95.3	94.4	75

Source: Sowunmi A, Oduola AMJ. Open comparison of mefloquine, mefloquine/sulfadoxine/pyrimethamine and chloroquine in acute uncomplicated falciparum malaria in children. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 1995, 89:303–305. Reproduced by permission.

[a] mefloquine/sulfadoxine/pyrimethamine.

[b] 31 patients.

[c] 26 patients.

[d] 27 patients.

[e] 30 patients.

[f] RI = parasitaemia disappears within 7 days but reappears within 14 days; RII = decrease but no complete disappearance of parasites from peripheral blood; RIII = no pronounced change in parasitaemia 48 hours after treatment.

■ What are the possible justifications for each of the selection criteria for admission to the trial?

■ What factors would you examine to assess whether the three treatment groups were comparable at the beginning of the study?

■ What measure of severity of disease might be used?

■ What other patient breakdown (distribution) would have been informative in Table 19.3?

■ What differences in the treatment responses were detected at day 14?

■ Is the difference between the percentage reduction of parasitaemia at 24 hours between the group receiving mefloquine and the group on chloroquine statistically significant?

■ What inferences can be made about the relative efficacy of the three treatment regimens?

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HANDOUT 19.1

Definitions of new terms and concepts

Clinical trial: Comparison between two or more treatment regimens in humans to assess their relative efficacy.

Cross-over trial: A trial in which patients act as their own controls by receiving both the treatment being assessed and the control treatment, in random order.

Historical controls: Results of a standard treatment (or no treatment) extracted from clinical records or from the literature.

Informed consent: Acceptance to participate in a trial having been informed of, and understood, all the trial procedures and their possible consequences.

Placebo: An inert or dummy pharmacological or surgical treatment.

Placebo effect: The subjective element introduced by the application of any treatment.

Randomized controlled trial: A trial in which patients are allocated at random — by chance methods — to the test treatment(s) and control group(s).

Single-blind and double-blind trial: In a single-blind trial, the patient is unaware which treatment he or she is receiving. In a double-blind trial, neither the patient nor the doctor assessing the response is aware which treatment the patient is receiving.

Clinical trial designs

Parallel groups design

Test treatment given to one group of subjects and a standard treatment to another group of subjects, both groups being tested simultaneously. The trial is a randomized clinical trial if the subjects are allocated to either treatment randomly (in the statistical sense).

Matched control design

Individual subjects, or groups of subjects, are first matched in pairs according to variables that are likely to influence the outcome of treatment (such as age, sex, weight), then the members of the pairs of individuals or groups are randomly assigned to the test and comparison treatments.

Cross-over design

Each subject receives, in succession, the test and comparison treatments, with a suitable "wash-out" period between the two treatments. The order in which the treatments are given is randomized so that half the subjects receive the test treatment first and vice versa.

Designs with external controls

The comparison group is not handled simultaneously with the group on the test treatment but developed outside the current study by, for example, using historical controls. These designs have the advantage of being cheaper than other designs but have the problems of:

- changes in patient selection;
- changes in experimental environment.

Sequential trials

Patients are allocated randomly to the test and comparison treatments, as they present themselves, and the results are analysed continuously. The trial is halted when the results reach a predetermined level of significance, or a closure boundary without demonstrating significance. The size of the trial is not fixed in advance.

OUTLINE 20 Use of computers in health sciences

Introduction to the lesson

The recent development in computer technology has had a notable impact on the handling of health statistics and provided better opportunities for their use. Computers and general-purpose software have made the collection, handling, analysis and storage of large amounts of data easier, faster and cheaper. They have also made it possible to produce tabulations, graphs and routine reports more efficiently.

Objective of the lesson

The objective of this lesson is to enable the students to appreciate the usefulness of computers in health sciences.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Describe major components of a computer system.

(*b*) Describe the importance, use and role of computers in the field of health.

(*c*) Demonstrate familiarity in the use of at least one sample statistical software, say, public domain Epi Info, by:

- creating a computer-based questionnaire;
- creating a simple data set using that questionnaire;
- making at least one analysis of that data set.

Required previous knowledge

A basic appreciation of the responsibilities of a health professional in providing quick and adequate care. Familiarity with the steps in data-based decision processes. No other previous computer knowledge is needed.

Lesson content

Parts of a computer system

Description and identification of various parts of a computer system.

- A computer system consisting of hardware, software and the computer operator (human being), the last being the most important element.
- Hardware: the central processing unit (CPU), consisting of chips, integrated circuits and printed circuit boards, hard disk, keyboard, monitor, printer, modem, mouse, power supply cables, etc.

- Software (the set of machine readable instructions):
  - —machine software resident on computer chips;
  - —other software loaded into a computer to perform specific types of tasks, such as operating the computer or data management.

Major functions of various parts (see Handout 20.1)

- The CPU controls the execution of instructions for the computer.
- The hard disk stores data, text, images and software.
- Keyboard, monitor, printer, modem and mouse are input and output devices.
- A software application consists of instructions to the computer in logical sequence for specific functions.

General uses of a computer system

As a data and word-processing machine:

— performing intricate or repetitious calculations;

— management of databases;

— preparing and formatting text.

As a storage and retrieval device:

— data and text storage on hard disk or on an external storage medium;

— retrieval of data and text from hard disk or an external storage medium.

As a communication device:

— through interfacing with a telephone or satellite communication.

As a device to process graphics, images and sounds:

— using special software and hardware for animation of films, manipulations of photographs and other pictures, and synthesizing music.

As a teaching device:

— computer-aided lessons, which can be interactive and paced, can be repeated as often as needed.

Uses of computers in health sciences

The primary role of computers in health is as a tool for data management and processing. Uses include:

- Easy access to, and full exploitation of, statistical tools, which would otherwise be seldom used because of the complexity of the calculations involved.
- Exploring the relationships of variables in data sets through use of different scenarios.
- Access to the international literature and its instant selective retrieval.

- Quick and more effective communication facilities using technologies such as electronic mail (e-mail).
- Record archiving.
- Use as a diagnostic tool in selecting an appropriate treatment, and in assessing prognosis.

Misuses of computers

- Indiscriminate use of statistical methods without worrying about underlying assumptions, such as normality, independence and equality of variance. Most statistical packages do not check these assumptions. Thus, conclusions of dubious value can be reached if sufficient care is not exercised.
- Over-dependency on computer-based systems without worrying about their limitations. For example, computer systems are sometimes used for decision-making rather than as tools. The ultimate decision should lie with the human expert and not with the machine. The machine can only help in providing clues and likely alternatives. The limitations of computer-based systems may also be ignored by the users of on-line bibliographic databases containing citations from scientific journals. Since many journals from developing countries and non-serial publications are not indexed, such databases cannot be considered perfect windows on the world's literature.
- Being unaware that a computer does only what it is asked to do. If the instructions are wrong, the results cannot be right. Thus, it is important that only well-tested software is used.

Software and operating systems

- Types of software
  - — Machine software which is resident on the computer chips and devices.
  - — Operating systems which interface between the machine software and application software. These systems regulate the functions and behaviour of the application software. The role is similar to that of a government.
  - — Application software, which performs tasks of direct interest to the user.
- The operating system selected depends on whether it is to support only one user per machine or to support terminals and thus allow several users to work simultaneously on the same CPU.
- Salient features of operating systems include: directory structure and path; utilities such as format, erase, copy, autoexecute; access to disk drives, and printer; and editing features to write or modify a text.

Epidemiological information processing package (Epi Info)

- A general purpose package for handling epidemiological data, from the stage of data collection to data analysis and report writing.

- Components of Epi Info:
  - — calculations of sample size for different kinds of studies;
  - — text editor;
  - — data entry;
  - — data analysis;
  - — data validation;
  - — statistical calculation;
  - — data transfer.

NEW TERMS AND CONCEPTS

Algorithm; application software; ASCII; bit and byte; chip; computer; directory; drive; file; hard copy; hardware; language; machine software; memory; operating system; path; PC; program; random access memory (RAM); read only memory (ROM); secondary memory; software; terminal.

Structure of the lesson

(*a*) The introduction of the students to the different applications of computers is best done in conjunction with the lessons covering the relevant topics (for example, data organization, presentation and analysis). Students should, whenever possible, have hands-on experience with a computer.

(*b*) The lesson should start with a simple but thorough description of the functional parts of a computer set-up:

- hardware;
- different types (mainframe, mini, micro, laptop, etc.);
- input and output media;
- software.

(*c*) A demonstration of the operating system should then be given, focusing on operations that students will need to know in order to use a computer successfully.

(*d*) An overall view of the use of computers in health sciences should be illustrated with actual demonstrations. A public domain software, such as Epi Info, could be used for this purpose.

(*e*) Explain the multipurpose use of Epi Info and its capacities to handle processing of information relating to epidemiological investigations. First demonstrate the generation of a questionnaire, data entry, analysis, graphics and report writing, and then assign the students to do this exercise. A short questionnaire of, say, just one page in length, with some skip patterns, should suffice. It should be on a topic of wide interest, such as birth weight and some antecedents. Let the students do at least one analysis (cross-tabulation, derivation of means, graphs, etc.). Writing the report may be optional, depending upon the facilities available and the students' interest.

Lesson exercises

The exercises for this lesson should aim at helping the students to appreciate the use of computers in the health field, rather than focusing on the details of computer configuration and programming. Students should, therefore, be provided with exercises that help them to practise using computers as a tool in handling their data.

- Generate a short questionnaire of about a page in length, on a topic of general interest.

- Analyse data on a small number of subjects, using a general purpose software such as Epi Info.

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Definitions of new terms and concepts

Algorithm: Logical arrangement of instructions to perform a task.

Application software: Packages of programs which perform special groups of tasks in a specific manner. These tasks are of direct interest to the user.

ASCII: Acronym for American Standard Code for Information Interchange. This code is widely used to exchange data and text which can be read by users of different applications. This helps to translate files written in one language to another language.

Bit and byte: The basic unit of a memory is a bit, and a set of 8 bits is a byte. One byte is required to store one character (alphabet, digit or space). One kB is 1024 bytes, roughly considered to be 1000 bytes and one MB is nearly one million bytes.

Chip: A small computer device containing memory space and machine software.

Computer: A machine that can be programmed to carry out a series of instructions.

Directory: A place in a disk containing the list of files. A directory may contain sub-directories, each sub-directory containing the files. The user assigns a unique name to each directory and sub-directory.

Drive: That part of the computer which is used to read the memory. Generally, three drives are available — called A, B and C. The first two are used to read floppy disks or diskettes and the last refers to the hard disk. Sometimes the hard disk is partitioned into several parts called C, D, E drives, etc.

File: A collection of data records, text or program statements which are put together and given a name for reference or retrieval.

Hard copy: A printed version of the inputs or the outputs.

Hardware: Tangible parts of a computer, such as integrated circuits, printed circuit boards, ports, keyboard, monitor, printer, terminal, modem and mouse.

Language: A system of words and symbols, obtained by combination of keyboard keys, which can be understood by the computer. Several languages are available, such as FORTRAN, COBOL, C and APL.

Machine software: Programs embedded in electronic devices during their manufacture. They come as part of the machine.

Memory: That part of a computer system where programs and data are stored.

Operating system: Software that governs the usage of the application software. It is an interface between the machine software and the application software.

Path: The route that a computer device should follow to locate a file in the memory. For example, C:\DIR_1\SUB_DIR_A\MYFILE means that the file called MYFILE is located in sub-directory SUB_DIR_A which is in the directory called DIR_1, and that this directory is available on the C-drive of the computer.

PC: An acronym for personal computer — a type of tabletop or smaller computer. These computers may be small in size but can have enormous capacity, including the capability for simultaneous handling of several tasks.

Program: Task-specific algorithm written in a language that can be deciphered by a computer.

Random access memory: Also known as RAM, is built into a computer for temporary storage of the software, the intermediary steps and the results — all required to perform the task the computer is asked to do.

Read only memory: Normally known as ROM, contains the instructions which start up when the power is turned on. Now also available in secondary memory (see the description below).

Secondary memory: Under control of the computer operator, such as hard disk, floppy disk, diskette and magnetic tape. Compact disk read only memory (CD-ROM) comes on disks containing large amounts of data or software which cannot be manipulated.

Software: Collection of interrelated programs sold as a package. These are of various types.

Terminal: Generally, a set of monitor and keyboard, without its own central processing unit (CPU), which is connected to a computer to provide a facility for additional persons to use the same CPU. A PC can also be connected to another CPU and can then be used as a terminal.

OUTLINE 21 Rapid methods for interim assessment

Introduction to the lesson

Health workers at all levels need to be able to assess their activities continuously, especially during the implementation of priority programmes. The assessment should be focused, simple and rapid, for corrective action to be timely. Conventional procedures for assessing health programmes tend to be lengthy, expensive and very often require sophisticated methodology. Other procedures for interim assessment have therefore been developed, which depend on less sophisticated methodology.

Objective of the lesson

The objective of this lesson is to introduce the students to the methods which could be used for rapid interim assessment of health programmes and activities.

Enabling objectives

At the end of the lesson the students should be able to:

(*a*) Explain the concept of rapid interim assessment.

(*b*) List at least two methods which could be used rapidly to assess health activities.

(*c*) Describe the strengths and weaknesses of those methods.

Required previous knowledge

Contents of previous lessons, particularly lessons based on Outlines 1–9, 16, 19 and 20.

Lesson content

Concept of rapid interim assessment

- Rapidity: referring to the time it takes to go through the entire assessment process.
- Interim: implying that the assessment is a stop-gap; definitive results need more rigorous methods.

The following methods should be covered by the lesson:

(*a*) The modified cluster survey methodology developed for the assessment of immunization coverage (EPI (Expanded Programme on Immunization) immunization coverage assessment methodology).

(*b*) Case–control methodology for programme assessment.

(*c*) Focus-group discussions.

(*d*) Delphi techniques (knowledgeable key informants).

(*e*) Geographical information systems.

Modified cluster survey (EPI immunization coverage assessment)

(*a*) General description of the methodology.

(*b*) Relationship to the classical cluster survey.

(*c*) Sample selection:

- cluster selection;
- sampling unit selection.

(*d*) Sample size:

- precision;
- design effect;
- sample size estimation.

(*e*) Data analysis:

- parameter estimations;
- weighted analysis.

(*f*) Strengths and weaknesses of the methodology.

Case–control methods for programme assessment

(*a*) General description of the methodology.

(*b*) Issues concerning identification of "cases" and "controls".

(*c*) Measurement of exposure.

(*d*) Minimum sample size for hypothesis testing in case–control studies.

(*e*) Sources of bias:

- selection;
- misclassification;
- confounding.

(*f*) Data analysis:

- odds of exposure;
- odds ratio as estimate of risk;
- significance testing for odds ratio;
- attributable risk.

(*g*) Strengths and weaknesses of the methodology.

Focus-group discussions

(*a*) General description of the methodology.

(*b*) Uses of focus-group discussions.

(*c*) Group formation:

- homogeneity;
- group size;
- logistic problems.

(*d*) Analysis of the discussion recordings:

- general issues relevant to analysis of qualitative data;
- linkage of the different recordings of the discussions (notes, audio and video).

(*e*) Srengths and weaknesses of the methodology.

Delphi techniques (knowledgeable key informants)

(*a*) General description of the methodology.

(*b*) Selection of knowledgeable informants.

(*c*) Formulation of questions.

(*d*) Data analysis:

- general issues relevant to analysis of qualitative and subjective data;
- consensus formation;
- validation of responses.

(*e*) Strengths and weaknesses of the methodology.

Geographical information systems

(*a*) General description of the methodology and its application to health research.

(*b*) Hardware and software for geographical information systems.

(*c*) Uses of geographical information systems.

- storage, management and integration of large spatially referenced data sets;
- spatial data retrieval;
- geographically related data analyses;
- data mapping.

(*d*) Strengths and weaknesses of the methodology.

NEW TERMS AND CONCEPTS

Attributable risk; bias; case–control; cluster survey; confounding; controls; data mapping; exposure; misclassification bias; odds ratio; odds of exposure; rapid interim assessment; selection bias; spatial data.

Structure of the lesson

Coverage of this topic may need more than one session. The methods do not have to be covered in any particular order. As many examples as possible should be used.

(*a*) For each method, prepare a general description of the methodology drawing the students' attention to linkages with some of the topics already covered in lesson Outlines 1–9, 16, 19 and 20.

(*b*) Coverage of each method should follow the order indicated in the "Lesson content" section, above.

(*c*) Emphasize the interim nature of these methods, explaining that for a definitive assessment more robust methods have to be used.

Lesson exercises

The teacher should obtain several examples of studies and ask students to identify the methods used for each study. The focus of the exercises should be on the circumstances for which each method can be used appropriately, and on the advantages and disadvantages of each method.

■ A nongovernmental organization is planning a study to determine the sustainability of its health delivery service in a country. It is interested to ascertain the motivation and job satisfaction of the staff, and the perception of the community regarding the service. Which survey approach would you advise, to be able to collect the required information? How is this different from, or similar to, the conventional approach?

■ In the immunization coverage survey described in the second exercise of Outline 8, give a critical appraisal of the survey methodology.

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Strengths and weaknesses of selected methods for interim assessment

Method	Strengths	Weaknesses
Modified cluster survey (EPI immunization coverage assessment)	• simple to use • has been shown to perform well for the situation it was designed for	• random selection is not used at the second stage of sampling • its application is limited to the situation it was designed for
Case–control studies	• timing of data collection — single round • high quality of outcome data, if not based on recall • less misclassification • faster • smaller sample size • no ethical problems	• does not allow for examination of effect of exposure on more than one outcome • not suitable for rare exposures • highly susceptible to bias
Focus-group discussions	• provide insight into motivation, attitude, feelings and behaviour • depending on the setting, could encourage free and frank expression • provide group interaction • responses given to please the interviewer are reduced • questions can be clarified on the spot • questions are less likely to be misunderstood • unexpected discussion avenues can be followed up	• group setting could be a hindrance to free expression • errors can be easily introduced in the discussion transcripts • group sizes are generally small • findings cannot be generalized • interpretation of the findings is prone to bias and subjectivity
Delphi techniques (knowledgeable key informants)	• low operational cost • community-based and problem-oriented • resources for subsequent intervention concentrated on high-risk communities	• information needs validation • results are mainly qualitative • findings cannot be generalized • interpretation of the findings is prone to bias and subjectivity
Geographical information systems	• provide epidemiological insights into spatially referenced relationships • provide health researchers with capabilities for handling spatial information • have high potential for collecting, storing, retrieving, analysing and displaying data • enable quick and effortless linkages of large sets of spatially referenced data with spatial analytical functions and map making	• large scale geographical information systems are unlikely to be a rapid assessment method • might need costly software and hardware outlay for efficient application

SEMINAR
OUTLINE 22

Statistical and medical ethics

Introduction to the seminar

The development of powerful new pharmaceutical products and surgical and diagnostic techniques, and the application of statistical methods to their evaluation, have brought in their wake many difficult ethical problems. Some of them are well recognized, some are not so obvious, but all need to be taken into account when a scientific investigation is planned in any field of medicine.

Objective of the seminar

The objective of the seminar is to help students to identify, give examples of, and discuss the ethical problems underlying the application of statistical methods to medical investigations.

Enabling objectives

At the end of the seminar the students should be able to:

(*a*) List the questions that should be asked about the ethics of any proposed investigation on patients or on healthy persons.

(*b*) Explain the reasons for these questions and give examples of their implications in practical situations.

(*c*) Explain, with examples, why it is unethical to publish results that are statistically incorrect.

(*d*) Explain, with examples, why it is unethical to present statistical results in a misleading way.

(*e*) Explain why it can be considered unethical not to seek statistical advice at the planning stage of an investigation.

Seminar content

The following section should be used to stimulate discussion during the seminar. Each question that is asked should be applied to every trial under investigation. For reference, the questions are listed in Handout 22.1.

Misuse of patients

(*a*) Are the proposed treatments, procedures or diagnostic techniques safe?

- Nearly all treatments, diagnostic procedures and methods of prevention carry some risk. One important objective of investigation is to detect and measure such possible risks before a new procedure is accepted for wider use.
- The seriousness of this risk has to be weighed against the seriousness of the disease being investigated, treated or prevented. Consider, for ex-

ample, what would be permissible in a trial of a new treatment for the common cold, and compare it with what might be permissible in a trial of a new treatment for leukaemia.

- Consider taking blood from veins (in adults, in children), exposure to ionizing radiation, amniocentesis, cardiac catheterization.

(*b*) Is it ethical to withhold the treatment under evaluation from some patients (namely, the controls)?

- If a clinician firmly believes that the new treatment under trial has clear advantages over the usual treatment, he or she may well believe the answer to this question to be "no", and will consequently wish not to (and should not) participate in the controlled trial. Another clinician may feel just as strongly that the patients given the new treatment under evaluation are being denied the benefits (already well accepted) of the usual treatment.
- This issue raises several other questions regarding, for example, the reasons (need) for the controlled trial, the amount and reliability of evidence already available on both the beneficial and the harmful effects of the treatment under evaluation, whether it is ethical to adopt a new treatment for routine use without adequate systematic investigation and evaluation, the nature and duration of the treatment being evaluated in relation to the disease being treated and to other available treatments, and so on.

(*c*) Is it ethical to bring certain persons into the trial?

- Consider a drug trial on a population that may contain women in the very early stage of pregnancy (risk of malformations), or people who are likely to be very sensitive to side-effects (those prone to asthma or with a history of drug allergies).

(*d*) Has informed consent been obtained from all patients?

- Consider the special problems of obtaining consent from patients who are mentally ill, mentally handicapped or senile, and from infants and children.

(*e*) Is it ethical to offer inducements to people to participate in a trial?

- Consider offers of remission of sentence to prisoners, and the use of medical students or junior doctors as guinea-pigs when, for career reasons, they may think it unwise to refuse.

(*f*) Is it ethical to use double-blind techniques?

- Consider how this may interfere with desirable components of a doctor/patient relationship, or with the doctor's need to adjust the dose of a drug in relation to the reaction to it (for example, a hypertensive patient's reaction to antihypertensive treatment).
- In any case, the physician managing the patients must have the right and opportunity to break the code at any stage of the investigation if this becomes necessary for clinical reasons.

(*g*) Is it ethical for patients to be randomly allocated to the different treatment and control groups?

(*h*) How far can one go with placebos and dummy treatments? Can placebo or sham surgery be justified?

(*i*) Who should make the decision about the answers to these questions? The persons in charge of the investigation? All members of the investigation team? Clinical colleagues? A formal ethics committee of clinical colleagues? A formal ethics committee of non-medical people? A formal ethics committee of medical and non-medical people?

Misuse of statistics

(*a*) Why is it unethical to publish results that for statistical reasons are incorrect? The following points should be considered:

- *False-positive results.* A statistically poorly designed randomized controlled trial may, falsely, show a clinically important benefit from a new drug or diagnostic procedure. This could lead to the decision that further trials would be unnecessary and unethical, and to wrongful use of the drug.
- *False-negative results.* An important benefit may be missed because a statistically poor investigation has produced negative results. The investigation may be considered too costly to repeat. This could seriously delay or prevent the adoption of the beneficial procedure.
- *Incompetent data analysis.* A clinically important benefit may be concealed within an investigation because the results have been incompetently analysed.

(*b*) Why is it unethical to present results in a misleading way? The following points should be considered:

- use of improper scales in graphical presentations;
- use of logarithmic scales to heighten a change of direction in a trend;
- interpretation of measurements lying more than 2 SD from the mean value as always being an indication of a pathological condition;
- misrepresentation of sampling method (for example, calling a method "random" when in fact it was purposeful or even haphazard);
- failure to mention the size and effect of the non-response and drop-out rates;
- misrepresenting, or failing to report, other weaknesses and limitations in the design and management of the investigations that could affect the validity of the conclusions drawn.

(*c*) Why should professional statistical advice be sought at the beginning of an investigation? Possible explanations include:

- to ensure that the sample size is large enough to show statistically significant results, taking into account both type 1 and type 2 errors;
- to ensure that the design of the investigation and the data collected will permit possible sources of bias to be uncovered and allowed for, or will have prevented or minimized their occurrence (possible sources of bias include ill-defined populations, self-selection of the study subjects,

use of non-calibrated measuring instruments, and subjective instrument reading and data recording);

- to plan ahead for the analysis of the data and the use of computers, appropriate statistical methods and significance tests.

Mode of conduct of the seminar

The subject of the ethics of statistical investigations in medicine is suitable for presentation as a student-centred seminar. All students are likely to be interested in, and to have opinions on the subject, which lends itself well to open discussion.

At least two weeks before the seminar, choose two students to prepare material for formal presentations, one on the misuse of patients, the other on the misuse of statistics. Give them a short reading list to provide background to the questions listed in Handout 22.1. Be available for consultation as required.

If the seminar is planned to last one hour, a reasonable division of the time within that hour would be as follows.

After a very short introduction (less than 5 minutes) by the tutor, the first student speaks for not more than 15 minutes on the misuse of patients. This is followed by a general discussion of about 10 minutes. The second student then speaks for not more than 15 minutes on the misuse of statistics and, as before, this is followed by a 10-minute discussion. To conclude, the tutor summarizes the important points that have been made.

If an hour and a half can be arranged for the seminar, the extra time should be given to discussion rather than to the presentations.

The students should be encouraged to use appropriate visual aids in their presentations and, because of the tight schedule, should have a trial run through their talks in front of the tutor before the seminar.

The value of the seminar will be greatly enhanced if an experienced clinician is present to give an opinion on some of the more difficult clinical examples.

The tutor should briefly make the following three points:

(*a*) Ethics, in the context of this seminar, refers to moral issues involved in statistical investigations in medicine, the scientific integrity of the investigator, and the obligations implicit in the doctor/patient relationship (see the Declaration of Helsinki, in Handout 22.2).

(*b*) Ethical problems are inherent in the nature of medicine and doctors have always appreciated this (refer to the Hippocratic oath).

(*c*) The application of scientific methods (of which statistics is an essential component) to the evaluation of new drugs, diagnostic procedures, surgical techniques and methods of prevention has highlighted the issues, and heightened doctors' awareness of the problems and the need to face them.

References

Colton T. *Statistics in medicine*. Boston, Little, Brown, 1995.

Hill AB. *Principles of medical statistics*. London, Arnold, 1991.

Hill AB. Medical ethics and controlled trials, *British medical journal*, 1963, 1:1043.

Questions to be answered during the seminar on statistical and medical ethics

Misuse of patients

(*a*) Are the proposed procedures or diagnostic techniques safe?

(*b*) Is it ethical to withhold the treatment under evaluation from some patients (namely, the controls)?

(*c*) Is it ethical to bring certain persons into the trial?

(*d*) Has informed consent been obtained from all patients?

(*e*) Is it ethical to offer inducements to people to participate in a trial?

(*f*) Is it ethical to use double-blind techniques?

(*g*) Is it ethical for patients to be randomly allocated to the different treatment and control groups?

(*h*) How far can one go with placebos and dummy treatments? Can placebo or sham surgery be justified?

(*i*) Who should make the decision about the answers to these questions? The persons in charge of the investigation? All members of the investigation team? Clinical colleagues? A formal ethics committee of clinical colleagues? A formal ethics committee of non-medical people? A formal ethics committee of medical and non-medical people?

Misuse of statistics

(*a*) Why is it unethical to publish results that for statistical reasons are incorrect?

(*b*) Why is it unethical to present results in a misleading way?

(*c*) Why should professional statistical advice be sought at the beginning of an investigation?

World Medical Association Declaration of Helsinki[1]

Recommendations guiding physicians in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, the 41st World Medical Assembly, Hong Kong, September 1989 and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The Health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

[1] 1996 version. Reproduced by permission of the World Medical Association.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

    Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical research combined with professional care (clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient — including those of a control group, if any — should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.
4. The refusal of the patient to participate in a study must never interfere with the physician–patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I, 2).
6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic biomedical research involving human subjects (non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The subjects should be volunteers — either healthy persons or patients for whom the experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

SEMINAR
OUTLINE 23

Critique of a scientific paper

Introduction to the seminar

Health professionals rely largely on the literature to keep up with the developments in medicine. They encounter published papers of wide-ranging quality and of varying scientific integrity. Readers have to make their own independent judgement regarding the adequacy and reliability of the information given, the validity of the conclusions drawn, and the recommendations offered by the authors. Developing the ability to do so is one of the major aims of a course of biostatistics for health professionals.

Objective of the seminar

The objective of this seminar is to provide the students with an opportunity to apply the knowledge gained so far in this course to evaluate the evidence presented in a published scientific paper, and to illustrate the manner in which such a paper should be assessed critically.

Enabling objectives

At the end of the seminar the students should be able to:

(*a*) List the major elements that need to be examined when making a critical assessment of a scientific paper.

(*b*) Demonstrate some capability to deal with each of these elements, with reference to a given published paper or manuscript.

Required previous knowledge

Contents of Outlines 1–22.

Seminar content

The content of the seminar will essentially follow the headings and items of the outline in Handout 23.1, modified if necessary to suit the particular paper being discussed.

Mode of conduct of the seminar

As an introduction to the seminar, the teacher should highlight the need for this type of activity.

The seminar should be centred around the students. The teacher should select a paper from the current literature, preferably of local interest, that has substantial but elementary statistical content. The content of the paper should be understandable to the students. A group of up to 10 students may be assigned a paper. In the case of a larger group of students, more than one paper would be required.

The guidelines given in Handout 23.1 cover some important non-statistical aspects. They too should be adequately discussed.

The task of the teacher is to ensure that the students are objective, unbiased, realistic and generally sound in their evaluation of the paper. Constructive, rather than destructive, criticism should be encouraged. Suggestions and recommendations made by the students should likewise be discussed critically, rather than simply being put forward superficially as possible options. The advantages and disadvantages of the different approaches suggested should be compared with those of the approach taken by the authors of the paper.

It is important for the teacher to be sufficiently familiar with the contents and the details of the paper to be able to draw the attention of the students to those points which they miss in their discussion.

The main objective of the critique is to evaluate the validity of the conclusions drawn in the paper. The teacher may have to intervene from time to time during the seminar in order to prevent the discussion from straying too far from this objective.

References

Campbell MJ, Machin D. *Medical statistics*. Chichester, John Wiley, 1990.

Colton T. *Statistics in medicine*. Boston, Little, Brown, 1995.

Gore SM, Altman DG. *Statistics in practice*. London, British Medical Association, 1982.

Riegelman RK, Hirsch RP. *Studying a study and testing a test: how to read the health science literature*, 3rd ed. Boston, Little, Brown, 1996.

HANDOUT 23.1

Checklist for the critique of a scientific paper

Introduction

(*a*) Are the objectives clearly and precisely stated?

(*b*) To which population are the results intended to be generalized?

Methodology

(*a*) Is the study an experiment, planned observations, or an analysis of records?

(*b*) Does the design meet the objectives?

(*c*) Is the study based on a sample? Is it a representative sample from the target population? Are the method of sampling and sample size adequate?

(*d*) If the study involves non-representative subjects such as volunteers, would the resulting bias affect the results?

(*e*) If the study is an experiment, is there randomization and is the randomization procedure explained?

(*f*) Are the definitions, methods and tools used to measure the antecedents and the outcomes appropriate, valid and reliable?

(*g*) Does the sample size provide for possible non-response and, if it is a follow-up study, drop-outs? What would be the effect of such non-responses and drop-outs?

(*h*) Is there any possible self-selection?

(*i*) Is the overall methodology adequate for achieving the objectives of the study?

(*j*) Is the methodology ethically sound?

Results

(*a*) Are the findings stated clearly and concisely, yet in sufficient detail for the readers to make their own judgement?

(*b*) Are the conclusions based on facts, with the opinions clearly indicated as such?

(*c*) Are all the tables and graphs needed? Are there tables and illustrations which should have been given? Is there any avoidable duplication?

(*d*) Are there any inconsistencies between findings on two or more variables?

(*e*) Are the statistical methods appropriate for the kind of variables observed, for the design adopted and for the number of subjects studied?

(*f*) Is the analysis focused on the objectives initially set out? Are coincidental findings specified?

(*g*) Are the results consequent to the analysis presented? Are the confounding and intervening variables properly handled in the analysis?

Discussion

(*a*) Is a proper explanation given for the results obtained?

(*b*) Is statistical significance clearly distinguished from medical significance?

(*c*) Are the consistencies and the inconsistencies with present knowledge (generally accompanied by a review of the literature) fully explained?

(*d*) Are the conclusions based on the results as presented? Are the reliability, validity and limitations of these conclusions adequately discussed?

(*e*) Do these conclusions really answer the questions posed in the objectives?

(*f*) Is it clearly stated how the results of the investigation advance the current knowledge on the topic?

ANNEX A Supplementary data sets

A.1 Intra-ocular pressure of 135 adults

A total of 135 adult factory workers were examined for intra-ocular pressure at the eye department of Korle-Bu Teaching Hospital, Accra, Ghana. The Perkins applanation tonometer was used to measure the pressure to the nearest integer. The following data record the age, sex, right and left eye pressure measurements, the difference between the eye measurements, and an assessment of the risk of glaucoma. The data are given in mmHg, but may also be expressed in kPa (1 mmHg = 0.133 kPa). (The data are reproduced by courtesy of Dr Christine Ntim-Amponsah.)

Age (yrs)	Sex	Rt[a]	Lt[b]	Diff[c]	Potential for glaucoma	Age	Sex	Rt[a]	Lt[b]	Diff[c]	Potential for glaucoma
24	M	20	27	−7	high	52	M	18	12	6	high
26	M	16	13	3	low	71	M	14	14	0	normal
49	M	13	14	−1	normal	28	M	17	16	1	normal
51	M	19	22	−3	low	41	M	19	17	2	low
17	M	14	14	0	normal	35	M	16	16	0	normal
52	M	13	14	−1	normal	31	M	19	19	0	normal
39	M	18	18	0	normal	54	M	14	14	0	normal
23	M	14	16	−2	low	35	M	10	13	−3	low
40	M	14	13	1	normal	42	M	16	15	1	normal
29	M	12	10	2	low	32	M	14	12	2	low
30	M	13	14	−1	normal	45	M	18	17	1	normal
56	M	14	13	1	normal	46	M	13	14	−1	normal
26	M	15	14	1	normal	48	M	15	18	−3	low
57	M	13	14	−1	normal	50	M	14	11	3	low
40	M	21	17	4	medium	39	M	9	7	2	low
39	M	13	13	0	normal	43	M	16	12	4	medium
41	M	11	12	−1	normal	46	M	20	20	0	normal
42	M	13	16	−3	low	35	M	13	14	−1	normal
41	M	20	17	3	low	41	M	13	12	1	normal
42	M	23	19	4	medium	26	M	14	12	2	low
41	M	9	12	−3	low	44	M	21	18	3	low
40	M	18	19	−1	normal	45	M	27	20	7	high
36	M	9	10	−1	normal	14	M	14	13	1	normal
52	M	13	15	−2	low	45	M	15	15	0	normal
55	M	19	17	2	low	49	F	12	12	0	normal
38	F	15	19	−4	medium	42	F	16	16	0	normal
35	F	14	11	3	low	23	F	15	18	−3	low

Age (yrs)	Sex	Rt[a]	Lt[b]	Diff[c]	Potential for glaucoma	Age	Sex	Rt[a]	Lt[b]	Diff[c]	Potential for glaucoma
21	F	12	9	3	low	40	F	13	13	0	normal
51	F	16	17	−1	normal	13	F	14	17	−3	low
29	F	16	13	3	low	40	F	18	18	0	normal
43	F	12	12	0	normal	28	F	16	14	2	low
38	F	13	12	1	normal	56	F	14	13	1	normal
28	F	13	12	1	normal	36	F	15	14	1	normal
22	F	17	19	−2	low	34	F	13	14	−1	normal
40	F	14	14	0	normal	14	F	16	12	4	medium
28	F	12	10	2	low	46	F	12	12	0	normal
39	F	18	16	2	low	47	F	17	16	1	normal
49	F	18	18	0	normal	64	F	16	17	−1	normal
35	F	15	16	−1	normal	43	F	11	11	0	normal
42	F	12	12	0	normal	46	F	18	22	−4	medium
41	F	13	14	−1	normal	31	F	20	20	0	normal
52	F	14	12	2	low	11	F	10	11	−1	normal
67	F	17	18	−1	normal	26	F	16	13	3	low
35	F	15	9	6	high	50	F	13	12	1	normal
25	F	19	21	−2	low	36	F	21	18	3	low
57	F	15	13	2	low	40	F	17	17	0	normal
39	F	16	17	−1	normal	32	F	12	12	0	normal
26	F	11	11	0	normal	26	F	10	12	−2	low
34	F	15	10	5	high	53	F	16	15	1	normal
39	F	18	17	1	normal	28	F	17	15	2	low
47	F	10	12	−2	low	41	F	14	22	−8	high
35	M	18	11	7	high	53	M	15	15	0	normal
36	M	23	20	3	low	29	M	6	6	0	normal
28	M	26	20	6	high	33	M	13	16	−3	low
34	M	17	14	3	low	43	M	17	17	0	normal
36	M	11	10	1	normal	36	M	12	15	−3	low
43	M	14	12	2	low	36	M	15	13	2	low
24	M	22	24	−2	low	42	M	11	11	0	normal
32	M	18	17	1	normal	40	M	16	13	3	low
43	M	15	15	0	normal	33	M	12	12	0	normal
26	M	12	15	−3	low	41	M	14	13	1	normal
46	M	19	16	3	low	44	M	11	12	−1	normal
33	M	20	22	−2	low	40	M	10	8	2	low
40	M	11	11	0	normal	32	M	17	14	3	low
42	M	21	24	−3	low	41	M	15	13	2	low
39	M	21	16	5	high	71	M	14	12	2	low
32	F	13	12	1	normal	38	F	13	12	1	normal
33	F	9	8	1	normal						

[a] Right eye (mmHg).
[b] Left eye (mmHg).
[c] Difference between the right and left eye measurements.

A.2 Relationship between breastfeeding practices and the duration of postpartum amenorrhoea

In a WHO study to examine the relationship between breastfeeding practices and the duration of postpartum amenorrhoea, 550 women were recruited at the birth of their babies and the infant–mother pair were followed up until the end of amenorrhoea. Several variables were measured for each mother and her infant on admission into the study. Five of the admission variables for the first 116 subjects recruited in one of the centres in South America are shown below.

Age (yrs)	Social class[a]	Smoking[b]	Alcohol[c]	Ht[d]	Wt[e]	Age (yrs)	Social class[a]	Smoking[b]	Alcohol[c]	Ht[d]	Wt[e]
31	I	No	Yes	167	65	27	II	No	Yes	156	59
27	III	No	No	154	60	31	I	No	No	145	60
29	II	Yes	Yes	158	56	29	I	No	No	160	55
33	I	No	No	156	63	27	II	Yes	No	153	51
23	I	No	Yes	160	69	22	I	No	Yes	158	63
24	III	Yes	Yes	162	65	24	I	No	No	155	51
29	III	Yes	No	152	55	31	III	No	Yes	160	64
25	II	No	No	160	65	30	II	Yes	Yes	154	59
26	I	No	Yes	163	65	23	II	Yes	No	153	66
37	I	No	No	152	54	22	III	No	Yes	158	54
31	I	No	Yes	150	53	21	III	No	No	148	56
20	III	No	No	158	59	26	II	Yes	No	167	61
29	II	Yes	No	164	65	29	III	No	No	159	63
29	II	Yes	No	159	64	28	II	No	No	159	55
32	II	No	Yes	155	60	22	I	No	No	164	66
24	I	No	No	158	61	21	I	Yes	Yes	157	52
28	II	No	No	151	55	23	II	Yes	Yes	152	52
20	II	No	Yes	150	51	28	I	No	Yes	149	58
29	II	No	No	154	56	23	II	No	No	151	68
25	III	No	No	154	67	23	II	Yes	No	160	61
22	III	No	No	161	60	22	III	No	Yes	165	57
27	III	No	No	153	59	26	I	Yes	Yes	155	56
28	I	No	No	155	59	20	III	Yes	No	150	51
21	III	Yes	No	147	51	28	II	No	No	155	61
27	II	No	No	154	64	25	I	Yes	Yes	165	65
27	I	No	No	159	64	22	III	Yes	No	157	60
25	III	No	No	151	54	23	II	No	No	157	63
25	I	Yes	Yes	157	59	25	II	No	Yes	147	54
30	I	No	Yes	160	60	28	I	No	Yes	165	72
28	III	No	No	152	56	22	II	No	No	152	52
20	I	No	No	154	53	23	III	No	Yes	152	55
22	I	No	No	152	57	24	II	No	No	152	56
29	III	No	No	156	64	30	III	Yes	Yes	158	62

Age (yrs)	Social class[a]	Smoking[b]	Alcohol[c]	Ht[d]	Wt[e]	Age (yrs)	Social class[a]	Smoking[b]	Alcohol[c]	Ht[d]	Wt[e]
22	III	No	No	145	57	26	III	No	Yes	142	50
24	II	No	No	148	49	32	II	No	No	156	68
22	III	Yes	Yes	160	63	28	I	Yes	No	160	56
30	II	No	Yes	164	65	22	III	No	No	155	57
35	I	No	No	163	64	24	II	Yes	No	155	69
25	I	No	No	157	61	25	I	No	Yes	159	61
26	II	No	No	160	63	22	I	Yes	Yes	162	73
21	I	No	Yes	158	66	29	II	No	No	155	69
23	II	No	No	154	57	25	II	No	Yes	163	64
28	II	No	Yes	151	58	26	II	Yes	No	148	53
29	II	No	Yes	162	65	21	III	Yes	No	154	66
27	III	No	No	139	52	29	I	No	No	149	48
27	I	No	No	155	58	27	I	No	Yes	153	59
27	III	No	No	164	59	26	II	No	No	148	56
26	II	No	Yes	153	59	26	I	No	No	154	54
20	III	No	No	148	58	29	II	No	No	158	60
32	III	No	No	152	60	32	I	Yes	No	157	61
28	I	Yes	Yes	150	61	30	I	Yes	No	154	59
30	I	No	Yes	148	48	26	I	No	Yes	158	60
27	I	No	No	154	60	26	III	Yes	No	150	54
37	II	No	No	155	61	29	I	No	Yes	150	60
28	II	Yes	No	155	58	27	I	No	No	158	59
26	I	No	No	160	57	24	III	No	No	147	60
35	I	No	No	151	60	20	II	No	Yes	150	51
26	II	No	No	156	63	23	II	No	No	159	60

[a] I = upper class; II = middle class; III = lower class. Social classes were defined by the investigators using local standards.
[b] "No" means that the woman has never smoked.
[c] "No" means that the woman has never drunk alcohol.
[d] Height in cm.
[e] Weight in kg.

A.3 Absenteeism from work data

The following data on absenteeism due to acute upper respiratory system diseases among the 250 employees in a carpentry factory in Ankara, Turkey, relate to all such absences which included one or more days during January 1995.

	Absent			Absent	
Patient	from	to	Patient	from	to
A	3 Jan	9 Jan	A	14 Jan	17 Jan
A	27 Jan	30 Jan	B	22 Dec	11 Jan
C	30 Dec	6 Jan	D	3 Jan	19 Jan
D	27 Jan	5 Feb	E	24 Dec	1 Feb
F	24 Jan	4 Feb	G	4 Jan	7 Feb
H	11 Jan	20 Jan	I	22 Jan	30 Jan
J	5 Jan	10 Jan	J	18 Jan	26 Jan
K	29 Dec	9 Jan	L	28 Dec	7 Jan
L	12 Jan	19 Jan	L	27 Jan	31 Jan
M	21 Jan	29 Jan	N	22 Dec	9 Feb
O	23 Jan	5 Feb	P	28 Jan	2 Feb
R	3 Jan	10 Jan	R	21 Jan	26 Jan
S	29 Dec	4 Jan	S	9 Jan	13 Jan
S	17 Jan	18 Jan	S	24 Jan	2 Feb
T	22 Jan	31 Jan	U	1 Jan	10 Jan
U	27 Jan	1 Feb			

ANNEX B Statistical tables

Table B.1 ***The normal distribution (standardized deviates for two-tailed areas p)***

p	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
0.0	∞	2.575829	2.326348	2.170090	2.053749	1.959964	1.880794	1.811911	1.750686	1.695398
0.1	1.644854	1.598193	1.554774	1.514102	1.475791	1.439521	1.405072	1.372204	1.340755	1.310579
0.2	1.281552	1.253565	1.226528	1.200359	1.174987	1.150349	1.126391	1.103063	1.080319	1.058122
0.3	1.036433	1.015222	0.994458	0.974114	0.954165	0.934589	0.915365	0.896473	0.877896	0.859617
0.4	0.841621	0.823894	0.806421	0.789192	0.772193	0.755415	0.738847	0.722479	0.706303	0.690309
0.5	0.674490	0.658838	0.643345	0.628006	0.612813	0.597760	0.582841	0.568051	0.553385	0.538836
0.6	0.524401	0.510073	0.495850	0.481727	0.467699	0.453762	0.439913	0.426148	0.412463	0.398855
0.7	0.385320	0.371856	0.358459	0.345125	0.331853	0.318639	0.305481	0.292375	0.279319	0.266311
0.8	0.253347	0.240426	0.227545	0.214702	0.201893	0.189118	0.176374	0.163658	0.150969	0.138304
0.9	0.125661	0.113039	0.100434	0.087845	0.075270	0.062707	0.050154	0.037608	0.025069	0.012533

Table B.1 is taken from Table I of Fisher & Yates: *Statistical tables for biological, agricultural and medical research*, published by Longman Group UK Limited, 1974.

Table B.2 ***Distribution of t (for two-tailed tests)***

	Probability of greater value, *p*												
df	**0.9**	**0.8**	**0.7**	**0.6**	**0.5**	**0.4**	**0.3**	**0.2**	**0.1**	**0.05**	**0.02**	**0.01**	**0.001**
1	0.158	0.325	0.510	0.727	1.000	1.376	1.963	3.078	6.314	12.706	31.821	63.657	636.62
2	0.142	0.289	0.445	0.617	0.816	1.061	1.386	1.886	2.920	4.303	6.965	9.925	31.598
3	0.137	0.277	0.424	0.584	0.765	0.978	1.250	1.638	2.353	3.182	4.541	5.841	12.941
4	0.134	0.271	0.414	0.569	0.741	0.941	1.190	1.533	2.132	2.776	3.747	4.604	8.610
5	0.132	0.267	0.408	0.559	0.727	0.920	1.156	1.476	2.015	2.571	3.365	4.032	6.859
6	0.131	0.265	0.404	0.553	0.718	0.906	1.134	1.440	1.943	2.447	3.143	3.707	5.959
7	0.130	0.263	0.402	0.549	0.711	0.896	1.119	1.415	1.895	2.365	2.998	3.499	5.405
8	0.130	0.262	0.399	0.546	0.706	0.889	1.108	1.397	1.860	2.306	2.896	3.355	5.041
9	0.129	0.261	0.398	0.543	0.703	0.883	1.100	1.383	1.833	2.262	2.821	3.250	4.781
10	0.129	0.260	0.397	0.542	0.700	0.879	1.093	1.372	1.812	2.228	2.764	3.169	4.587
11	0.129	0.260	0.396	0.540	0.697	0.876	1.088	1.363	1.796	2.201	2.718	3.106	4.437
12	0.128	0.259	0.395	0.539	0.695	0.873	1.083	1.356	1.782	2.179	2.681	3.055	4.318
13	0.128	0.259	0.394	0.538	0.694	0.870	1.079	1.350	1.771	2.160	2.650	3.012	4.221
14	0.128	0.258	0.393	0.537	0.692	0.868	1.076	1.345	1.761	2.145	2.624	2.977	4.140
15	0.128	0.258	0.393	0.536	0.691	0.866	1.074	1.341	1.753	2.131	2.602	2.947	4.073
16	0.128	0.258	0.392	0.535	0.690	0.865	1.071	1.337	1.746	2.120	2.583	2.921	4.015
17	0.128	0.257	0.392	0.534	0.689	0.863	1.069	1.333	1.740	2.110	2.567	2.898	3.965
18	0.127	0.257	0.392	0.534	0.688	0.862	1.067	1.330	1.734	2.101	2.552	2.878	3.922
19	0.127	0.257	0.391	0.533	0.688	0.861	1.066	1.328	1.729	2.093	2.539	2.861	3.883
20	0.127	0.257	0.391	0.533	0.687	0.860	1.064	1.325	1.725	2.086	2.528	2.845	3.850

Table B.2 **(continued)**

	Probability of greater value, *p*												
df	**0.9**	**0.8**	**0.7**	**0.6**	**0.5**	**0.4**	**0.3**	**0.2**	**0.1**	**0.05**	**0.02**	**0.01**	**0.001**
21	0.127	0.257	0.391	0.532	0.686	0.859	1.063	1.323	1.721	2.080	2.518	2.831	3.819
22	0.127	0.256	0.390	0.532	0.686	0.858	1.061	1.321	1.717	2.074	2.508	2.819	3.792
23	0.127	0.256	0.390	0.532	0.685	0.858	1.060	1.319	1.714	2.069	2.500	2.807	3.767
24	0.127	0.256	0.390	0.531	0.685	0.857	1.059	1.318	1.711	2.064	2.492	2.797	3.745
25	0.127	0.256	0.390	0.531	0.684	0.856	1.058	1.316	1.708	2.060	2.485	2.787	3.725
26	0.127	0.256	0.390	0.531	0.684	0.856	1.058	1.315	1.706	2.056	2.479	2.779	3.707
27	0.127	0.256	0.389	0.531	0.684	0.855	1.057	1.314	1.703	2.052	2.473	2.771	3.690
28	0.127	0.256	0.389	0.530	0.683	0.855	1.056	1.313	1.701	2.048	2.467	2.763	3.674
29	0.127	0.256	0.389	0.530	0.683	0.854	1.055	1.311	1.699	2.045	2.462	2.756	3.659
30	0.127	0.256	0.389	0.530	0.683	0.854	1.055	1.310	1.697	2.042	2.457	2.750	3.646
40	0.126	0.255	0.388	0.529	0.681	0.851	1.050	1.303	1.684	2.021	2.423	2.704	3.551
60	0.126	0.254	0.387	0.527	0.679	0.848	1.046	1.296	1.671	2.000	2.390	2.660	3.460
120	0.126	0.254	0.386	0.526	0.677	0.845	1.041	1.289	1.658	1.980	2.358	2.617	3.373
∞	0.126	0.253	0.385	0.524	0.674	0.842	1.036	1.282	1.645	1.960	2.326	2.576	3.291

Table B.2 is taken from Table III of Fisher & Yates: *Statistical tables for biological, agricultural and medical research*, published by Longman Group UK Limited, 1974.

Table B.3 ***Cumulative distribution of χ^2***

	Probability of greater value, *p*													
n	**0.99**	**0.98**	**0.95**	**0.90**	**0.80**	**0.70**	**0.50**	**0.30**	**0.20**	**0.10**	**0.05**	**0.02**	**0.01**	**0.001**
1	0.0^3157	0.0^3628	0.00393	0.0158	0.0642	0.148	0.455	1.074	1.642	2.706	3.841	5.412	6.635	10.827
2	0.0201	0.0404	0.103	0.211	0.446	0.713	1.386	2.408	3.219	4.605	5.991	7.824	9.210	13.815
3	0.115	0.185	0.352	0.584	1.005	1.424	2.366	3.665	4.642	6.251	7.815	9.837	11.345	16.268
4	0.297	0.429	0.711	1.064	1.649	2.195	3.357	4.878	5.989	7.779	9.488	11.668	13.277	18.465
5	0.554	0.752	1.145	1.610	2.343	3.000	4.351	6.064	7.289	9.236	11.070	13.388	15.086	20.517
6	0.872	1.134	1.635	2.204	3.070	3.828	5.348	7.231	8.558	10.645	12.592	15.033	16.812	22.457
7	1.239	1.564	2.167	2.833	3.822	4.671	6.346	8.383	9.803	12.017	14.007	16.622	18.475	24.322
8	1.646	2.032	2.733	3.490	4.594	5.527	7.344	9.524	11.030	13.362	15.507	18.168	20.090	26.125
9	2.088	2.532	3.325	4.168	5.380	6.393	8.343	10.656	12.242	14.684	16.919	19.679	21.666	27.877
10	2.558	3.059	3.940	4.865	6.179	7.267	9.342	11.781	13.442	15.987	18.307	21.161	23.209	29.588
11	3.053	3.609	4.575	5.578	6.989	8.148	10.341	12.899	14.631	17.275	19.675	22.618	24.725	31.264
12	3.571	4.178	5.226	6.304	7.807	9.034	11.340	14.011	15.812	18.549	21.026	24.054	26.217	32.909
13	4.107	4.765	5.892	7.042	8.634	9.926	12.340	15.119	16.985	19.812	22.362	25.472	27.688	34.528
14	4.660	5.368	6.571	7.790	9.467	10.821	13.339	16.222	18.151	21.064	23.685	26.873	29.141	36.123
15	5.229	5.985	7.261	8.547	10.307	11.721	14.339	17.322	19.311	22.307	24.996	28.259	30.578	37.697
16	5.812	6.614	7.962	9.312	11.152	12.624	15.338	18.418	20.465	23.542	26.296	29.633	32.000	39.252
17	6.408	7.255	8.672	10.085	12.002	13.531	16.338	19.511	21.615	24.769	27.587	30.995	33.409	40.790
18	7.015	7.906	9.390	10.865	12.857	14.440	17.338	20.601	22.760	25.989	28.869	32.346	34.805	42.312
19	7.633	8.567	10.117	11.651	13.716	15.352	18.338	21.689	23.900	27.204	30.144	33.687	36.191	43.820
20	8.260	9.237	10.851	12.443	14.578	16.266	19.337	22.775	25.038	28.412	31.410	35.020	37.566	45.315
21	8.897	9.915	11.591	13.240	15.445	17.182	20.337	23.858	26.171	29.615	32.671	36.343	38.932	46.797
22	9.542	10.600	12.338	14.041	16.314	18.101	21.337	24.939	27.301	30.813	33.924	37.659	40.289	48.268
23	10.196	11.293	13.091	14.848	17.187	19.021	22.337	26.018	28.429	32.007	35.172	38.968	41.638	49.728
24	10.856	11.992	13.848	15.659	18.062	19.943	23.337	27.096	29.553	33.196	36.415	40.270	42.980	51.179
25	11.524	12.697	14.611	16.473	18.940	20.867	24.377	28.172	30.675	34.382	37.652	41.566	44.314	52.620

Table B.3 **(continued)**

	Probability of greater value, *p*													
n	**0.99**	**0.98**	**0.95**	**0.90**	**0.80**	**0.70**	**0.50**	**0.30**	**0.20**	**0.10**	**0.05**	**0.02**	**0.01**	**0.001**
26	12.198	13.409	15.379	17.292	19.820	21.792	25.336	29.246	31.759	35.563	38.885	42.856	45.642	54.052
27	12.879	14.125	16.151	18.114	20.703	22.719	26.336	30.319	32.912	36.741	40.113	44.140	46.963	55.476
28	13.565	14.847	16.928	18.939	21.588	23.647	27.336	31.391	34.027	37.916	41.337	45.419	48.278	56.893
29	14.256	15.574	17.708	19.768	22.475	24.577	28.336	32.461	35.139	39.087	42.557	46.693	49.588	58.302
30	14.953	16.306	18.493	20.599	23.364	25.508	29.336	33.530	36.250	40.256	43.773	47.962	50.892	59.703

Table B.3 is taken from Table IV of Fisher & Yates: *Statistical tables for biological, agricultural and medical research*, published by Longman Group UK Limited, 1974.

For larger values of n, the expression $\sqrt{(2\chi^2)}-\sqrt{(2n-1)}$ may be used as a normal deviate with variance, remembering that the probability for χ^2 corresponds to that of a single tail of the normal curve.

ANNEX C Random numbers

88008	13730	06504	37113	62248	04709	17481	77450	46438	61538
01309	13263	70850	11487	68136	06265	36402	06164	35106	77350
45896	59490	98462	11032	78613	78744	13478	72648	98769	28262
50107	24914	99266	23640	76977	31340	43878	23128	03536	01590
71163	52034	03287	86680	68794	94323	95879	75529	27370	68228
76445	87636	23392	01883	27880	09235	55886	37532	46542	01416
84130	99937	86667	92780	69283	73995	00941	65606	28855	86125
00642	10003	08917	74937	57338	62498	08681	28890	60738	81521
64478	94624	82914	00608	43587	95212	92406	63366	06609	77263
02379	83441	90151	14081	28858	68580	66009	17687	49511	37211
32525	44670	57715	38888	28199	80522	06532	48322	57247	46333
01976	16524	32784	48037	78933	50031	64123	83437	09474	73179
67952	41501	45383	78897	86627	07376	07061	40959	84155	88644
38473	83533	39754	90640	98083	39201	94259	87599	50787	75352
91079	93691	11606	49357	55363	98324	30250	20794	83946	08887
72830	10186	08121	28055	95788	03739	65182	68713	63290	57801
40947	75518	59323	64104	24926	85715	67332	49282	66781	92989
44088	70765	40826	74118	62567	75996	68126	88239	57143	06455
19154	29851	16968	66744	77786	82301	99585	23995	15725	64404
13206	90988	34929	14992	07902	23622	11858	84718	22186	35386
24102	13822	56106	13672	31473	75329	45731	47361	47713	99678
59863	62284	24742	21956	95299	24066	60121	78636	61805	39904
57389	70298	05173	48492	68455	77552	87048	16953	45811	22267
63741	76077	44579	66289	88263	54780	76661	90479	79388	15317
17417	56413	35733	27600	06266	76218	42258	35198	26953	08714
85797	58089	91501	34154	96277	83412	70244	58791	64774	75699
65145	97885	44847	37158	54385	38978	20127	40639	80977	73093
24436	65453	37073	81946	36871	97212	59592	85998	34897	97593
20891	03289	98203	05888	49306	88383	56912	12792	04498	20095
81253	41034	09730	53271	92515	08932	25983	69674	72824	04456
64337	64052	30113	05069	54535	01881	16357	72140	00903	45029
35929	76261	43784	19406	26714	96021	33162	30303	81940	91598
34525	54453	43516	48537	60593	11822	89695	80143	80351	33822
27506	45413	42176	94190	29987	90828	72361	29342	72406	44942
92413	00212	35474	22456	76958	85857	85692	75341	32682	00546
76304	57063	70591	06343	38828	15904	79837	46307	40836	69182
17680	92757	40299	98105	67139	01436	68094	78222	61283	40512
43281	36931	26091	42028	62718	38898	64356	19740	77068	78392

30647	40659	23679	04204	67628	81109	73155	68299	62768	58409
26840	42152	80242	57640	19189	47061	44640	52069	98038	49113
70356	18201	88552	54591	68945	57225	92109	07030	47296	40164
28577	15590	61477	96785	90709	53143	01967	40866	86811	04804
38403	68247	63353	92870	53557	42535	06235	91986	97934	09235
87534	31527	72736	73298	67797	89494	27571	47587	53547	31389
73830	65077	51022	32879	11985	69389	06764	84624	24842	51545
24032	98536	79706	15902	86947	78664	57706	51749	94860	33561
56318	00120	85872	45897	07733	15237	57442	05430	31406	62406
58389	25189	48073	53316	84652	43202	28630	32863	07363	16011
46826	99095	64962	18086	50284	47728	67035	92946	07467	55890
97589	70925	77108	98739	57058	81215	05150	62879	44837	02277
10890	70458	41454	73113	62946	82771	24072	91593	33505	18089
55477	16684	69066	72658	73424	55250	01147	58078	97168	69002
59688	82108	69870	85266	71787	07846	31548	08558	01935	42329
80744	09229	73891	48306	63604	70829	83549	60958	25769	08967
86026	44830	93996	63509	22690	85741	43555	22962	44941	42156
93711	57131	57271	54405	64093	50501	88610	51036	27254	26865
10223	67197	79520	36563	52148	39004	96351	14319	59138	22260
74059	51819	53517	62234	38397	71718	80076	48795	05009	18003
11960	40636	60755	75707	23668	45086	53678	03116	47910	77951
01467	84719	96945	43072	50023	11928	21690	74722	62420	77690
70918	56572	72014	52221	00756	81437	79282	09838	14647	04536
36894	81550	84614	83081	08450	38782	22219	67360	89328	20001
07415	23581	78984	94824	19906	70606	09417	13999	55960	06708
60021	33739	50837	53540	77186	29730	45408	47195	89119	40244
41772	50234	47352	32239	17611	35145	80340	95114	68463	89158
69444	19478	95346	83581	90109	00573	47790	64065	60205	80643
66970	27493	75777	10117	63266	54058	74717	02382	44211	63006
73322	33272	15183	27914	83074	31286	64330	75909	77787	56056
95378	15283	62105	95780	91088	59918	57913	44220	63174	16438
29647	85768	80778	99379	51431	15459	31573	52389	01216	64665

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Note: Page numbers in **bold** type indicate definitions and main discussions.