Chapter 3

Measuring, Monitoring, and Evaluating the Health of a Population

Learning Objectives

Upon completion of this chapter, the student should be able to:

1. Explain the basic terms and concepts of epidemiology;
2. Interpret health data from an epidemiological viewpoint;
3. Apply a systemic approach in evaluating the health status of a population.

INTRODUCTION

The history of health, health concepts, and scientific developments has been discussed in previous chapters. Measuring the health of populations is fundamental to improving their health status. Traditionally, public health deals with the health of populations, while the New Public Health deals with the health of both individuals and population groups. This chapter discusses how measurements are used to describe, analyze, prescribe, and justify interventions to protect and improve the health of populations and of individuals, and to monitor the outcomes of interventions.

The public health professional working with individual and community health needs to acquire the knowledge and skills necessary to measure and interpret the factors that relate to disease and health, both in the individual and in population groups. Demography and epidemiology are the basis of health information systems, but the social and basic medical sciences are also vitally important in understanding public health, providing an expanding array of health status indicators and measures of the impact of interventions.

Demography deals with the recording of the characteristics and trends of a population over time. The field has broadened to include social demography, which has a broader focus on economic, social, cultural, and biological factors, an important aspect of the New Public Health because of the vital role that risk factors, which are deeply affected by social conditions, play in health protection and disease prevention. Epidemiology measures the distribution, causes, control, and outcomes of disease in population groups. It provides the basic tools for quantification of the extent of disease, its patterns of change, and associated risk factors. Epidemiology also provides basic information needed for planning, evaluating, and managing health services. Other disciplines provide additional information and insights needed for community and national health assessment. These include the social sciences (sociology, psychology, anthropology, and economics), as well as clinical fields such as pediatrics and geriatrics, and basic sciences such as microbiology, immunology, and genetics.

This chapter is an introduction to epidemiology and health information systems intended to familiarize the student with basic terms, concepts, and methods. The scope of this text does not lend itself to detailed discussion of biostatistics and epidemiological methods, but instead focuses on the basic ideas and their relevance to the New Public Health. This chapter is meant to provide a general overview of the role of epidemiology and health information systems in the context of the New Public Health; it cannot serve as an authoritative, detailed text on the subject. Specialized texts and reviews, such as the Centers for Disease Control and Prevention's (CDC's) Health Disparities and Inequalities Report – United States 2011, are listed in the bibliography at the end of this chapter and on the companion web site (http://booksite.elsevier.com/9780124157668).

DEMOGRAPHY

Demography is "the study of populations, especially with reference to size and density, fertility, mortality, growth, age distribution, migration, and vital statistics and the interaction of all these with social and economic conditions" (Last, 2001). Demography is based on vital statistics reporting and special surveys of population size and density; it measures trends over time. It includes indices such as fertility, birth, and death rates; rural–urban residential patterns; marriage and divorce rates and migrations; and their interaction with social and economic conditions. Since public health deals with disease as it occurs in the population, the definition of populations and their characteristics is fundamental.

The New Public Health. http://dx.doi.org/10.1016/B978-0-12-415766-8.00003-3

Vital statistics include births; deaths; and population by age, gender, location of residence, marital status, socioeconomic status (SES), and migration. Birth data are derived from mandatory reporting of births and mortality data from compulsory death certificates. Other sources of data include population registries, including marriage/divorce, adoption, emigration, and immigration, residential patterns, as well as census data, economic and labor force statistics, and data from special household surveys conducted by home visits, telephone, or electronic media methods.

A census is a survey covering the entire population of a defined geographic, political, or administrative entity. It is an enumeration of the population, recording the identity of all people in every residence at a specified time. The census provides important information on all members of the household, including age, date of birth, gender, occupation, national origin, marital status, income, relation to head of the household, literacy, education level, and health status (e.g., permanent disabling conditions). The census also covers residents of health and social facilities such as nursing homes or similar care facilities. Other information on the home and its facilities may be included. A census may assign people according to their location at the time of the enumeration (*de facto*) or to the usual place of residence (*de jure*). A census tract is the smallest geographic area for which census data are aggregated and published. Data for larger geographic areas (metropolitan/regional statistical areas) are also published. More extensive data may be collected for representative samples of the population. These surveys are carried out over a period of years by a specialized national agency (e.g., Bureau of the Census in the USA and the Central Bureau of Statistics, Office of Population, Censuses and Surveys in the UK).

Census data are published in multiple-volume series with availability for research on computer disks, CD-ROMs, and the Internet. Intercensus surveys are systematically collected information sets, without prior hypothesis, usually by questionnaires with questions carefully composed and tested for validity and consistency (Last, 2007). They may include interviews, biological samples and physical examination. An outstanding example is the US National Health and Nutrition Examination Surveys (NHANES) conducted by the US Center for Health Statistics. These are carried out to determine trends in important economic or demographic data such as individual and family incomes, nutrition, employment, and other social indicators. Such a complex and costly process can never be 100 percent accurate, but great care is taken to maximize response and standardization in interview methods and processing to ensure precision.

Despite its limitations, the census is accepted as the basis of statistical definition of a population. It is well established in developed countries, but is problematic in developing countries where birth and death registration may be inadequate, requiring community-based registration systems. In the Scandinavian countries, population censuses have been replaced by continuously updated databases containing information about all inhabitants, who are assigned a personal identification number at birth or upon immigration.

Demographic transition is a long-term trend of declining birth and death rates, resulting in substantive change in the age distribution of a population. Population age and gender distribution is mainly affected by birth and death rates, as well as other factors such as migration, economics, war, political and social change, famine, or natural disasters. *Biodemography*, the study of the senescent process, focuses on aspects such as the length of life, the length of healthy life, and the limits to the lifespan. Economic development has a profound effect on population patterns, and demographic transition may be characterized by the following stages:

1. *Traditional* – high and balanced birth and death rates.
2. *Transitional* – falling death rates and sustained birth rates.
3. *Low stationary* – low and balanced birth and death rates.
4. *Graying of the population* – increased proportion of elderly people as a result of decreasing birth and death rates, and increasing life expectancy.
5. *Regression* – low birth rates, migration, or increasing death rates among young adults due to trauma, acquired immunodeficiency syndrome (AIDS), early cardiovascular disease (CVD) mortality, or war can result in a steady or declining population (i.e., demographic regression).

Fertility, mortality, disease patterns, and migration are the major influences on this transition within the population. The many factors that affect fertility decline and increasing longevity are outlined in Box 3.1. Education of women, urbanization, improved hygiene and preventive care, economic improvement with better living conditions, and declining mortality of infants and children are the major factors. This is an important issue in developing countries where high fertility rates and declining mortality of children contribute to rapid population growth and poverty.

Birth rates in the industrialized countries have fallen over the past half-century and are continuing to fall in many countries to levels below rates needed to sustain or maintain population size and age distribution. This contributes to aging of the population, with important economic and societal effects. Economic prosperity, efficient and easily available methods of birth control, and greater education and work opportunities for women in the workforce are major factors in choices made in terms of the number of children a woman wishes to have, and her right to determine the number and spacing of pregnancies. In some countries, access to prenatal diagnosis of the gender of the fetus has resulted

BOX 3.1 Factors in Fertility Decline and Increasing Longevity

Factors in Fertility Decline

- Education, especially of women.
- Decreasing infant and child mortality, reducing pressure for more children to ensure survivors.
- Economic development, improved standards of living, rising expectations and family income levels.
- Urbanization – family needs and resources change compared to rural society.
- Birth control methods – safe, inexpensive, supply, accessibility, and knowledge.
- Government policy promoting fertility control as a health measure.
- Mass media can raise awareness of birth control, and aspiration to higher standards of living.
- Health system development and improved access to medical care.
- Changing economic status, social role, and self-image of women.
- Changing social, religious, political and ideological values.

Factors in Increasing Longevity

- Increasing family income, education level and standards of living.
- Improved nutrition including improved food supply, distribution, quality, and nutritional knowledge.
- Control of infectious diseases.
- Reduction in non-infectious disease mortality.
- Adequacy of safe food and water, sewage and garbage disposal, adequate housing conditions.
- Disease prevention, reducing risk factors, promoting healthy lifestyle.
- Medical care services with improved access and quality.
- Health promotion and education activities of the society, community, and individual.
- Social security systems, child allowances, pensions, unemployment insurance, national health insurance.
- Improved conditions of employment and recreation, economic and social well-being.

BOX 3.2 Commonly Used Fertility Rates

- *Crude birth rate* (CBR) – the number of live births in a population over a given period, usually one calendar year, divided by the midyear population of the same jurisdiction, multiplied by 1000.
- *Total fertility rate* (TFR) – the average number of children that a woman would bear if all women lived to the end of their childbearing years and bore children according to age-specific fertility rates; most accurately answering the question "how many children does a woman have, on average?"

Source: *Modified from Last JM, editor. A dictionary of public health. New York: Oxford University Press; 2007.*

in wide-scale abortion of females because of birth policies, with parental preference for male children in China and India as examples. This is resulting in a major numerical deficiency of young women in the population with many attendant social and political effects. Reduced fertility and mortality, as in Japan and many countries in Western Europe, also have many societal and economic consequences, as a smaller workforce has to maintain a higher elderly population dependent on social security benefits.

Fertility

Fertility is the bearing of living children and is clearly determined by more than biological potential. Fertility is a complex issue influenced by cultural, social, economic, religious, and even political factors. Although economic prosperity may initially promote higher birth rates, increases in education levels and economic prospects, as well as in survival of those born, are generally related to reduced birth rates and natural population growth (Box 3.2). Changes in the status of women, and sexual and reproductive health standards and methods have contributed to changing birth patterns and expectations of family size in evolving societies. In recent decades, new medical advances have led to in vitro fertilization methods becoming widely available in upper- and middle-income countries; these are now an option in some instances of infertility, as is surrogate motherhood.

Population Pyramid

A population pyramid provides a graphic display of the percentage of men and women in each age group in a total population (Figures 3.1 and 3.2). A wide population base and a high birth rate in a country or region result in a large percentage of its population being under 15 years of age; when accompanied by limited economic resources, this is a formula for continued poverty. A population pyramid with a narrow base (i.e., few young people) and a growing elderly population will have a smaller workforce to provide the economic base for the "dependent age" population (i.e., both the young and the old). Aging of the population represents an increase in the over-65 population to some 13 percent of the population (Figure 3.3).

With a smaller working-age population to support these social costs of dependent subgroups, adverse economic consequences may prejudice costly pension and health services for the population. Other factors may also affect the population pyramid; for example, the loss of a large number of people during wartime. This loss affects a particular age–gender group as well as fertility patterns during and after the war; for example, the postwar "baby boom" after World War II. With aging of the population in many countries due

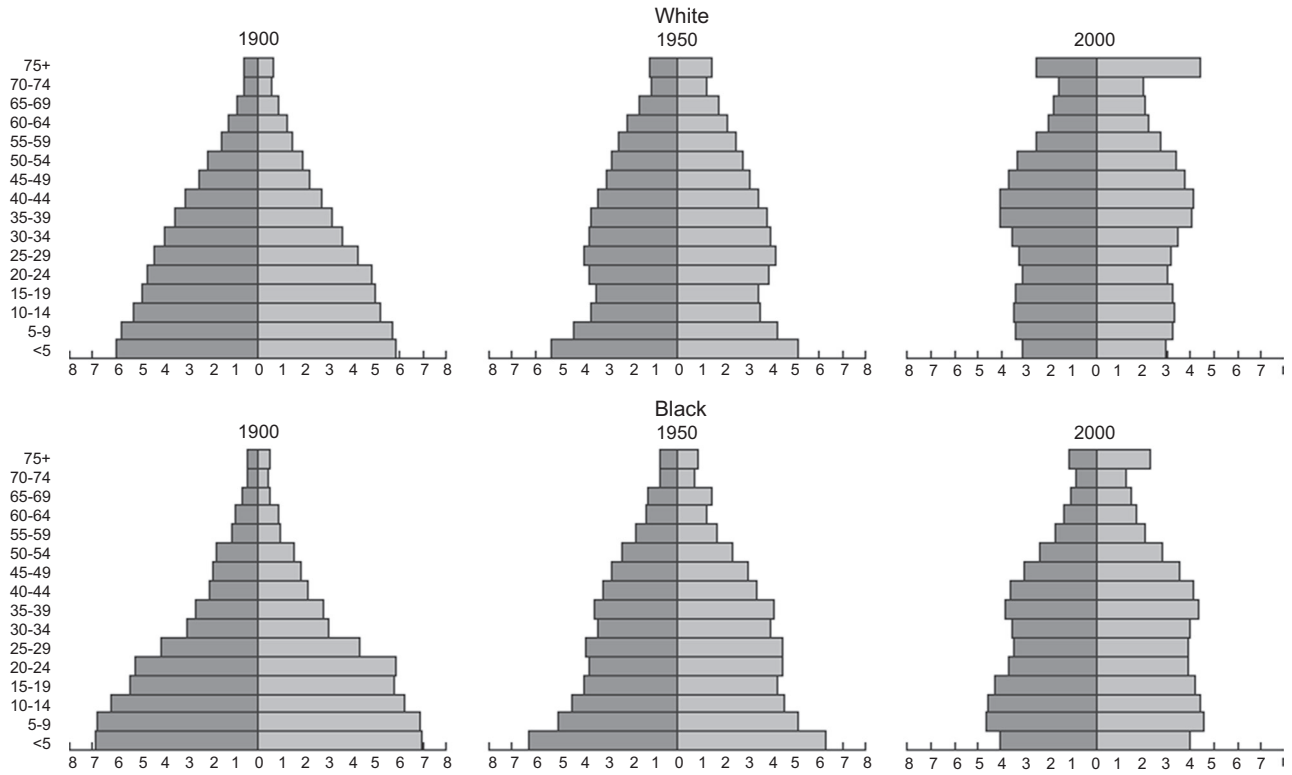

FIGURE 3.1 Population pyramids for the USA, 1900, 1950, and 2000, by gender for white and black populations. Note: bars (left) = male; bars (right) = female. *Source: Hobbs F, Stoops N. US Census Bureau: Census 2000 special reports, Series CENSR-4, Demographic trends in the 20th century. Washington, DC: US Government Printing Office; 2002.*

to low birth rates and increasing longevity, the concept of dependent population groups of those under the age of 15 and those over 65 as a percentage of the total population is increasingly relevant to social and economic planning.

LIFE EXPECTANCY

Life expectancy is an important health status indicator based on the average number of years a person at a given age may be expected to live given current mortality rates. Life expectancy can be measured at birth (age 0), which is most commonly used for national and international comparisons (Table 3.1).

Life expectancy is also reported at other specific ages, representing expected survival time once a person has reached that age; for example, at age 15, 60, or 75 by gender and by ethnic group, or by specific medical conditions such as cancer of the colon, myocardial infarction, and others.

Between 1970 and 2009, life expectancy for people aged 65 by gender and race was similar (Figure 3.4). However, variation in life expectancy at birth by gender and race remains constant. Looking at the years 1900–2000, life expectancy at birth in the USA increased dramatically in the first half of the century, reflecting mainly the reduction in infectious diseases and adverse conditions of maternity and infancy. The second half of the century was characterized by an increase and then a decrease in CVD as a cause of mortality and an increase in cancer and trauma-related deaths, so that life expectancy increased, but at a lower rate than in the earlier period.

Life expectancy at birth increased dramatically in the USA from 47.3 years in 1900 to 68.2 years in 1950. Since the 1950s, life expectancy increased to 73.7 years in 1980, and to 78.3 years in 2011. In 2011, male life expectancy was 76.2 years and female life expectancy 81.0 years (Hoypert and Xu, National Vital Statistics Report, 2012). From 1900 to 1999, the average lifespan of people in the USA lengthened by more than 30 years; 25 years of this gain can be attributed to advances in public health. Life expectancy (76.8 years in 2000) at birth among US residents increased by 62 percent during the twentieth century with great improvements in population health status at all stages of life, and this process of decline in death rates is continuing in the twenty-first century (Ten Great Public Health Achievements – United States, 2001–2010, MMWR, 2011).

Country ranking by estimated life expectancy in 2012 is shown in Table 3.2, based on vital statistics and the CIA *World Factbook.* The USA ranks low among in life expectancy, in 2012 coming in 51st, ranking below many countries with lower per capita gross domestic product (GDP)

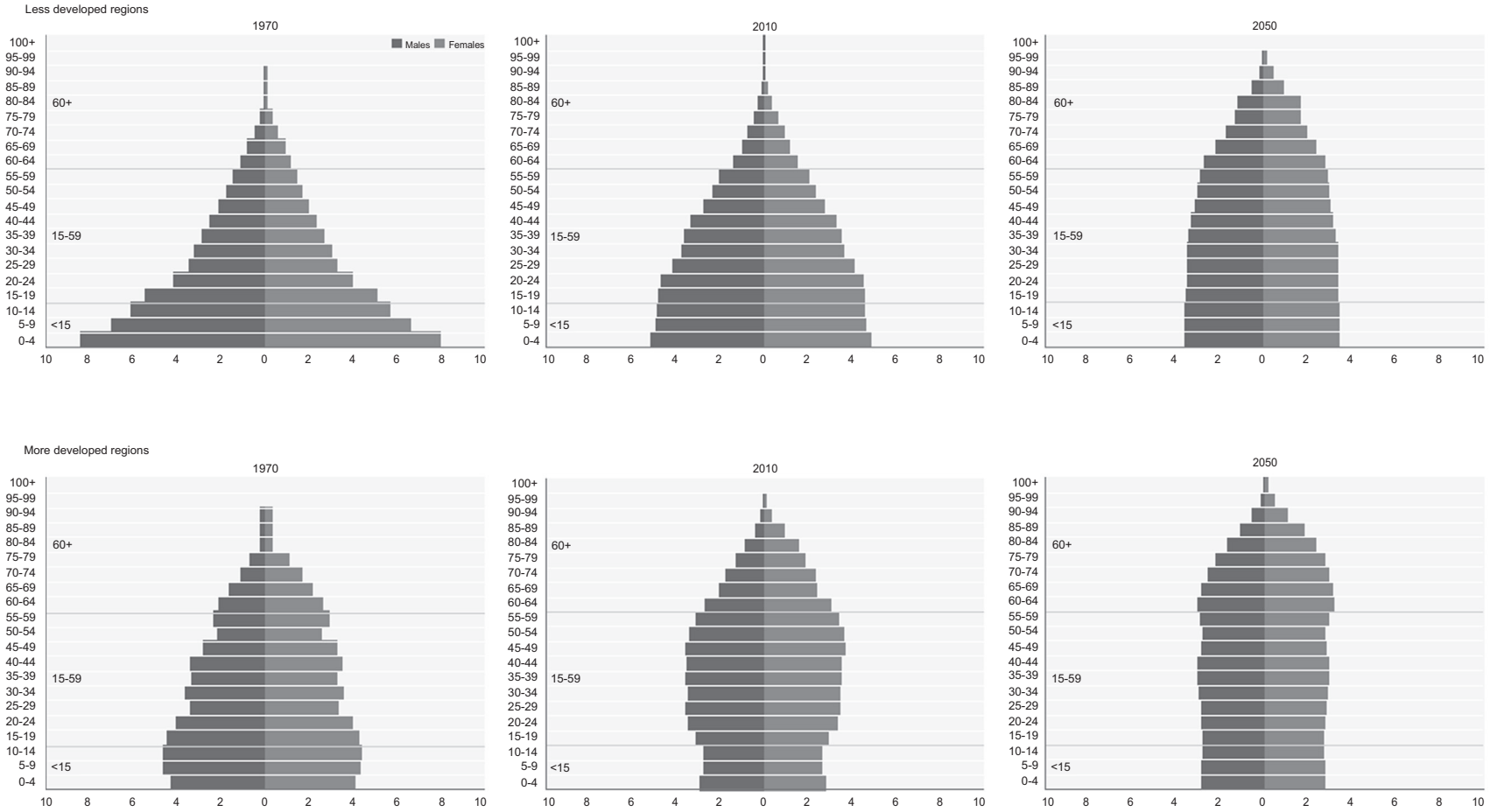

FIGURE 3.2 Age–gender distribution of world population in less developed and more developed regions, 1970, 2010, and 2050. *Source: World Health Organization. Ageing and development 2012, wall chart. Available at: http://www.un.org/esa/population/publications/2012WorldPopAgeingDev_Chart/2012PopAgeingandDev_WallChart.pdf [Accessed 3 January 2013].*

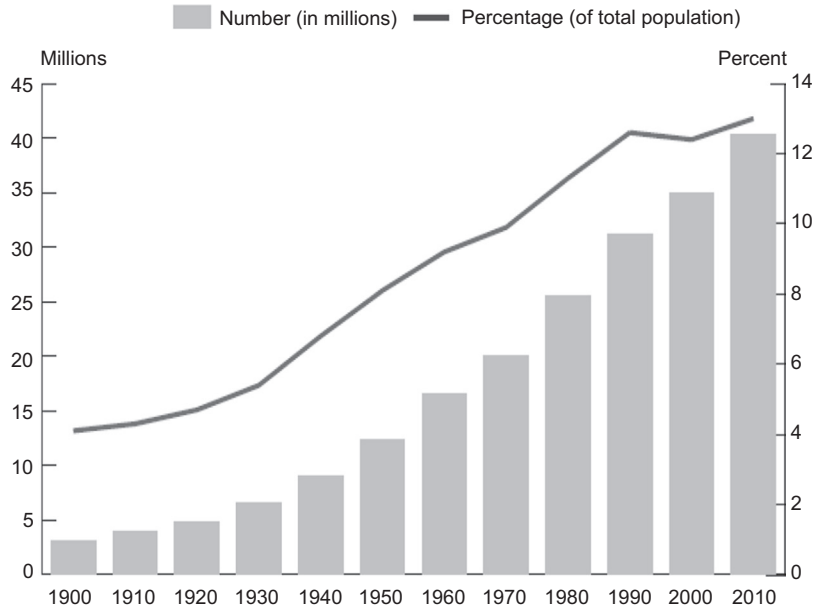

FIGURE 3.3 Population over age 65, USA, 1900–2010. *Source: US Census Bureau. The older population: 2010 Census Briefs. Decennial census of population, 1900–2000; 2010 census Summary File 1. Available at: http://www.census.gov/prod/cen2010/briefs/c2010br-09.pdf [Accessed 3 January 2013].*

TABLE 3.1 Life Expectancy at Birth in Years for Selected Organisation for Economic Co-operation and Development Countries and Russia, 1970–2009

	1970	1980	1990	2000	2009
Canada	72.8	75.3	77.6	79.0	80.7[a]
Denmark	73.3	74.3	74.9	76.8	79.0
Finland	70.8	73.6	75.0	77.7	80.0
France	72.2	74.3	76.8	79.0	81.0
Germany	70.5	72.9	75.3	78.2	80.3
Ireland	71.2	72.8	74.9	76.6	80.0
Israel	71.8	73.9	77.5	78.8	81.6
Japan	72.0	76.1	78.9	81.2	83.0
Korea	62.1	65.9	71.4	78.0	80.3
Netherlands	73.7	75.8	77.0	78.0	80.6
New Zealand	71.5	73.2	75.5	78.3	80.8
Russian Federation	68.3	67.3	69.0	65.7	68.7
Sweden	74.7	75.8	77.6	79.7	81.4
UK	71.8	73.2	75.7	77.8	80.4
USA	70.9	73.7	75.3	76.8	78.2
OECD average	70.5	72.6	74.9	77.1	79.5

Note: [a] 2007 data.
Source: Organisation for Economic Co-operation and Development. OECD factbook 2011–2012: economic, environmental, and social statistics. OECD Publishing; 2012. Available at: http://www.oecd-ilibrary.org/economics/oecd-factbook-2011-2012_factbook-2011-en [Accessed 3 January 2013].

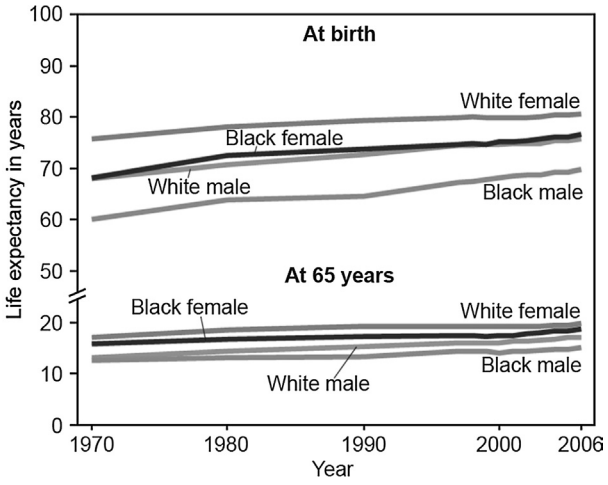

FIGURE 3.4 Life expectancy at birth and age 65, by gender and ethnicity, USA, 1970–2006. *Source: US Department of Health and Human Services. Health United States, 2009 with chartbook on health of Americans (Figure 16).*

and other markers of prosperity and civil society. This is in contrast with the high ranking in Human Development Index (HDI) measures and the high level of expenditure on health. The reasons for this are debated: most attribute it to a lack of universal health coverage, but the regional variations in mortality rates seen in the USA suggest that the key issues include differences in diet and life habits. Life expectancies are as much as 5 years longer in other high-income countries such as Singapore, Japan, Israel, Scandinavia,

TABLE 3.2 Country Ranking by Estimated Life Expectancy, selected countries 2012

Rank	Country	Years	Rank	Country	Years
3	Japan[a]	83.9	74	Uruguay	76.4
4	Singapore	83.8	78	Poland	76.3
9	Australia	81.9	89	Macedonia	75.4
10	Italy	81.8	90	West Bank	75.2
12	Canada[a]	81.5	93	Hungary	75.0
14	France	81.5	96	China[a]	74.8
15	Spain	81.3	98	Colombia[a]	74.8
16	Sweden[a]	81.2	99	Algeria	74.7
17	Switzerland	81.2	108	Saudi Arabia	74.4
19	Israel[a]	81.1	109	Romania	74.2
21	Netherlands[a]	81.0	110	Gaza Strip	74.1
25	New Zealand	80.7	111	Venezuela	74.0
26	Ireland	80.3	122	Egypt	72.9
27	Norway[a]	80.3	124	Brazil	72.8
28	Germany[a]	80.2	125	Turkey	72.8
29	Jordan	80.2	129	Vietnam	72.4
30	UK[a]	80.2	133	Philippines	71.9
31	Greece	80.1	147	Iran	70.4
36	European Union[a]	79.8	149	Kazakhstan	69.6
38	Belgium	79.7	155	Mongolia	68.6
40	Finland[a]	79.4	162	India	67.1
41	Korea, South	79.3	164	Russia[a]	66.5
48	Denmark[a]	78.8	166	Pakistan	66.4
49	Portugal	78.7	177	Kenya	63.1
51	USA[a]	78.5	192	Ghana	58.6
54	Chile	78.1	196	Ethiopia	56.6
60	Cuba	77.9	205	Uganda	53.5
62	Albania	77.6	212	Nigeria[a]	52.0
65	Czech Republic	77.4	218	Afghanistan	49.7
69	Argentina	77.1	220	South Africa	49.4

Note: [a]Discussed in Chapter 13.
Source: CIA. The world factbook. Country comparison, life expectancy at birth. Available at: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2102rank.html [Accessed 7 January 2012].

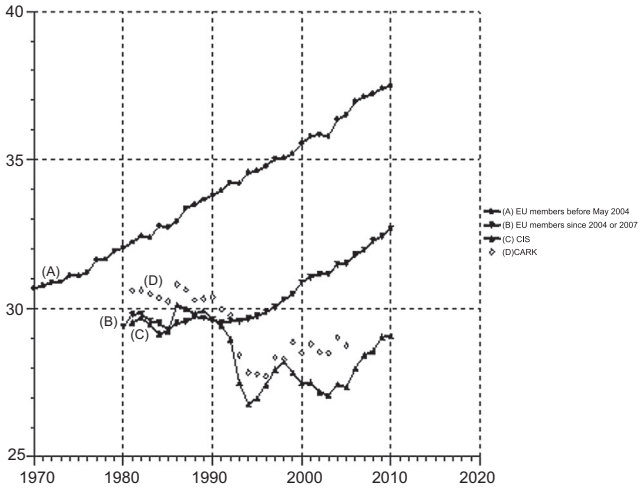

FIGURE 3.5 Life expectancy at age 45 years, European Region, 1970–2010. Note: CARK = Central Asian Republics; Old EU = members of the European Union before 2004; New EU = members of the European Union after 2004; CIS = Commonwealth of Independent States (Russia, Ukraine, Byelorussia). *Source: Health for All Database, WHO European Region, August 2012.*

Canada, and the UK than for the US population. Figure 3.5 shows life expectancy at the age of 45 since 1970: it has risen steadily with variation between western countries, including Western European countries, with the Central and Eastern European countries also rising, but the countries of the former Soviet Union lagging well behind.

Life expectancy is also used in chronic disease epidemiology to summarize patterns of mortality and survival in a population, such as people with breast cancer. This is important in clinical epidemiology where studies of effectiveness of specific interventions are assessed. Life expectancy is quite different for males and females; thus, gender is an important factor in the assessment of disease prevalence and also in the effectiveness of interventions.

Demography is becoming a major political and social issue in countries where demographic transition is resulting in major shifts in population make-up, and less severely in Western European countries. Russia is experiencing a major reduction in population, with low birth rates and low life expectancy. In the late 1970s, China implemented a "one child per family" policy, and a preference for males means that the country now has a major gender imbalance, with excess males and a deficit in the female population. Developing countries with high birth rates are experiencing population growth exceeding economic growth capacity. The USA has the benefit of steadily improving life expectancy and high immigration rates to offset low birth rates. Japan and many European countries with very high life expectancy and low birth rates face declining and aging populations. These population transitions have important political and economic implications in every country and in regions within countries (see Chapter 13).

International migration has important demographic, economic, social, cultural, political, and health implications for the migrants original and adopted countries. The World Bank estimates that 215 million people, or 3 percent of the world's population, are living in countries other than their home countries. Internal migration has even more importance for the development of many countries, with huge transfers of the rural population to urban settings. Developing countries, where more than 80 per cent of the world's

population live, are a significant source of international migration to industrialized countries as people search for better opportunities in more developed economies and for political freedom in stable civil societies. In aging western societies, migration provides young workers to sustain jobs that local educated young people avoid. High birth rates in poor countries and stagnant economies offer little opportunity to young adults in many developing countries.

Migration is a modest but complex and important factor in demography. Vastly differing birth rates, together with increased life expectancy in most regions, are important factors in regional differences in population growth and aging which affect the supply of labor. As the twentieth century drew to a close, the rate of global population growth began to fall, due primarily to continuing declines in population replacement and declining fertility rate, but partially offset by longevity and an aging population.

Population projection is fraught with many uncertainties such as fertility rates, death rates, life expectancy, and economic, cultural, and political factors. Demographic research explores the potential for further extensions of the lifespan in mathematical, evolutionary, and empirical contexts, as well as economic transfers, both public and private, between age groups and social inequalities in terms of poverty, prosperity, economic growth, and lifetime choices. Migration changes traditional demographics and ethnicity in many countries along with differing religious, cultural, political, and fertility patterns. In a spatially and socially mobile world, civil and human rights issues arise with security and threats to public order are frequent. Passions of nationalism can emerge with incitement and actual events of ethnic cleansing, even genocide, and birth policies promoting gender selection or ethnic preference.

World population growth is uneven, as high- and medium-income countries have reduced their birth rates to near or below population replacement levels, while low-income countries continue with high birth rates, so that world population growth will continue to levels that will challenge the provision of basics such as water, food, and economic development. The United Nations (UN) world population projection for 1950–2050 is shown in Figure 3.6.

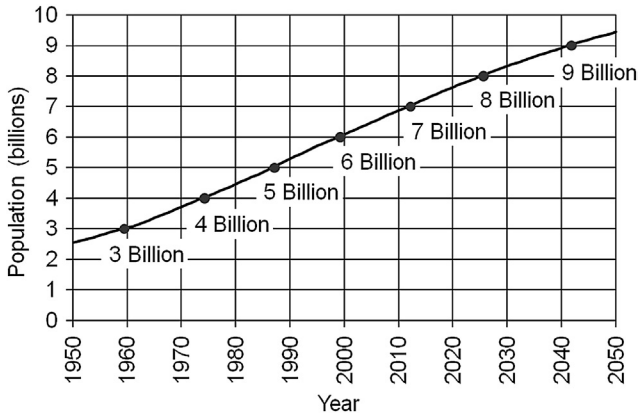

FIGURE 3.6 World population, 1950–2050. *Source: US Census Bureau. International programs. International data base, June 2011 update. Available at: http://www.census.gov/population/international/data/idb/worldpopgraph.php [Accessed 5 January 2012].*

EPIDEMIOLOGY

Health care providers are generally oriented towards individual patient assessment and care. However, every health worker, especially the specialized clinician, must have a basic understanding that disease is not an event isolated to an individual, but affects population groups and communities alike, and vice versa. Many epidemics are first identified

BOX 3.3 Goals, Methods, Ethics and Challenges of Epidemiology

Goals

- To eliminate, contain or reduce health problems and related consequences.
- To prevent the occurrence or recurrence of problems.

Methods

- Describe the distribution and size of disease problems in human populations.
- Identify etiological (i.e., the cause of disease) processes and factors involved in the pathogenesis of disease.
- Provide data essential to the planning, implementation, and assessment of services for the prevention, control, and treatment of disease and to establish priorities among these services.

Ethical Principles

The Helsinki Declaration is primarily concerned with experimental designs in clinical research, and does not cover many of the observational designs used so often in public health enquiry. There are four general ethical principles for research: autonomy (respect for individual rights), beneficence (do good), non-maleficence (do no harm), and justice.

Current Challenges of Epidemiology

Addressing health inequities and promoting health equity in all fields of disease and health, including: injury epidemiology, occupational health, infectious diseases, chronic diseases, maternal and child health, surveillance and field epidemiology, mental health, violence (from self-directed, e.g., suicide, to interpersonal to structural), psychoactive substance use (including tobacco), and measures of subjective health. Attention will be given to epidemiology's theoretical frameworks and emphasizing knowledge translation, from epidemiology to health systems, and policy.

Sources: *International Epidemiologic Association. http://www.dundee.ac.uk/iea/GEP07.htm [Accessed 8 July 2007].*
Monsour BB, Johnston JM, Hennessy TW, Schmidt MI, Krieger N. Visions for the 20th International Epidemiological Association's World Congress of Epidemiology (WCE 2014). Public Health 2012;126:274–6. http://dx.doi.org/10.1016/j.puhe.2011.12.015.

by "index cases" being reported to public health authorities who begin to put together a picture of moving events. The human immunodeficiency virus (HIV) epidemic was first reported with a small number of cases in New York City [reported in CDC's *Morbidity and Mortality Weekly Report* (MMWR)], soon followed by a new group of cases in San Francisco and the rapid spread to become a pandemic globally costing millions of lives. The epidemic of severe acute respiratory syndrome (SARS) crossed borders and continents, spreading from China to Canada in a matter of days, and closing down the city of Toronto for many days.

The importance of monitoring disaster events is exemplified by the British Petroleum oil spill in the Gulf of Mexico in 2011. A recent epidemic of fungal meningitis was suspected by a hospital clinician and followed by public health authorities in Tennessee, who found the source to be contaminated medication produced in Massachusetts, leading to the US Food and Drug Administration (FDA) establishing new regulations on pharmaceutical company safety standards (see Chapter 15). The clinician must be aware of the potential for epidemic and pandemic disease as well as the risk factors for a non-communicable disease (NCD), such as CVD, affecting the individual patient, in order to determine management over the long term.

Epidemiology is the study of health events in a population. The goals and methods of epidemiology incorporate ethical principles consistent with the Helsinki Declaration (Box 3.3). Its purpose is to help understand disease processes and outcomes, determine factors in causation, assess the effectiveness of interventions, and provide direction for medical or public health interventions. The distribution and determinants of health-related states, conditions, or events in defined populations are important in the identification of potential interventions and priorities to control health problems and reduce "avoidable or "amenable" deaths (Box 3.4). Methods include surveillance, observation, and hypothesis generation and testing in analytical research and experiments. Health events occur in population groups and the study of epidemiology requires definition of the events and the population studied. Specified populations are those with common, identifiable characteristics that can be quantified, such as gender, age, ethnicity, and region of residence. Potential determinants include physical, biological, social, cultural, economic, environmental, and psychological and behavioral factors.

BOX 3.4 Amenable Mortality as a Public Health Outcome Indicator

One challenge of epidemiology is to measure the contribution of health care to population health outcomes with precision, given the often multifactorial nature of many outcomes. The concept of "amenable" or avoidable mortality is one approach shown to provide a useful approximation. Using this concept, previous work illustrated how health care impacted positively on population health in many industrialized countries during the 1980s and 1990s. However, the pace of change has differed among countries and over time.

Recent work demonstrated, for example, that progress in the USA on this indicator was lagging behind other industrialized countries. The USA had a higher rate than European countries, that is, a higher rate of deaths from conditions such as diabetes or acute infection that could potentially have been treated with timely and effective care. In 2007, for example, US rates of such deaths were almost twice those in France, which had the lowest rates of the countries studied.

The USA spends an average of nearly $8000 a year per person on health care – roughly double the average in Western European countries. Yet Americans die sooner and also experience poorer health throughout life than people in many other countries. While the USA enjoyed steady increases in the length of life during the twentieth century in particular, in the latter part it fell increasingly behind other high-income countries.

This can be illustrated by recent trend in amenable mortality, comparing the USA with France, Germany, and the UK. Thus, between 1999 and 2007, the rate of potentially preventable deaths among men under the age of 75 fell by 18.5 percent in the USA compared to a 37 percent decline in the UK, a 28 percent decline in France, and a 24 percent decline in Germany. For women, the rates fell by 17.5 percent in the USA, compared to 32 percent in the UK, and 23 percent in both France and Germany.

The lag in improvement was most notable among American men and women under the age of 65. These individuals are more likely to be uninsured than are Americans over 65, who are eligible for Medicare. The observed differences are not inevitable, however, and there are regional variations, as in all countries. For example, the state of Minnesota achieved outcomes on a par with those found in many European countries and an amenable mortality rate less than half that of Mississippi or the District of Columbia.

Evidence indicates that these outcomes were achieved with patients receiving care that meets best practice guidelines and preventive care to reduce unneeded hospitalization. These findings underscore the importance of improving access to timely and effective health care in the USA. Amenable or avoidable mortality is an important tool for epidemiological monitoring and comparisons of population health between countries and between regions within countries.

Sources: *Nolte E, RAND Europe; McKee M, London School of Hygiene and Tropical Medicine. Personal communication; January 2013.*
Nolte E, McKee M. Does healthcare save lives? Avoidable mortality revisited. London: Nuffield Trust; 2004.
Nolte E, McKee M. In amenable mortality – deaths avoidable through health care – progress in the US lags that of three European countries. Health Aff 2012;31:2114–22.
Woolf SH, Aron L, editors. Shorter lives, poorer health. Washington, DC: National Academies Press; 2013.

BOX 3.5 Health Determinants and Measures of the Individual and Community

Factors

- *Biology* – age, gender, genetics
- *Geography* – urban, rural, climate, nomadic
- *Economics* – GDP per capita, family income, unemployment, living standards, poverty levels
- *Social security* – pensions for the elderly, disability and chronic illness pensions
- *Cultural, religious, and economic factors*
- *Education* – literacy, gender differences, higher education
- *Lifestyle, personal habits* – diet, smoking, exercise, drug use, risky sexual habits
- *Occupation* – injuries, toxic exposures, mental and physical stress
- *Environment* – exposure to toxins, air pollutants, carcinogens, infectious agents
- *Societal factors and physical urban and rural environment*
- *Nutrition* – food security and safety, diet, cost, quality with fortification with essential nutrients
- *Health services and insurance* – accessibility, quality of care, comprehensiveness, organization, financing
- *Public health infrastructure and policies*
- *Family and social support* – stability and family function.

Measures

- *Demography* – births, deaths, marriages, divorces, migration
- *Infrastructure* – safe water, food, air, solid waste disposal, transport measures
- *Health insurance* – coverage, comprehensiveness
- *Resources* – hospital beds and medical personnel per 1000 population, and their distribution
- *Process* – utilization, immunization, hospitalization rates
- *Outcomes*:
  - mortality: by age, gender, cause
  - morbidity: by cause, time, place, common exposure, nutritional micronutrient deficiencies
  - physiological indicators: growth and development, body mass index
  - functions of daily living and disability
- *Quality measures* – accreditation, peer review, quality improvement
- *Knowledge, attitudes, beliefs, practices*
- *Satisfaction and self-assessment*
- *Costs and benefits.*

Variables are "any attribute, phenomenon, or event that can have different values" (Last, 2001). They include all the physical, biological, social, cultural, environmental, economic, psychological, and behavioral factors that influence health. Health-related states and events include diseases, causes of death, behavior such as use of tobacco, compliance with preventive regimens, and provision and use of health services. Distribution includes analysis by time (e.g., month, season, time of day), place, identifying individuals or groups of people affected by common events such as foodborne disease at a festival, on a cruise ship, or in a workplace, nursing home, hospital, or school. Health status monitoring covers a large range of health-related states and events including diseases, handicapping conditions, causes of death, fertility and fecundity, birth defects, growth and development in childhood, health-related behavior (e.g., use of tobacco), compliance with public health intervention (e.g., immunizations), and access to and use of health services (Box 3.5).

Avoidable mortality includes deaths for diseases that are totally or largely preventable by public health and clinical care, such as measles, or lung cancer from smoking. Amenable mortality is death from a disease that can be managed with prolongation of life, such as diabetes or hypertension. Box 3.4 addresses the changes in amenable mortality comparing countries to indicate the effectiveness of their health and social systems.

Epidemiological studies may include descriptive studies of routinely or ad hoc reported and collected data on mortality, morbidity, and related factors. They focus on the distribution of disease or risk factor by time, place, and person characteristics, and form a crucial basis for public health activities and evaluation. Analytical epidemiological studies are based on hypothesis testing and include observational studies such as cross-sectional, case–control, and cohort studies, as well as intervention studies, including clinical and program trials. They focus on exposures and outcomes, and attempt to determine their associations. An interpretation of this wide range of data sources is shown in Figure 3.7. CDC's vision for public health surveillance for the twenty-first century represents the broad scope of information and professions involved in population health monitoring (CDC, 2012).

Classically, the clinician diagnoses and treats a patient who presents for medical care, including remedial and preventive care. Community public health workers focus on health protection and preventive care for the population. Epidemiologists study the health of a defined population in partnership with the many other disciplines represented in Figure 3.7, including geneticists, microbiologists, information specialists, statisticians, economists, social scientists, and others. This provides a strong base for assessment of the need for preventive action. Epidemiologists also evaluate the effects of preventive or treatment measures and share the need to understand risk factors and the natural process of disease. Epidemiology studies a particular disease in a population, taking into account factors such as age, gender, ethnicity, exposure to known or suspected risk factors, and socioeconomic patterns, as well as the effect of various interventions. This study is undertaken to understand the natural history of disease and related diagnostic criteria, to identify risk groups and relevant target groups for intervention and, accordingly, appropriate methods of prevention or

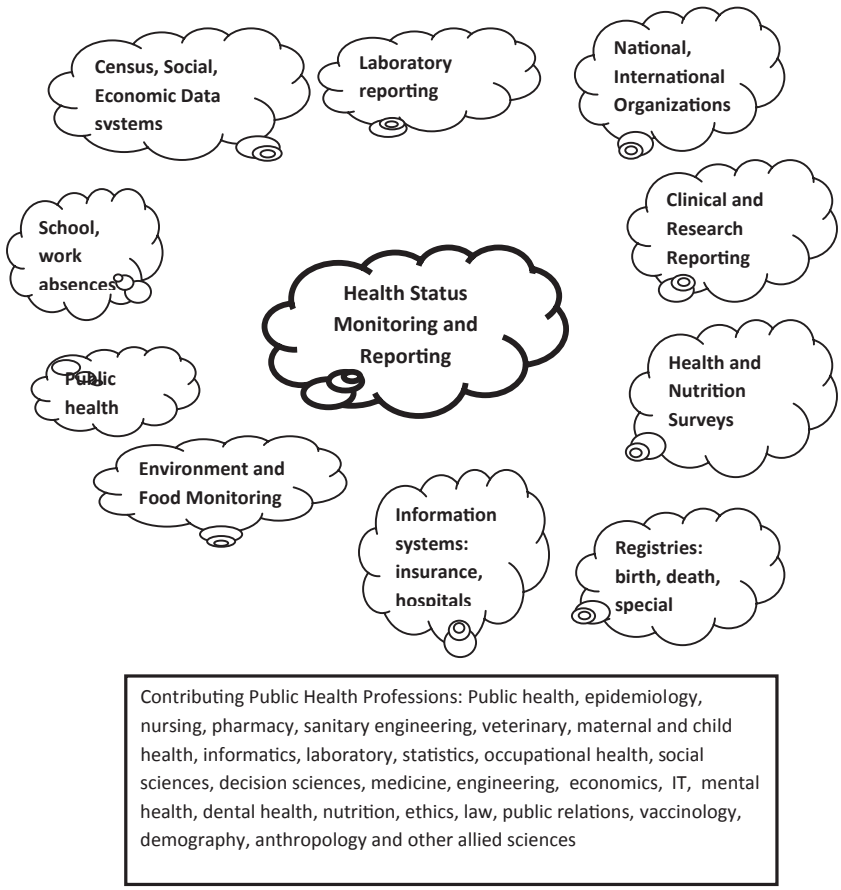

FIGURE 3.7 Centers for Disease Control and Prevention model of information systems and professions in public health monitoring. *Adapted from Lee LM, Thacker SB. CDC's vision for public health surveillance in the 21st century. The cornerstone of public health practice: public health surveillance, 1961–2011. MMWR Morb Mort Wkly Rep Suppl 2011;60(04):15–21.*

management, outcomes to be expected, and the costs and benefits of the different methods of control in addition to aspects relevant to ethical assessment.

Clinicians and epidemiologists depend on each other, need to collaborate with professionals from other fields, such as health economics and management, and require documented experience of interventions to improve care and efficient use of resources. Reliance is also placed on interaction with the various disciplines within public health, health policy, health systems management, and clinical medicine. Difficult choices in public policy regarding allocation of resources must be made with many factors in mind, including the epidemiology of the condition, cost-effectiveness of intervention, and ethical questions.

In the nineteenth to twentieth centuries, a profound transition occurred in the industrialized countries as the diseases of "pestilence and famine" waned, and chronic diseases became the leading causes of death. Many of these were associated with human-caused environmental problems and personal lifestyle. This epidemiological transition took place, initially primarily because of the cumulative effects of successful public health activities such as environmental sanitation and food safety, and later through communicable disease control with the success of vaccines and antibiotics in reducing the major diseases of childhood, and improvements in living conditions. A "second era" in public health occurred during the latter half of the twentieth century with the rise and fall of chronic disease in the industrialized countries, but this era is still a great challenge in countries in transition (e.g., former Soviet countries, especially in the Russian Federation, Ukraine, and Central Asian Republics), and increasingly in developing countries as well. Now a "third era" of health has arrived, with people living well into their seventies and eighties, often not only free from serious morbidity but leading vibrant and active lives, requiring a reorientation of personal perspectives as well as adjustments in the community and the health system (Breslow, 2006). In the second decade of the twenty-first century people in their nineties and even some centenarians are living healthful active lives.

During the 1950s and 1960s, rising standards of living in the industrialized world were associated with increases in NCDs, including CVDs, malignancies associated with smoking, other "lifestyle" diseases, and trauma associated

with industrialization, violence, self-injury, and motor vehicle accidents. This transition is playing an important role in the disease patterns of developing countries as they urbanize and the middle class grows. The Global Burden of Diseases, Injuries, and Risk Factors Study 2010 (GBD 2010), sponsored by the Bill and Melinda Gates Foundation, launched in spring 2007, is the most comprehensive effort since the GBD began in 1990. The new GBD will produce complete and comparable estimates of the burden of diseases, injuries, and risk factors for 21 regions of the globe for the years 1990, 2005, and 2010. The study is the collective work of a large community of experts and leaders in epidemiology and other areas of public health research from around the world. The main methods and findings from the study are published in *The Lancet* in a series of seven papers, commentaries, and accompanying material totaling over 2300 pages in length. This database will be important to develop strategies for global health to follow on from the Millennium Development Goals (MDGs) of 2001–2015. Table 3.3 shows the leading causes of death globally in 2008, with ischemic heart disease, stroke, and other CVDs far ahead of other causes. NCDs are discussed in depth in Chapter 5.

Since the 1960s, a new and equally profound epidemiological transition has occurred with the decline of heart disease, stroke, and trauma as causes of death, in the industrialized world but also increasingly in the developing countries. This decline has contributed to increasing longevity. Greater health consciousness and self-care, improved social security for the elderly and disabled and vulnerable adults, and advances in medical care have contributed to this phenomenon.

In the early 1980s, a dramatic new epidemiological challenge appeared with the advent of a pandemic of HIV infection and a return of diseases thought to have been under control. Potentially dangerous infectious diseases can be transmitted far from their original habitat with the rapid transportation and movement of populations, including migrants, tourists, and other travelers around the globe. Other infectious diseases are becoming resistant to available treatments, and multidrug-resistant (MDR) infectious diseases, especially tuberculosis (TB), are emerging.

TABLE 3.3 Leading Causes of Death Worldwide, 2008

Country Groupings	World Total		Low-Income Countries		Middle-Income Countries		High-Income Countries	
Diseases	Deaths (millions)	Deaths (% total)	Deaths (millions)	Deaths (% total)	Deaths (millions)	Deaths (% total)	Deaths (millions)	Deaths (% total)
Ischemic heart disease	7.25	12.8	0.57	6.1	5.27	13.7	1.42	15.6
Stroke and other cardiovascular disease	6.15	10.8	0.45	4.9	4.91	12.8	0.79	8.7
Lower respiratory infections	3.46	6.1	1.05	11.3	2.07	5.4	0.35	3.8
Chronic obstructive pulmonary disease	3.28	5.8	NA	NA	2.79	7.2	0.32	3.5
Diarrheal diseases	2.46	4.3	0.76	8.2	1.68	4.4	NA	NA
HIV/AIDS	1.78	3.1	0.72	7.8	1.03	2.7	NA	NA
Trachea, bronchus, lung cancers	1.39	2.4	NA	NA	NA	NA		
Breast cancer	NA	NA	NA	NA	NA	NA	0.17	1.9
Tuberculosis	1.34	2.4	0.40	4.3	0.93	2.4		
Diabetes mellitus	1.26	2.2	NA	NA	0.87	2.3	0.24	2.6
Road traffic accidents	1.21	2.1	NA	NA	0.94	2.4	NA	NA
Prematurity, low birth weight, birth asphyxia and trauma, neonatal infections	NA	NA	0.81	8.7	NA	NA	NA	NA
Alzheimer's and dementias	NA	NA	NA	NA	NA	NA	0.37	4.1
Hypertensive heart disease	NA	NA	NA	NA	0.83	2.2	0.21	2.3

Note: HIV = human immunodeficiency virus; AIDS = acquired immunodeficiency syndrome; NA = not indicated.
Source: World Health Organization. The top 10 causes of death. Fact sheet no. 310 [updated June 2011]. Geneva: WHO. Available at: http://www.who.int/mediacentre/factsheets/fs310/en/index.html [Accessed 8 January 2013].

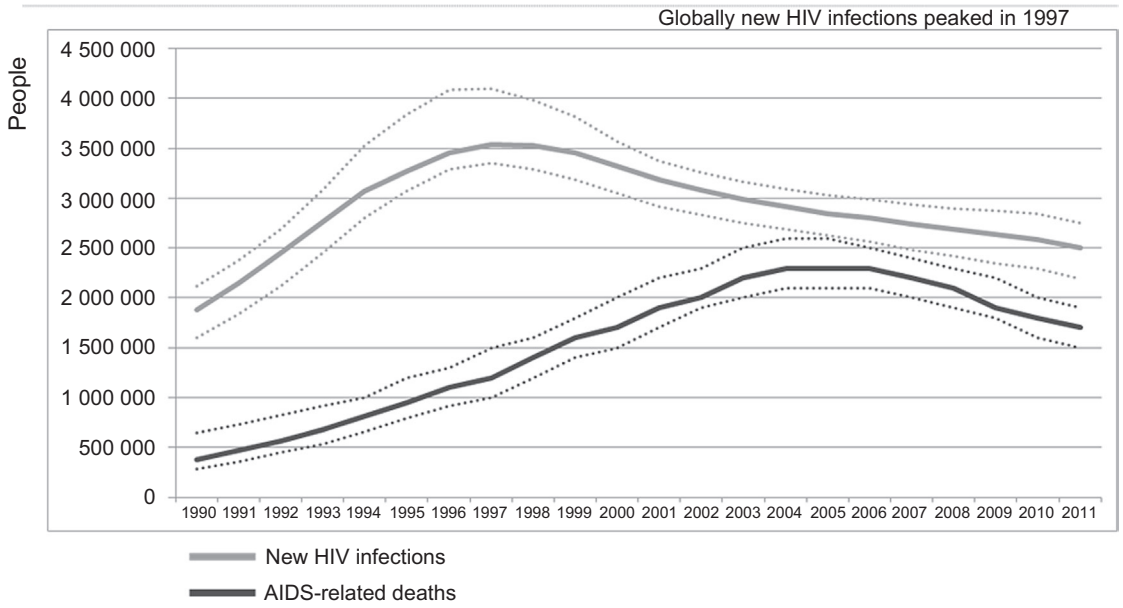

FIGURE 3.8 Global new HIV infections and AIDS-related deaths. *Source: World Health Organization. Core slides HIV/AIDS, 2012. Available at: http://www.who.int/hiv/data/en/ [Accessed 4 January 2013].*

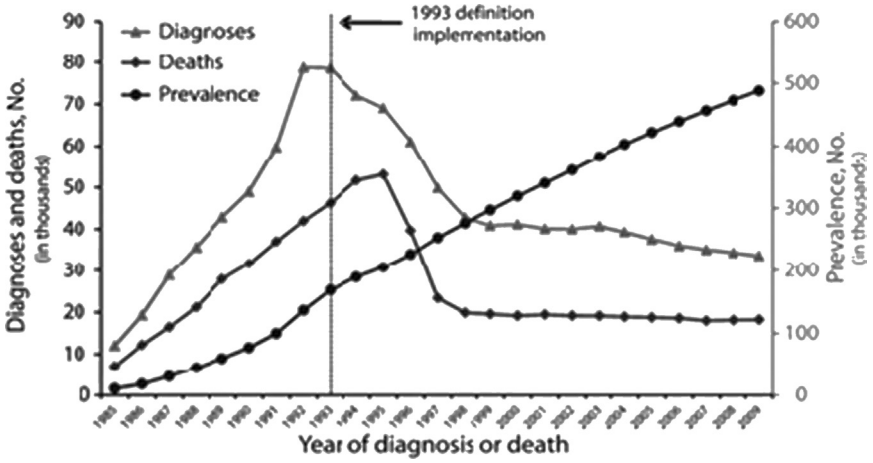

FIGURE 3.9 AIDS diagnoses, deaths and people living with AIDS, USA, 1985–2009. *Source: Centers for Disease Control and Prevention. HIV surveillance report. Diagnoses of HIV infection and AIDS in the USA and dependent areas, 2008, Vol. 20. Available at: http://www.cdc.gov/hiv/topics/surveillance/resources/slides/trends/index.htm [Accessed 3 January 2012].*

The HIV/AIDS epidemic (see Chapter 4) created a new and deadly situation with a worldwide pandemic. The epidemic rose to vast proportions in the 1990s but appears to have peaked and fallen since 2000, although it is still spreading in Central and Eastern Europe. Globally, 34 million people are living with HIV, including 3.3 million children, and 1.7 million people died of AIDS-related illnesses in 2011 (Figure 3.8). There are an estimated 2.5 million new infections globally per year, but this is a reduction of over 20 percent since 2001. Antiretroviral therapy (ART) is holding down the epidemic through treatment and preventing further spread. Progress in reducing maternal–infant HIV transmission by ART drugs, now used widely in Africa by international donor agencies, has been a very impressive achievement. This experience gives cause for cautious optimism, but economic recession may slow this process.

The transmission of HIV is still high among some groups in the USA (see Chapter 4), where the number of people living with HIV is estimated at 1.1 million. Most transmission is via male-to-male sexual contact. An estimated 20 percent of infected people are undiagnosed and therefore not in treatment and still transmitting the diseases (Figure 3.9). In countries of Eastern Europe and the former Soviet Union, the disease is still primarily among intravenous drug users and the official agencies are not actively promoting ART or other control measures, so the epidemic has yet to run its course.

Partial control of the spread of HIV was achieved in the industrialized countries through scientific achievements and the application of public health measures. AIDS has had enormous effects on the need for trained infectious disease clinicians, epidemiologists, and virologists to provide the care and to carry out the monitoring and research that will be needed to control this devastating pandemic. Hope for a vaccine is still unfulfilled but trial and error have produced a promising start to control with education, condom use, circumcision, and the revolutionary ART that has saved so many lives. This work has involved partnerships and cooperative activities among governments, international organizations, bilateral aid agencies, non-governmental organizations (NGOs), and private agencies to establish screening, education, risk-reduction programs, prophylaxis, and treatment with ART to improve clinical care and prevent transmission of the virus.

"Newly emerging" diseases are a notable threat to the gains made in the health status of the industrialized world, and an even greater threat to the struggling health systems of developing countries (see Chapters 4 and 16). However, the chief threat to the public's health remains the massive deprivation in developing countries and poverty still present in the industrialized countries. Newly emerging diseases present a growing challenge to public health, with new disease entities (AIDS, Ebola, SARS, avian influenza, H1N1) along with renewed threats from diseases present for centuries, and multi-drug resistant (MDR) cases of TB, methicillin-resistant *Staphylococcus aureus* (MRSA), and others from abuse of antibiotics and molecular shifts in the organisms. Even diseases thought to have been brought under control by vaccines, such as pertussis and measles, have reappeared in imported and localized epidemic forms.

In the 1990s, there were new breakthroughs in the epidemiology of infections causing highly prevalent chronic diseases. A new infectious agent, the prion, was identified by Stanley Pruziner (Nobel Prize 1997) as transmitting Creutzfeld–Jakob disease, a serious degenerative and fatal neurological disorder. This experience resulted in a closer relationship between veterinary public health and those with responsibility for a variety of agricultural products used for animals. This aspect of veterinary public health is coming into greater focus. A new bacterium first identified in the 1980s, *Helicobacter pylori*, was shown to be the cause of peptic ulcers and cancer of the stomach (B. J. Marshall and J. R. Warren, Nobel Prize 2005). The previously known relationship of hepatitis B to cancer of the liver and chronic cirrhosis took on new importance as an effective and inexpensive vaccine became available. Furthermore, nutritional deficiencies were found to be cofactors in a variety of diseases.

In the first years of the twenty-first century, human papillomavirus (HPV), a sexually transmitted virus, was identified as the cause of cancer of the cervix. An effective vaccine was approved in the USA by the Food and Drug Administration (FDA) in 2006 and is already being used in the industrialized countries, but is too costly for developing countries where it is most needed. It provides the means to control and possibly eliminate one of the leading causes of cancer in women worldwide, but will need to be used along with Papanicolaou (Pap) smear screening for many years to come.

Such breakthroughs in medical science and public health practice demonstrate the vital importance of combining epidemiological and clinical investigations to confirm these relationships and to seek out preventive mechanisms.

SOCIAL EPIDEMIOLOGY

Epidemiology has evolved from its origins as a factor in sanitary statistics in the first half of the nineteenth century, as exemplified in the political arithmetic and vital statistics of Farr and the social statistics of Chadwick and Shattuck. It helped to foster the sanitary movement and public health benefits through the development of drains, sewage systems, and community sanitation. In the late nineteenth century through the first half of the twentieth century, epidemiology was associated with the germ theory of single agents relating to one specific disease, and public health activities focused on interruption of transmission or primary prevention through vaccinations. In the latter half of the twentieth century, chronic disease epidemiology showed associations among multiple risk factors and outcomes, without full understanding of the intervening factors or pathogenesis. Some landmarks of epidemiology are shown in Table 3.4. They are further discussed in Chapters 1, 4, 5, 8, and 13.

Chronic disease epidemiology led to health promotion as a key approach in risk-control public health measures, affecting lifestyle (diet, exercise, smoking), products (food, guns, cars), and environment (pollution, passive smoking). A new era of epidemiology is emerging in the twenty-first century in which organization, information, and application of biomedical technology are vital in population health. A wider, multidisciplinary approach is taken, in which statisticians, economists, social scientists, health systems managers, and epidemiologists bring different skills to a more complex paradigm of public health.

Social inequalities in morbidity and mortality have been a major field of interest in epidemiological studies for many years. A study of late-stage diagnosis of colorectal cancer in New York State showed that women and African Americans were more likely to have late-stage cancer than men and whites. Individuals living in areas of low SES were significantly more likely to be diagnosed at a later stage than those living in higher SES areas. Similar patterns of socioeconomic disparity in mortality have been shown among men in the state of São Paulo, Brazil, with the poor having three times greater rates of mortality than the wealthy minority. In the UK, regional differences in mortality patterns are closely linked to socioeconomic conditions, with poverty

TABLE 3.4 Selected Landmarks in Epidemiology

	Vital Statistics and Social Epidemiology		Non-Infectious Disease Epidemiology
1662	Graunt publishes *Natural and Political Observations Made upon the Bills of Mortality*	1747	Lind demonstrates prevention of scurvy by citrus fruits
1836	Registrar General's Office established by UK Parliament	1775	Pott shows high rate cancer of scrotum in chimney sweeps
1842	Chadwick: *Report on the Sanitary Condition of the Labouring Population of Great Britain*	1914	Goldberger demonstrates nutritional cause of pellagra
1848	Virchow: "medicine is a social science"	1950	Doll and Hill relate cigarette smoking to lung cancer
1858	Simon maps mortality by district in relation to social and environmental conditions	1954	Framingham study reports on heart disease risk factors
1974	LaLonde: *New Perspectives on the Health of Canadians* – lifestyle, genetics, environment, and medical care key health factors	1960s	US Surgeon General's Report on Smoking and Health. Decreasing mortality from cardiovascular diseases, trauma
1982	Black Report: social class differences in mortality in the UK	1980s	Infections as causes of chronic diseases; *Helicobacter pylori* causing peptic ulcers and cancer of stomach
1986	Ottawa Charter on Health Promotion	1980s	Advances in cardiovascular epidemiology and successful preventive and treatment interventions
1995	Beijing Conference on Women, empowerment for health of women and children	1990s	Vaccines for hepatitis B to prevent cancer of liver. Health promotion plays increasing role in public health
2001	UN Millennium Development Goals (MDGs) and Human Development Index (HDI)	2006	Human papillomavirus vaccines to prevent cancer of cervix
	Infectious Disease Epidemiology		**Health Policy Epidemiology**
1796	Jenner uses cowpox to vaccinate against smallpox	1883	Bismarck initiates workers' compensation and national health insurance
1854	Snow identifies and interrupts water transmission of cholera in London	1917	Semashko establishes Soviet state health system
1882	Koch discovers tubercle bacillus and cholera. Koch–Henle postulates on causation of disease	1948	UK establishes National Health Service
1920–2000	Sanitation, vaccines and antibiotics control many infectious diseases	1961	Canada's provincial Medicare plans advance
1980	Eradication of smallpox declared achieved (WHO)	1965	US Medicare and Medicaid amendments to Social Security Act of 1935
1980s	HIV and other newly emerging or resurging infectious diseases	1978	Declaration on Alma-Ata and Health for All 2000
1990s	Vaccines for hepatitis B prevent cancer of liver	1979	US Surgeon General: Health People, health targets
2000s	Antiretroviral therapy for HIV is a dramatic success. Progress in elimination of yaws, poliomyelitis, leprosy, dracunculiasis, measles, mumps, and rubella being achieved	1990s	Health promotion plays central role in HIV management, tobacco control, CVD risk factor reduction
2000s	Terrorism, potential bioterrorism	1990s	Managed care expansion in the USA
2000s	SARS, avian flu, multidrug-resistant organisms. Control of *Helicobacter pylori*, chronic peptic ulcer disease and cancer of stomach	2000s	Health reforms in Central and Eastern Europe, Commonwealth of Independent States, central Asia, and emerging developing countries
2007–2012	H1N1 avian influenza spread and threatened pandemic	2008	Recession in USA and Europe
2010–2013	Measles epidemic in Europe; diphtheria and pertussis return in USA, Canada, and Europe	2010	Affordable Care Act in USA ("Obamacare") to add millions of Americans to health insurance; reforms in health care

Note: See Chapter 1 timeline.
Source: Adapted from Susser M, Susser E. Choosing a future for epidemiology: eras and paradigms. Am J Public Health 1996;86:668–73.

and its associated conditions as key variables despite universal access to the National Health Service (NHS). In contrast, a study in Denmark of regional and social class variation in relative risk of death showed little social variation except for people with no known address. Social inequities in health occur in virtually all societies, even those with "universal" access to health care, including the USA, the UK, Israel, and many others, with differences in physical access to care; differences in lifestyle and risk factors; socioeconomic conditions, and knowledge, attitudes, and practices related to health and health care.

Social epidemiology in some senses reflects the nineteenth-century traditions of Virchow, Chadwick, Shattuck, and Farr (see Chapter 1), and a return to the "miasma theory" of disease, in which health of populations is largely determined by environmental factors of society, and that to understand causation of disease it is essential to understand its historical and social context. This social epidemiology necessarily incorporates qualitative methodologies based on the social sciences in addition to the quantitative epidemiological tools of measuring associations between exposure and disease in individuals or groups. The New Public Health integrates the qualitative and quantitative methods with management sciences based on successful applications of all these modalities to public health issues over the past century and more.

EPIDEMIOLOGY IN BUILDING HEALTH POLICY

Epidemiology, originally seen as the study of epidemics, evolved rapidly in the latter part of the nineteenth century with the growth of bacteriology and the physical sciences. "Epidemiology burgeoned as an increasingly rigorous science based on observation, inference, and experimentation, and around the middle of the twentieth century with development of methods, notably case control and cohort studies to investigate non-communicable diseases such as coronary heart disease and cancer, and randomized control trials to evaluate therapeutic and preventive regimens aimed at control of the conditions" (Last, 2007) (see Chapter 5).

Empirical documentation increased in Europe in the middle of the nineteenth century, concerning health, disease, and mortality, in the form of death certificates and mortality registers. The most influential events in establishing infectious disease epidemiology were the discovery by Edward Jenner in 1797 that vaccination with cowpox could prevent smallpox, Peter Panum's description of the spread of a measles epidemic in the Faroe Islands in 1846, and John Snow's and William Farr's successful analyses of the London cholera epidemic of the 1850s. James Lind's classic case-controlled experiment showing the nutritional cause of scurvy in 1847 opened up the field of nutritional epidemiology; and the work of Edwin Chadwick and William Farr concerning social inequity in mortality and on classification of causes of death initiated social epidemiology. Farr observed that "Hunger destroys a much higher proportion than is indicated by the registers in this and every other country, but its effects, like the effects if excess, are generally manifested indirectly in the production of disease of various kinds" (Whitehead, 2000). Ramazzini's work in occupational health and Percivall Pott's identification of cancer of the scrotum among chimney sweeps opened up new areas of epidemiological investigation. Ignaz Semmelweis improved maternal health by documenting the causes of high neonatal mortality in a maternity ward, identifying a lack of hand washing by medical doctors as the culprit. These pioneers set the stage for infectious disease, NCD, occupational, women's health, maternity, and social epidemiology (see Chapter 1).

Until a few decades ago, epidemiology was considered the dominating, central discipline of public health. The 1980s and 1990s brought increasing acknowledgement that public health epidemiology – with the probability concept – must interact with qualitative methodology, and public health must integrate a variety of disciplines, including sociology, social psychology, health economics, environmental health, systems analysis, and political science. Selected landmarks in the development of epidemiology from the early twentieth century are highlighted in Table 3.4.

Epidemiology proved itself in enormously successful interventions for public health in the first half of the nineteenth century. The golden period of infectious disease epidemiology in the late nineteenth and first half of the twentieth centuries established the basis for control of communicable disease, a revolution still in process. During the mid-twentieth century, the development of non-infectious epidemiology and social epidemiology provided the basis for health promotion and lifestyle changes contributing to reduced morbidity and mortality from CVD and the potential for control of cancer, trauma, and other non-communicable conditions. In the case of HIV/AIDS, health promotion was the only tool available until the antiretroviral drugs became available, but the hoped-for vaccine is still in the future. There is an important role for controlled trials for preventive modalities and treatment in relation to chronic disease (mammography, hormone therapy, and many others). Highlights of the development of modern epidemiological methods are discussed in Box 3.6.

The fundamentals of epidemiology are as vital for the student of health sciences as are the study of bacteriology, biochemistry, or surgery. It is equally important that health planners, economists, and others concerned with the policy aspects of health be conversant with epidemiology. This is so that they understand the need to adapt health services to changes occurring in the epidemiological and technological aspects in health and in society, as well as the application of data from studies to the changing needs for health care.

David Sackett, one of the founders of evidence-based medicine (EBM), defined it as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients". Medical students and students in medically related programs must be

BOX 3.6 Highlights of the Development of Modern Epidemiological Methods

Early twentieth century theoretical developments of epidemiology included contributions of Ronald Fisher and others from the 1920s onwards creating the foundations for modern statistical science. Multivariate analysis methods enabled epidemiological concurrent analysis of various potential health risk factors. Karl Popper's work on the logic of scientific discovery, published in German in the 1930s, reached wide recognition after publication in English in 1959. It provided a philosophical theory of science and a basis for academic epidemiology.

Since the mid-twentieth century, epidemiological activity has grown gradually and substantially, so that today's epidemiological research production is breathtaking compared to the situation just a few decades ago. Cancer, tuberculosis, birth defect, and heart and other disease registries have been developed, which are the data basis for epidemiological analysis. Population cohorts were established and followed for years. Cancer and cardiovascular epidemiology developed to become major fields. The etiologies of most large disease categories were a productive sphere of epidemiological methods, including mental disease prevalence studies (see Chapters 4–9).

An early breakthrough in modern epidemiology was the 1954 publication of the British Doctors' study by Doll and Hill, showing a strong association between smoking and lung cancer. In the first part of the 1980s, the interaction between developments in immunology and developments in epidemiological methods and in biostatistics resulted in the identification of HIV as the infectious cause of AIDS.

Major theoretical, methodological, practical, and organizational developments have taken place in the last half-century. In 1960, MacMahon, Pugh, and Ipsen published their groundbreaking theory, the "Web of Causation", moving epidemiology from monocausality to multicausality, so that it came work with other sciences in etiological studies. In 1964, Bradford Hill published his 10 criteria for causality. Increasing development of the logical foundation of epidemiological designs, as well as theoretical development, included more precise and consistent validity and bias concepts, such as:

- cohort designs ("prospective"), fixed and open, dynamic
- case–control ("retrospective"), case–referent, case–base designs
- quasi-experimental designs
- experimental designs and randomized controlled population experiments, inspired by the work of Cochrane.

Interaction between the development of theory, principles and methods in epidemiology and biostatistics increased, especially from the 1970s onwards. Discriminant analysis and other types of discrete analysis of central importance for epidemiological thought and documentation were developed, e.g., multiple logistic regression, multilevel logistic regression, Cox regression, Poisson regression, longitudinal analysis, structured equation modeling, Markov chains and processes, and multidimensional methods for forecasting.

Clinical epidemiology developed as a discipline in the last part of the twentieth century, applying population-epidemiological methods to patient populations. Modern technology opens new perspectives in epidemiology, including genetic epidemiology, with the use of disease, occupation, and population registries linking individual data on health and health services consumption with social conditions (e.g., education, occupation, employment, and family structure), economy, and residence. With lifelong follow-up, this makes possible large-scale, multidimensional, observational population (and patient) studies, which are suitable for the study of rare diseases – as well as quasi-experimental estimation of effects of structural and dynamic interventions in health systems and other systems.

The World Health Organization pioneered multiple-country databases, such as WHO Europe's Health for All Database (HFA-DB), publicly accessible on the Internet, which includes major health indicators for European countries since the 1970s. Such databases are vital tools for education and policy analysis to inform national and international health policies.

Sources: *Foldspang A, Aarhus University. Personal communication.*
Saracci R. Introducing the history of epidemiology. Chapter 1. In: Olsen J, Saracci R, Trichopoulos D, editors. Teaching epidemiology. Oxford: Oxford University Press; 2010.
Fisher R. Statistical methods for research workers. Edinburgh: Oliver and Boyd; 1925.
Popper KR. The logic of scientific discovery. London: Hutchinson & Co.; 1959.
Doll R, Hill AB. Lung cancer and other causes of death in relation to smoking; a second report on the mortality of British doctors. BMJ 1956;ii:1071–81.
Pugh B, Ipsen TF, MacMahon H. Epidemiologic methods. Boston, MA: Little, Brown & Company; 1960.
Bradford Hill A. The environment and disease: association or causation? Proc R Soc Med 1965;58:295–300.

exposed to the sources of evidence and therefore require grounding in search techniques, medical databases, and the structure and function of the medical library (both the physical and the virtual entities).

Medical and public health decision-making requires skills in communication, information retrieval, and formulating and answering focused clinical questions. Medical students need increasing exposure to the principles of EBM and methodological training in epidemiology and biostatistics in order to cope with the explosion of medical information and to appraise, interpret, and perform clinical investigations and research. The principles applied to teaching these subjects to medical students, and to students in Master's programs who will pursue careers in public health or clinical research are outlined in Box 3.7.

The combination of a Doctor of Medicine (MD) with a Master of Public Health (MPH) program as a joint degree is becoming more widespread as a means of educating future physicians towards applying public health principles to clinical work and research. The core curriculum for MPH programs is discussed in Chapter 14. Sound methodological training provides the basis of evidence-based public health practice,

BOX 3.7 Syllabus in Epidemiology, Clinical Epidemiology and Biostatistics for Medical Schools and Master's Degree Students

Medical School Education

- Measures of disease frequency, morbidity, and mortality
- Rates and standardization
- Morbidity and mortality
- Research design I: Cohort studies
- Measures of association
- Statistical inference
- Research design II: Case–control studies
- Sample size
- Occupational and environmental epidemiology
- Clinical trials
- Analysis of clinical trials (multivariate models)
- Survival analysis
- Diagnostic tests
- Screening
- Meta-analysis
- Evidence-based medicine
- Causal and non-causal associations; bias in research
- Preventive medicine
- Workshop in preventive medicine (e.g., smoking cessation)
- Small group critical appraisal sessions: prognosis; therapy; prevention
- Final written examination: short answers, multiple choice based on lectures and journal articles

Master's in Clinical Epidemiology

- Basic courses: as in column 1
- Principles and uses of epidemiology
- Survey methods
- Basic statistics
- Interpretation of epidemiological data
- Statistical analysis of rate and proportions
- Clinical trials
- Logistic regression
- Survival analysis
- Seminar in clinical epidemiology
- Health economics and economic assessments
- Advanced topics in epidemiology
- Examinations
- Thesis

Sources: *Paltiel O, Hebrew University; Brezis M, Hadassah Hospital; Cohen MJ, Hadassah Medical Center, Jerusalem. Personal communication. Sackett DL, Strauss SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-based medicine. How to practice and teach EBM. 2nd ed. London: Churchill Livingstone; 2000.*
Paltiel O, Brezis M, Lahad M. The principles for planning the teaching of evidence-based medicine/clinical epidemiology in an MPH and for medical students. Public Health Rev 2002;30:261–70.

in health promotion or health administration and its application in clinical medicine. Life-long learning provides essential knowledge for scientific reasoning, and the ability to evaluate the literature critically, skills essential for physicians and other health workers to analyze and incorporate new information.

Epidemiology and demography are necessary, but not sufficient alone, for the determination of health policy. Other factors include the funds, human resources, and facilities availability, and their utilization, community attitudes, and political will. Epidemiology, health care financing, and resource allocation relate to supply and demand, and ultimately to policy. These are all issues of great importance to the management of health systems and addressing the changing needs of an aging population with growing obesity, diabetes, and other chronic diseases, while infectious diseases continue to play an important role in population health. They are also of importance in addressing issues of inequalities in health even in countries with universal access through national health insurance. In the USA, without universal health insurance, a serious gap in social policy has many downstream effects perpetuating social and ethnic disparities in health.

The multidisciplinarity of epidemiology is also essential to the formulation of policy and operation of health systems. It is essential for the smooth functioning of a health system, as a method of analysis, and as a monitoring tool. Assessment and monitoring of the health status of a population are, by their very nature, multifactorial. Preliminary and, perhaps, impressionistic reading of the situation makes use of data available from routine sources and serves to generate hypotheses for testing. Evaluation is a more formal and systematic approach in determining the quality of the health of a population as objectively as possible. All evaluations need to look at the input, process, and output of a system. The epidemiological method is applied to measurements (indicators) of inputs (resources) of a health system, the process (manner) of their utilization, and outcomes of care (indicators of morbidity, mortality, or functional status of a population).

Analysis of these complex factors provides the intelligence or feedback for managing the broad scope of public health. The New Public Health integrates assessment, evaluation, and epidemiological analysis with the organization, supply of health care, and other factors relating to the health of the community as a whole. These disciplines provide vital material to link population health needs and the use of resources.

Epidemiology is addressing new challenges of social equity in health; this has become an important part of modern epidemiology with the growing understanding that social conditions and cultural background are key factors not only in disease incidence and prevalence, but in access to health care, both preventive and curative. While the epidemiological identification of health inequality/inequity has been important in identifying the extent and severity of the issues, it is in the utilization of these data in policy making and action where the real challenge lies. Gender, sexual preference and behavior, ethnicity, place of residence, income, family status, religion and religiosity, social connectivity, occupation, and education are all part of the health–sickness spectrum.

DEFINITIONS AND METHODS OF EPIDEMIOLOGY

Rates and Ratios

Measuring the extent of a disease (or risk factor) in a population relates known cases to a population base, and is expressed as a rate or a risk. These rates can be standardized for age and gender for comparisons (see below). Comparing the extent of a disease or a risk factor among population groups can be expressed as a ratio (or a relative risk). The *risk group* may be the entire population defined by a geographic area, an occupational group, a school, a health service, an insurance system, or any other specified groups of people such as defined by occupation, place of work, or lifestyle. The population may also be people who share a risk factor for disease, such as smokers, substance abusers, sex workers, or people attending a celebration who eat certain foods that may be the common source of a disease outbreak.

Incidence of a disease is a measure of the new events or cases which can be stated as numbers or as rates. *Prevalence* is the term used for new and pre-existing cases of a specific condition. The denominator is a fixed population about which information is available on the condition under study for each individual within that population. Identification of cumulative case incidence and prevalence may be complex, with people entering and leaving the study population (representing the denominator), but risks may be estimated.

Rates indicate the occurrence of a phenomenon, such as the occurrence of a health event, in a defined population, in a given period. The components of a rate are the numerator (A) defining the number of cases of a specified condition, over the denominator (B) defining in a specified time-frame in which the events occurred in a defined population, place, region, or country. A multiplier to convert the fraction to a decimal number may be used for convenient comparisons between the frequencies of the event in different population groups.

Crude rates are summary rates based on the actual number of events (e.g., births or deaths) reported in a total population in a given period. Cause-specific rates measure specified conditions (e.g., TB) occurring in the total population or in a designated population group (e.g., age–gender groups) in a specified period. The population used for annual rate calculations is usually estimated at 1 July of that year or may use an average for the entire year.

Cumulative incidence of reported cases of the disease under study that occur in a defined population group may be followed over a period of time to allow the identification of incidence of new cases, such as in mesothelioma among a group of people exposed to asbestos at work or in the community (Box 3.8).

Rates may be crude or specified by age, gender, or other characteristics. Ways of computing them are identical in principle. Furthermore, rates may be compared between two or more populations or population groups, using classical tools of the two techniques of standardization. There are many other ways of comparing rates, such as performing multivariate regression for discrete data (e.g., logistic regression).

Defining the population at risk is a crucial aspect of any epidemiological study and is subject to common errors. Defining the number of cases of a disease or the risk factors being studied is essential to provide the numerator of the rate or ratio. This is also difficult because not all cases of a disease may be reported at the same time or at all. Outreach may be needed to contact exposed people who do not report ill, such as passengers on an aircraft in which a person with a serious infectious disease (e.g., drug-resistant TB, measles, or Ebola virus) may have traveled.

The numerator may be an underestimation of the true value in the population. This problem can occur with common infectious diseases (e.g., mumps, rubella) or where many cases of disease are not clinically diagnosed and therefore go unreported. The same applies in chronic diseases (e.g., hypertension or diabetes mellitus) for many reasons, including non-presentation to the medical system of asymptomatic cases, unclear case definition, and medical error. There may be discrepancies in reporting, such as in coronary heart disease where symptoms differ quite significantly between men and women, or when access to care varies between people in different socioeconomic groups.

A *proportion* is a ratio where the numerator is included in the denominator population, such as describing the number of cases found in a given population, or the proportion of people with a certain attribute or risk factor within the defined population; for example, the proportion of smokers within a certain community.

When cases are relatively rare, an approximation can be made using the total population (including both the disease free and the cases) as the numerator. In such conditions, the odds ratio may serve as a good estimate of the relative risk.

Measures of Disease Occurrence or Morbidity

A measure of disease occurrence or morbidity is a departure, subjective or objective, from a state of physiological and psychological well-being or normal function. It can be measured as the number of people who are ill, periods or spells of illness, or duration of illnesses (days, weeks, months). Morbidity is also described in terms of frequency or severity, including indicators of deaths, disease, disability, and risk factors related to health outcomes. Disability or incapacity rates measure the extent of long-term reduction of a person's capacity to function in society. These measures are also related to disability-adjusted life years (DALYs) and quality-adjusted life years (QALYs) combining morbidity, impact on longevity, and quality of life or disability (see Chapter 11) (Box 3.9).

BOX 3.8 Commonly Used Mortality Rates and Ratios

- *Crude death rate* (CDR) – the number of deaths from all or a specific cause (*A*) per 1000 population (*B*) in a given year = *A*/(*B* × 1000) (total deaths/average population × 1000, or per 10,000).
- *Age-specific mortality rate* – the number of deaths of people in the specified age group per 1000 live population in that age group over a period of time, usually a year for all causes or for specific causes.
- *Cause-specific mortality rate* – the number of deaths from a specific cause per 100,000 live population (estimated on 1 July of the given year); e.g., annual number of deaths from lung cancer in a given year = 400 in a population of 1 million = 400/1,000,000 = 40 lung cancer deaths per 100,000 population.
- *Case fatality rate* (CFR) – The number of deaths from a specified cause during a given period over the number of diagnosed cases of that disease during the same period × 100; e.g., 10 deaths from measles among 5000 cases is a CFR of (10/5000) × 100 = 0.2%.
- *Proportional mortality rate* (PMR) (for a specific cause) – the number of deaths from that cause in a specified period over the total number of deaths in that population in the same period × 100; e.g., 25 deaths from motor vehicle accidents/1000 total deaths from all causes × 100 = 2.5% (the denominator includes the numerator).
- *Standardized mortality rate or ratio* (SMR) – the ratio of the number of deaths from a specified condition observed in a study population over the number that would be expected if the study population had the same specific rates as the standard population × 100. There is both indirect standardization and direct standardization.
- *Risk* – the measure of estimated probability that an event will occur. Analysis of risk is based on review of the evidence related to a particular risk or group of risks; this may be due to an agent, e.g., toxic, biological, radiological, nutritional (deficiency or excess), behavioral (smoking, risk taking, lack of exercise), stress, alcohol and drug abuse, social deprivation, and others.
- *Hazard identification and quantification* – to determine the extent or degree of exposure of the exposed population to a toxin, carcinogens, air pollutants, alcohol and drug abuse, driving habits, gun exposure, and other risk factors.
- *Relative risk* or *risk ratio* (RR) – the ratio of the risk of a disease (or death or other exposure outcome) among those exposed to the agent or risk factor relative to those not exposed; RR also defined as relative cumulative incidence rate among those exposed to the same cumulative incidence among the non-exposed; in analysis of results in a case–control study this is often expressed as the *odds ratio* (OR).
- *Risk characterization* – to quantify exposure, dose–effect, and dose–response relationships.
- *Risk estimation* – to assemble the relevant data, to define the risk level of the exposed population, leading to quantification of the estimate of the numbers in the population at risk to be affected by the exposure.

Source: *Modified from Last JM, editor. A dictionary of public health. New York: Oxford University Press; 2007.*

Morbidity data are derived from reported communicable diseases or chronic, genetic, and other conditions for which there are established, recognized reporting systems and registries, which are usually operated by ministries or departments of health for the population of their jurisdiction. Databases are provided for monitoring and providing direction for etiological studies and for priorities and avenues for intervention to control the spread of disease. Morbidity is measured by incidence and prevalence rates, as well as severity and duration, although these are not usually available on routine reporting and may require special investigation. Incidence is more useful for acute conditions, whereas prevalence is more important in measuring chronic disease and assessing the long-term impact of a disease.

Latency is the period between exposure to a disease-causing agent and the appearance or manifestation of the disease. For an infectious disease, it is called the *incubation period*. A disease may appear clinically days, weeks, months, or even years after exposure to the causative agent, whether it is microbiological, toxic, carcinogenic, or traumatic.

An attack rate is a specific incidence rate expressed as the percentage of the exposed population suffering from the disease. When the population is at risk for a limited period, such as during an epidemic, the study period can readily encompass the entire epidemic. The attack rate gives a measure of the extent of the epidemic and may provide information needed to control it. For example, if an epidemic of measles spreads from the initial, or index, cases with an increasing attack rate among the exposed population, a change in vaccination tactics and control measures may be needed in order to avoid rapid spread to other vulnerable groups.

Incidence rates measure the frequency of health-related events in a certain population during a specified period. The denominator for incidence rates is defined as the "population at risk", in which the studied events may occur. For example, the incidence rate for breast cancer in a certain region will be the number of new cases diagnosed over a 1-year period, divided by the total number of women in that region. An attack rate is the cumulative incidence of infectious cases in a group, observed over a period during an epidemic, either by identification of cases or by seroepidemiology (Last, 2001).

BOX 3.9 Measures of Frequency of Disease in a Population

$$Rate = \frac{Number\ of\ cases\ in\ a\ given\ time\ period}{Population\ at\ risk\ in\ the\ same\ time\ period} \times N^{th}$$

where N^{th} = 100, 1000, 10,000, 100,000, or 1,000,000; Period: usually = 1 year; Population: mid-year (1 July) estimate.

- *Incidence rate* – the rate at which new health-related events occur in a population. The numerator is the number of new events occurring in a defined period (usually 1 year); the denominator is the population at risk of experiencing the event during this period.
- *Prevalence* – the total number of all individuals who have an attribute or a given disease or condition at a point in time or a designated period. The *prevalence rate* (or rather the *prevalence proportion*) is the number of individuals with the attribute divided by the population at risk, at that point in time (*point prevalence*). Period prevalence usually is defined as the sum of (a) the point prevalence at the beginning of the period, plus (b) the cumulative incidence during the period.
- *Attack rate* – the cumulative number of cases of a specified disease among the population known to be exposed to that disease over a defined period.

Source: *Modified from Last JM, editor. A dictionary of public health. New York: Oxford University Press; 2007.*

There are several ways to define the denominator for incidence rates:

- *Ordinary incidence rate* is used when calculating incidence rates in a changing population; for instance, where there is a natural movement in and out of the studied population (due to births, deaths, and migration). In that case, the average size of the population in the specified period is used as the denominator, usually including both the "population at risk" and cases already with the disease (prevalence). Although only the "population at risk" should theoretically be included, such an approximation is often made. The reason for this is that when the condition is relatively rare, the influence that prevalence cases will have over the denominator can be considered negligible. In addition, the information about prevalence cases is often not available.
- *Cumulative incidence rate* is usually calculated in longitudinal epidemiological studies. When a cohort (a group of people), initially free from the disease, is being followed during a certain period, incidence cases can be identified as they occur. The sum of those incidence cases is referred to as "cumulative incidence". Here, the denominator includes only the "population at risk"; therefore, cumulative incidence may also be termed risk of the condition (Abramson, 2001).
- *Person–time incidence rate or incidence density* is usually used in follow-up studies in which individuals are "at risk" or may be followed up during different periods. In this case, the total number of events is divided by the sum of all subjects' periods at risk, measured, for example, in years, months, or days. In order to calculate the denominator, each individual's "period at risk" must be calculated, measuring the time from the beginning of the follow-up until withdrawal from the study (due to either occurrence of the condition under study, or "censoring"; i.e., any other reason causing cessation of follow-up).

Prevalence Rates

Unlike incidence (indication of occurrence), prevalence is the measure of the total existing situation of a health-related condition or risk factor, including old and new cases. A prevalence rate measures the proportion of individuals having that condition within a defined population group at or during a specified time. Several measures of prevalence rates exist:

- *Point prevalence* – the proportion of people with the condition being studied at a certain point in time is divided by the size of the group or population. Point prevalence is influenced by the incidence rate of the condition, as well as its mean duration up to death or recovery.
- *Period prevalence* – the proportion of people who developed the condition before and during the specified period. The denominator includes all the individuals who have or had the condition during the defined period, including those who left, died, or recovered during that period. It allows comparison over time with the same or other population groups. Thus, morbidity from a specific condition during one year can be compared to previous years, weeks, or months, and between countries or regions in a country.
- *Lifetime prevalence* – the proportion of people who have had the condition at any time during their lives; for instance, those who have or had the condition divided by the total population.

The prevalence rate is calculated on the basis of the number of cases and the number of people exposed, and may be compared to the non-exposed population. Estimation of case prevalence in an exposed population may be underreported if insufficient time has elapsed for a disease with a long latency period. An example of period prevalence is the number of cases of cancer among people exposed to a carcinogenic agent in the past; for example, mesothelioma cases occurring in a former asbestos worker population over a 30-year latency period following exposure.

Measures of Mortality

A death rate (mortality rate) is the incidence rate that measures the frequency of deaths over a given period in

a defined population. Mortality rates may be standardized to allow comparability between population groups and may be specific to defined diseases or conditions. Modern epidemiology originated in studies of mortality derived from the Bills of Mortality (publication of deaths by location and cause) in the UK by John Graunt in 1662. Mortality data are based on the mandatory reporting of all deaths (see Chapter 1).

Death certificates are mandatory in most countries and must be signed by a licensed physician before the body can be buried or cremated and before insurance payment or inheritance can occur. The contents of the death certificate are important because the medically certified cause of death is the basis for mortality statistics. Personal data include the age, gender, ethnicity, place of residence, and other variables such as occupation and injury. Completeness of reporting, accuracy of diagnosis, and coding of causes of death may limit the conclusions that can be drawn from such data. In practice, however, the data reported in large disease categories are an acceptable guide to actual events.

Analysis of causes of death may take into account more than one diagnosis so as to determine the underlying causes of death such as diabetes. This seems straightforward, but standardization of reporting causes of death is far from simple. Doctors who fill in the form may vary in their perception of diagnosis and the difference between immediate and underlying cause of death. In developing countries, data from death certificates may not be available and determination of leading causes of death may have to be studied by "verbal autopsies" conducted as part of community surveys.

A standard national death certificate is vital for public health as it provides basic information needed for demographic and epidemiological purposes. Box 3.10 (see companion web site at http://booksite.elsevier.com/9780124157668) presents the data required in a standard death certificate as modified in 2003 in the USA, although the format may vary from country to country.

Causes of death recorded on the death certificate include the immediate cause of death (e.g., cardiac arrest); the second and third lines include contributing conditions (e.g., acute myocardial infarction and congestive heart failure); and the fourth line is the underlying cause (e.g., coronary heart disease). The death certificate is filed with a public registry office and forwarded to a vital records office where the causes of death are recorded by a registrar trained to federal standards to interpret and code medical diagnoses, according to the 10th revision of the International Classification of Diseases (ICD-10), adopted by the World Health Organization (WHO) in 1990.

Overall patterns of mortality are examined by age, gender, and ethnic group, and by cause of death. Mortality trends will be discussed under communicable and non-communicable disease in Chapters 4 and 5. National mortality trends give vital information on disease and changing epidemiological patterns, allowing for regional and international comparisons, and help to define health programs and targets (Box 3.8).

Mortality patterns can be studied in a particular year or over time. A cohort is usually a group of people born in a particular year, but it can be any defined group being followed epidemiologically. Cohorts of people born in particular years can be followed to observe and compare mortality patterns. With suitable age standardization, the mortality patterns of men born, for example, in 1900, 1920, 1940, and 1990 can be compared with each other.

Mortality statistics are fundamental to epidemiology and provide some of the most reliable data available. Epidemiological analysis of mortality data depends on the registration of deaths with basic demographic data and causation of death as recorded by the physician certifying it. Total, age-specific, and gender-specific mortality are usually calculated on an annual basis, with the mid-year population as the denominator. This provides crude, age-specific, cause-specific, and proportional mortality rates from which standardized mortality rates or ratios (SMRs) are calculated. Case fatality rates (CFRs) relate mortality from a cause to the incidence or prevalence of that disease.

Changes in mortality patterns may occur as a result of a number of factors affecting the outcome of a disease, such as changes in socioeconomic conditions, disease prevention, or methods of treatment. Diagnostic criteria or accuracy of death certificates may also change over time. Thus, a change in mortality may reflect a change in incidence of the disease or CFRs related to treatment methods and access to care, or changes in the definition or classification of diseases.

Social Classification

The British Registrar General's Classification of Occupations was established in 1911 and is updated every 10 years (Box 3.11). It is easy to use and provides an excellent demographic and epidemiological tool that has been used in many studies of disease outcomes. It can help to illustrate the different health experiences of the various social classes, even within the universal NHS. It has become part of the database of vital statistics and morbidity patterns in the UK.

Many other classifications are used for research purposes in the UK and in other countries, addressing other issues in social inequality such as unemployment. Other proxy indicators for social class or social inequality include number of siblings, infant and maternal mortality, single parenthood, and many others. The UK uses social indicators of deprivation to classify counties and collate them with health outcome data.

The USA and most other western countries do not have social class data recorded on death certificates and therefore proxy measures of social classification are used, such

BOX 3.11 British Occupational Based Social Class

- Class I – professional and business occupations (e.g., physician, banker)
- Class II – intermediate occupations (e.g., schoolteacher, storekeeper)
- Class III – non-manual occupations (e.g., clerk)
- Class III – manual skilled occupations (e.g., foreman)
- Class IV – partly skilled occupations (e.g., salesperson, factory worker)
- Class V – unskilled occupations (e.g., porter, waiter)

Note: Before 1990 known as the British Registrar General's Classification of Occupations.

Source: *Galobardes B, Shaw M, Lawlor DA, Lynch JW, Smith GD. Indicators of socioeconomic position (part 2). J Epidemiol Community Health 2006;60:95–101. http://dx.doi.org/10.1136/jech.2004.028092 PMCID: PMC2566160. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2566160/ [Accessed 8 January 2013].*

as ethnicity, national origin, education, and poverty levels. In the USA, race is recorded on death certificates and these mortality data can be analyzed by racial groups including Native American or Alaskan Native, Asian or Pacific Islander, Black, Hispanic, and White. Education level and occupation are also recorded, but mortality data are generally presented by racial group, not social indicators.

The interrelationship between ethnicity and disease or mortality often masks other socioeconomic factors, such as higher levels of poverty or reduced access to medical care among African American and Hispanic groups in the USA or immigrant groups in European countries. Because there are wide variations in socioeconomic and educational levels within ethnic or racial groups, and many confounding factors in ethnicity or race that may affect disease patterns, data classified in this way should be interpreted carefully.

Social class is increasingly identified as a major variable in health status. It serves as a proxy measure for many health-related issues, such as nutrition, access to care, and dependence on occupations with hazards, with little opportunity for personal development, or lacking security. Social class variations in health status exist even where universal access health systems are well established, in countries with universal health insurance or services; for example, the UK, Sweden, and Israel. However, social differences are less pronounced in the Nordic countries where social gaps are generally narrower than in countries with less developed social welfare systems. These systems are, however, coming under pressure from immigrant and migrant worker populations, which have become significant both demographically and with regard to health issues.

SENTINEL EVENTS

The US Joint Commission defines a sentinel event as: "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof". The Commission includes a review of organizations' activities in response to sentinel events in its accreditation process, including all full accreditation surveys and random unannounced surveys (Joint Commission, 2013). Health facility errors and adverse events are considered major causes of preventable deaths and high costs to the health system.

Sentinel events include the suicide of a patient who was supposed to be under constant surveillance, unexpected maternal or infant deaths, infant abduction or discharge to the wrong family, rape, hemolytic transfusion reaction due to mismatched blood, surgical deaths, surgery on the wrong patient or wrong body part, or an instrument left in a patient during surgery. They can also include unusual rates of infection, poor surgical outcomes, medication errors, infections occurring in a hospital that may jeopardize patients' health, and many others. Such events occur frequently enough to pose both health risks and an economic burden to the hospital, the insurer, and of course, the patient.

Sentinel events are taken as measures of problems in a health care process. They are events, such as avoidable deaths, which should be uncommon if all goes well with preventive and curative care, and acceptable standards are in place. Avoidable deaths will vary according to the state of health development of a country, and each country may define its own sentinel events for review. The response to such events and preventive measures to reduce such errors are part of quality assessment in hospitals, nursing homes, and other health care programs.

In infectious disease epidemiology, the index case is the first case or group of cases of a condition that come to attention, providing the first clues in an outbreak or epidemic. In non-infectious conditions, the sentinel event may be a death, where the investigation of the circumstances may help in understanding the process of the disease or the care that was received. One case of clinical poliomyelitis represents up to 1000 people infected with the virus, which can develop in the gut of a person protected from the disease by the killed vaccine. Several epidemiologically linked cases of measles in a country previously free from the disease must be considered sentinel events that should not happen, and their investigation may show errors of omission or commission which explain the event and point to a need for remedial action or a change in policy.

Reporting and data systems should be arranged to indicate avoidable deaths from vital records or hospital discharge information systems. Comparison between areas may also include avoidable deaths as a health status indicator. There are selected conditions that are generally preventable or treatable, and therefore warrant investigation when they occur. Maternal deaths (i.e., deaths associated in time and related to pregnancy or the postpartum period),

deaths within 24 hours of hospital admission, or deaths following surgery (usually within 48 hours) are examples of sentinel events which are uncommon and should always be investigated. Deaths from appendicitis or appendectomy, tonsillectomy, hysterectomy, tubal ligation, or other elective surgical procedures should be investigated as sentinel avoidable deaths until other explanatory factors are found. Nosocomial (hospital-acquired) infections are a major cause of mortality, increased length of hospital stay, and health care expenditures, and require an active program of surveillance and prevention within the care setting.

With the advent of newly emerging frightening diseases such as SARS, Ebola, and avian flu, the development of rapid reporting of cases of suspect infectious disease takes on a new urgency. The situation is even more worrying with the potential for bioterrorism in the twenty-first century, raising specters not seen before in modern public health. Hospital emergency rooms and doctors' offices in the community become front-line monitoring sites for such disease, and depend on current information on possible symptoms or forms of presentation of a disease even in the earliest stages of its development. The identification of index cases and sentinel events is crucial to the functions of public health, especially with emergence of newly identified diseases, such as Legionnaire's disease, Ebola and Marburg viruses, and many others which sometimes move from their natural habitat via travelers and can become entrenched and even endemic in new environments, as has happened with West Nile fever, Rift Valley fever, Chikungunya, Lyme disease, dengue, and others. It is fundamental to detect and localize outbreaks of such highly dangerous infectious diseases.

THE BURDEN OF DISEASE

Burden of disease refers to the combined measurement of mortality and nonfatal health outcomes. The assessment of burden of disease serves to design, test, and implement methodologies to aid in setting priorities for the effective allocation of health resources. The challenge is to develop valid, reliable, comparable, and comprehensive measures of population health and comparative assessments of the burden of diseases, injuries, and risk factors. This assessment can then be linked with the investigation of costs, efficacy, and effectiveness of major health interventions to establish appropriate cost-effectiveness estimations, which should be a major tool in policy design and decision making.

The burden of disease is an important epidemiological research instrument. This approach recognizes that social and other factors contribute to diseases which are multifactorial in origin. These estimations, combining economic and epidemiological data, use the DALY as the unit of measurement of the burden of disease, representing the loss of 1 year of "healthy" life.

YEARS OF POTENTIAL LIFE LOST

Years of potential life lost (YPLL) are calculated based on age-specific rates of mortality or disability. They provide a refinement in epidemiology which has added important new perspectives in the analysis of specific problems. The leading causes of death in the USA, as in most developed countries, are coronary heart disease, cancer, and stroke. However, when the data are examined from the point of view of YPLL, trauma (unintentional injuries, homicides, and suicides) becomes the leading cause of death.

YPLL is a better reflection of the impact of diseases on a society than other mortality rates because it is age related, showing the relative impact of early mortality, which should be taken into account when determining national health priorities. Trends in YPLL for the years 1980–1996 are shown in Table 3.5 (see companion web site at http://booksite.elsevier.com/9780124157668). There was a large drop in YPLL for total mortality of most specific causes. There was also a substantial decline in YPLL for total and some categories from 1995 to 1996, especially in HIV, suicide, and homicide deaths.

Qualitative Measures of Morbidity and Mortality

QALYs and DALYs are calculations of morbidity introduced in the international health literature (Box 3.12). They serve as statistical measures of the burden of disease, allowing for international comparisons. Other terms used include disability-free life expectancy (DFLE) and health expectancy, which are both measures of mortality, morbidity, and impairment or disability. Burden of disease measures are used to assess the cost-effectiveness of specific interventions (see Glossary).

The World Bank calculates the variation in burden of disease between demographic regions, varying from nearly 600 DALYs lost per 1000 population in sub-Saharan African countries to approximately 120 per 1000 in the industrialized countries. These measures are used in economic analyses of health status, helping to focus on outcome measures to justify resource allocation by comparing benefits in terms of reduced mortality and morbidity.

MEASUREMENT

Epidemiology and public health are dependent on quantitative and qualitative observations to establish relationships and possible points of intervention. Therefore, an appreciation of the methods of handling statistics and their interpretation is fundamental. A complete presentation of this field is beyond the scope of this text; however, some general concepts are important to establish.

BOX 3.12 Measures of the Burden of Disease

- *Potential years of life lost* (PYLL) – PYLL is a measure of the relative impact of various diseases and lethal forces on society. It highlights the loss to society as a result of youthful or early deaths. The figure for PYLL due to a particular cause is the sum, over all people dying of that cause, of the years that these people would have lived had they reached a specified age.
- *Disability-adjusted life year* (DALY) – DALYs are units for measuring the global burden of disease and the effectiveness of health interventions and changes in living conditions. The DALY is a summary measure of population health. DALYs are calculated as the present value of future years of disability-free life that are lost as a result of premature death or disability occurring in a particular year.

  DALYs are calculated by a formula that includes five main components: the duration of time lost due to a death at each age, disability weights, age weights, time preference (expressed as a discounting function), and the integration of health measures among a population.

  DALYs for a disease or health condition are calculated as the sum of the years of life lost (YLL) due to premature mortality in the population and the years of healthy life lost from some degree of disability (YLD) for incident cases of the health condition.

  For detailed procedures on how to calculate DALYs, see WHO (2001, 2010).
- *Quality-adjusted life year* (QALY) – QALYs are an adjustment or reduction of life expectancy reflecting chronic conditions, disability, or handicap, derived from survey, hospital discharge, or other data. Numerical weighting of severity of disability is established on the basis of patient and health professional judgment.

Sources: *Last JM, editor. A dictionary of public health. New York: Oxford University Press; 2007.*
Harvard School of Public Health, Burden of Disease Unit. http://www.hsph.harvard.edu/organizations/bdu [Accessed 21 April 2008].
Murray CJ. Quantifying the burden of disease: the technical basis for disability-adjusted life years. Bull World Health Organ 1994;72:429–45.
World Health Organization. Global burden of disease. Available at: http://www.who.int/topics/global_burden_of_disease/en/ [Accessed 2 January 2013].
World Health Organization. Global health risks: mortality and burden of disease attributable to selected major risks. Geneva: WHO; 2009. Available at: http://www.who.int/healthinfo/global_burden_disease/global_health_risks/en/index.html [Accessed 6 January 2013].
World Health Organization. Health statistics and information systems. Metrics: disability-adjusted life years (DALY). Quantifying the burden of diseases from mortality and morbidity. Geneva: WHO; 2010. Available at: http://www.who.int/healthinfo/global_burden_disease/metrics_daly/en/ [Accessed 1 February 2013].
World Health Organization. National burden of disease studies: a practical guide. Edition 2.0. Geneva: WHO; October 2001. Available at: http://www.who.int/healthinfo/nationalburdenofdiseasemanual.pdf [Accessed 1 February 2013].
World Health Organization. The top ten causes of death. Available at: http://www.who.int/mediacentre/factsheets/fs310/en/index.html [Accessed 2 January 2013].

Routine data sets and their analysis can provide vital information for state- and county-level health agencies as well as to members of the health professions and the public at large. New York State has developed a remarkably ambitious and highly developed Community Health Data Set of the state by county, with many indicators (see Box 3.13 on companion web site at http://booksite.elsevier.com/9780124157668).

Research and Survey Methods

The scope and depth of research methods and the many other quantitative and qualitative sciences related to conducting investigations of health and disease in population groups are now important elements of training in public health. This area of public health is basic not only for research but also in reading the literature of a dynamic field such as public health, and in the design of policies and intervention programs, resource allocation, and the management of health systems. Research and surveys are integral parts of public health practice, and especially of academic public health. Familiarity with their basic principles is an important part of the preparation of public health professionals and a responsibility of academic centers training the public health workforce.

A thorough review of the peer-reviewed literature is a prerequisite for development of a study, requiring skills in the use of Internet search engines such as PubMed and Medline, as well as important sources such as the CDC Atlanta, the WHO, and other respected professional bodies. Organized literature reviews are called Cochrane Reviews, after the leading British epidemiologist Archie Cochrane, using meta-analysis. This is a formal method of review and analysis of multiple studies of a causal relationship of a therapeutic or preventive measure that yields a quantitative aggregate summary of all results. Meta-analysis includes selection of studies of similar design, mostly of randomized controlled trials (RCTs), pooling of the data to make a larger sample. This increases the chance that any change and comparison of study and control groups would be statistically significant, but also based on critical analysis and selection of those studies meeting acceptable criteria of methodology. A 2007 study reported in *The Lancet* on meta-analysis of previous studies showed a significant benefit of folic acid supplementation in reducing the incidence and severity of stroke, whereas individual studies were equivocal or showed change that was not statistically significant.

The formulation of a study question and its hypothesis includes defining its purposes and objectives. This leads to basic study design, definition and selection of the study population, sample selection, and selection of variables to be measured. A study is dependent on funding and the presentation of the proposal is crucial for success. The study design requires development and testing of survey instruments, organization of the study team, and collection of

data. Assessment of reliability and validity of the data is a key part of preparing it for analysis. Training in research methods is thus integral to studies of epidemiology and descriptive and inferential statistics.

Qualitative methods, including quantitative measures used in the social and behavioral sciences, are also important in public health, with health behavior as a basis for "lifestyle" or personal choices. These methods are also applied to societal conditions, cultural, socioeconomic and geographic factors, and support systems, which are all related to fundamental risk factors for some diseases and their severity, access to health care, and health outcomes. They are also related to organizational systems, management of health systems, economics, and professional interactions.

In these areas, the applicable social sciences include sociology, psychology, anthropology, political science, organization theory, and information technology. "Social marketing" is based on the study of human behavior and how to change it. Public health campaigns against risk factors such as smoking or high-risk sexual behavior depend on such knowledge of awareness, attitudes, behavior, and practices. Qualitative studies are more exploratory and developmental in pursuit of non-numerical aspects of the study question, and relate to attitudes, concerns, fears, and social aspects of study questions crucial to success in public health. Examples include studies of teen pregnancies, parental concerns regarding new vaccines, sexual practices such as condom use, interfamilial relationships and their impact on risk behavior and antisocial behavior, and smoking-related issues. Epidemiological and qualitative studies can be complementary to each other, providing important scientific evidence related to real public health issues of national and international importance.

Interpretation of statistical events requires a familiarity with methods of gathering and processing basic information. Statistics is "the science and art of collecting, summarizing, and analyzing data that are subject to random variation" (Last, 2001). Biostatistics is the application of statistics to biological problems.

Variables

A variable is any factor being studied which is considered to affect health status and which can be measured. It may be an attribute, a phenomenon, or an event that can have different values, such as age, gender, SES, behavior, other disease conditions, characteristics of the health care system, or exposure to a toxic or an infectious agent. A dependent variable is the outcome being studied. An independent variable is the characteristic being observed or measured which is hypothesized to cause or contribute to the event or outcome being studied, but is not itself influenced by that event. For instance, in the study of the association between smoking and coronary heart disease, smoking (described as the average number of cigarettes smoked per day, for example) is the independent variable, or the exposure. Coronary heart disease is the dependent variable, or the outcome.

The Null Hypothesis

The null hypothesis is the assumption that one variable has no association with another variable, and that two or more populations being studied do not differ from one another. A statistical test is used to decide whether the null hypothesis may be rejected or accepted; that is, the probability that any differences observed may be due to chance alone and not indicative of a real difference.

If the probability of chance alone explaining the observed differences is very low then the null hypothesis may be rejected, suggesting that the studied association or difference may actually exist. The definition of the threshold for "low probability" depends upon the decision of the level of significance required. Statistical testing thus provides the basis for inference or decisions regarding the results of a study as statistically significant and to what degree.

Confounders

A confounding variable (confounder) is a factor other than the one being studied that is associated both with the disease (dependent variable) and with the factor being studied (independent variable). A confounding variable may distort or mask the effects of another variable on the disease in question. For example, a hypothesis that coffee drinkers have more heart disease than non-coffee drinkers may be influenced by another factor (Figure 3.10). Coffee drinkers may smoke more cigarettes than non-coffee drinkers, so smoking is a confounding variable in the study of the association between coffee drinking and heart disease. The increase in heart disease may be due to the smoking and not the coffee. More recent studies have shown coffee drinking to have substantial benefit in heart health and in the prevention of dementia.

In public health, researchers are often limited to observational studies to find evidence of causal relations. Experimental studies may not be possible for many technical, ethical, financial, or other reasons. The proper causal interpretation of the relations from carefully developed epidemiological studies is vital to the development of effective measures of prevention.

Sampling

The majority of epidemiological studies cannot collect information about every individual in the target population (the general population of a country or a region, or a defined group of people). Therefore, a sample, which is

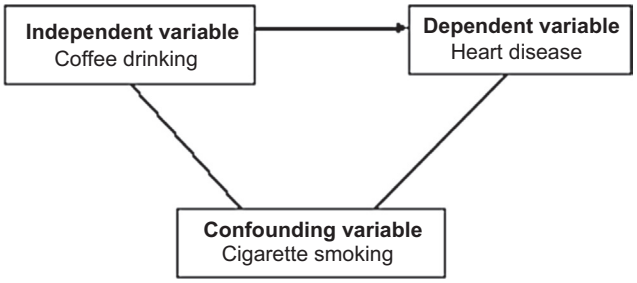

FIGURE 3.10 Independent, dependent, and confounding variables in a study.

chosen from that target population, is defined and used as the study population, for which all the required information is collected. The appropriate choice of the study population is crucial to ensure that the results obtained from the study can later be generalized to the general population. Therefore, a sample must be selected randomly, representative of the general population, and of sufficient size as to increase the likelihood (or probability) that the results obtained from the sample are close enough to the actual situation in the general population (i.e., where the level of significance of a statistical test is acceptable) (Box 3.14).

Random Sampling

A distinction should be made between sampling and randomization, which is the allocation of two or more groups to different interventions.

The main sampling methods are described as follows.

- *Simple randomization* – when all individuals in the population have an equal chance of being selected, the group is known as a *random sample*. This is often achieved by assigning each person in the group a number and then selecting the sample from a table of random numbers until the desired sample size is reached.
- *Systematic randomization* – every *n*th unit is selected.
- *Stratified randomization* – the population is divided into strata (subgroups) and simple randomization is applied within subgroups. For example, if 20 percent of the population is in the age group 40–59 and 20 percent of the sample comes from this age group, and similarly for other age groups, then all strata are fairly represented with regard to numbers of people in the sample.
- *Cluster sampling* – a population is non-randomly divided into subgroups (such as households, schools in a city, or classes in a school) and clusters (subgroups) are randomly selected.
- *Multistep sampling* – groups are randomly selected, and then individuals within groups are chosen.

A non-random sample is one in which a form of bias is introduced into the sampling process. For example, a convenience sample is a group of people who are readily accessible, such as volunteer blood donors or people who appear at a health fair for blood pressure examination. The bias in such samples is that there may be a self-selection process not representative of the total population. A selection of a group at special risk, for example, might entail choosing districts with known low immunization coverage in order to attempt to determine the reasons for this. Such a study would then be applicable to those districts and, although not generalizable to the total population, could provide valuable information affecting the immunization program.

BOX 3.14 Sample Size

Principles

- Samples are drawn to represent a population and the larger the number of samples and their sizes, the higher the probability that their average value (of the parameter under study) is equal to the value in the population.
- Because sample sizes are limited, sampling error (i.e., the probable difference between the value in the sample and in the population) must always be taken into account.
- The size of the sampling error is affected by the size of the sample drawn, and by other factors, some of which are called biases. Increasing the sample size decreases the size of the sampling error, unless there is a selection bias, in which case increasing the size will sustain the sampling error.
- The principles of sampling rest on the assumption that samples are randomly obtained.

Factors in the Calculation of Sample Size

- *Type 1 error* – the risk of a false positive result (α) (i.e., the chance of detecting a statistically significant difference when there is no real difference).
- *Type 2 error* – the risk of a false negative result (β) (i.e., the likelihood of not detecting a significant difference when there really is a difference that is greater than the specified threshold).

The power of a study is its ability to demonstrate an association if one exists. It is determined by several factors, including the frequency of the condition under study, the magnitude of the effect, the study design, and sample size. It is defined as the chance of not getting a false-negative result and is equal to $1 - \beta$ (type 2 error).

Calculation of sample size is beyond the scope of this text and is found in free computer programs, including those in the Sources below.

Sources: *Last JM, editor. A dictionary of public health. New York: Oxford University Press; 2007.*
Centers for Disease Control and Prevention. Epi Info 7 [updated December 2012]. Available at: http://wwwn.cdc.gov/epiinfo/7/index.htm [Accessed 3 January 2013]
Abramson JH. WINPEPI (PEPI-for-Windows) [new version posted 17 December 2012]. Available at: http://www.brixtonhealth.com/pepi4windows.html [Accessed 3 January 2013].

Conclusions based on sample results may be attributable to the population from which the sample is taken. Extrapolation to the total population or a different population is a judgment, which may be justified but must be qualified by description of the sampling methods and the potential biases with appropriate statistical testing used. Despite these limitations, careful sampling is essential for assessing a particular characteristic in a larger population and should give results that are reproducible by other investigators.

NORMAL DISTRIBUTION

The evaluation of certain characteristics in a population group is based on the assumption of normal distribution (nutrition, height, weight). A normal distribution is continuous and symmetrical about a mid-point. It is often described as a bell-shaped frequency distribution of observations. A normal distribution has upper and lower values that may extend to infinity, but it has an arithmetic mean, mode, and median from a central point (Figure 3.11).

Mean, median, and mode are measures of central tendency in a group of numbers (Box 3.15). The symmetrical bell-shaped (Gaussian) curve represents the normal distribution of biological characteristics, such as heart rate, height, weight, or blood pressure in a normal population group. In such a distribution, approximately two-thirds of the observations fall within one standard deviation and approximately 95 percent fall within two standard deviations of the mean.

Normality may be defined in several senses. It is a range of variation in a given population, within two standard deviations below and above the mean, or between specified percentiles, for example, the 10th and 90th of the distribution. *Normal* also refers to the limits of a range of a test or measurement and is an indication of the finding being conducive to good health.

Deciding when a group of observations is "normal" or "abnormal" requires defining cut-off points, both in clinical medicine and in epidemiology. In clinical medicine, deciding what is a normal blood pressure, cholesterol level, or growth of a child is based on norms determined from a large number of observations of what is assumed to be a "normal" population. For example, growth patterns of children used as an international standard are based on data derived from a white, middle-class American population (see Chapter 6).

STANDARDIZATION OF RATES

Age structures of populations vary widely in countries around the world. For comparisons, it is important to standardize rates. After many years of examining alternative standard populations, standardization now uses the WHO standard population based on world average population estimated between 2000 and 2025 (Ahmad et al., WHO, 2001).

The age-adjusted death rate is the number of deaths per 1000 people of a specified population during 1 year, with the rate adjusted to prevent distortion by the age composition of the population. A standard population is used for determining this rate.

BOX 3.15 Summarizing a Group of Numbers

- *Mean* – the average value of the observations, i.e., the sum of values of the observations divided by the number of observations.
- *Median* – the midpoint value to which half of the observations are equal or less, and half are equal or greater. It is the middle observation when a set of observation numbers is arranged in order of increasing value.
- *Mode* – the most frequently occurring value in a set of observations. In a normal distribution, the mean, median, and mode are all equal to one another.
- *Standard deviation* – the common method of summary of how widely spread or dispersed the observed values are from the mean of the observations.
- *Confidence interval* – the range or interval within which the true value of a variable, such as mean, proportion, or rate, lies at a specified degree of probability (e.g., 95% or 99%). It indicates how precisely the results of an analysis based on a sample approaches the true value of the rate in the population which the sample is meant to represent.

Sources: *Adapted from Last JM, editor. A dictionary of epidemiology. 4th ed. New York: Oxford University Press; 2001.*
Last JM, editor. A dictionary of public health. New York: Oxford University Press; 2007.

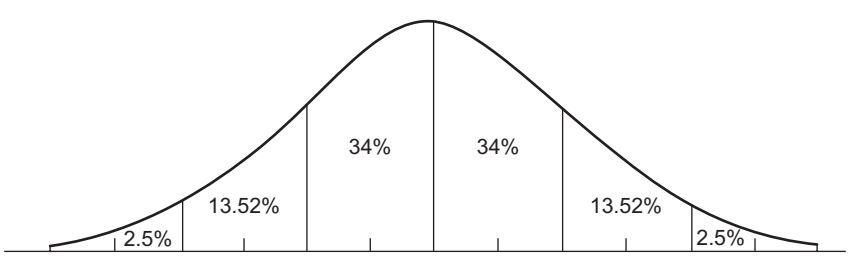

FIGURE 3.11 Normal distribution. *Source: Last JM, editor. A dictionary of epidemiology. 4th ed. New York: Oxford University Press; 2001.*

Standardization of rates is important in comparing data between populations of different age and gender distribution and to remove, as far as possible, the effects of confounders in epidemiological studies. Comparing mortality rates in one country, for example, will require using a standard population such as that of the USA in 1940 to compare mortality in 1940 with subsequent rates, thus removing the effects of changes in the age and gender composition of the populations. Without standardization of the population, the age–gender changes would act as confounders when describing distributions or comparing mortality or disease incidence between two or more designated groups.

Standardization uses a "standard population" selected to adjust for differences in the distribution of the relevant variables between groups being compared, or between the sample used in a study and the population it was chosen from. The standard population in this procedure is one in which the age and gender composition is known and therefore is used as a benchmark to compare rates for a number of different population groups. Comparisons between different states in the USA or countries in Europe would use a US, European, or world population distribution. Standardization can be done by direct or indirect methods.

It is important to note that although age and gender distributions often act as confounders, many other variables may affect the outcome being measured, depending on the study. For example, smoking and coffee drinking may act as confounders when studying the association between physical activity and coronary heart disease. If such a confounding effect is present and identified, then the study analysis must control for the confounder in order to correctly assess the main study variables.

TABLE 3.6 Age-Standardized Mortality from Non-Communicable Diseases (NCDs), Rates per 100,000 Population, Selected Countries, 2004

	Total NCD Mortality	CVD	Cancer	Injury
Canada	374	131	135	33
Egypt	891	515	81	36
Ethiopia	817	384	142	105
France	387	123	154	45
India	713	382	100	116
Israel	368	121	121	29
Japan	284	103	120	39
Russia	904	645	142	218
Sweden	372	171	115	32
UK	441	175	147	26
USA	450	179	133	50

Note: Rates are age-standardized to WHO's world standard population.
CVD = cardiovascular disease.
Sources: World Health Organization. World health statistics, 2009. Table 2. Geneva: WHO; 2009. Available at: http://www.who.int/gho/publications/world_health_statistics/EN_WHS09_Full.pdf and http://www.who.int/whosis/whostat/EN_WHS09_Table2.pdf [Accessed 9 January 2013].
Ahmad OB, Boschi-Pinto C, Lopez AD, Murray CJL, Lozano R, Inoue M. Age standardization of rates: a new WHO standard. GPE discussion paper series no. 31. Geneva: WHO; 2001. Available at: http://www.who.int/healthinfo/paper31 [Accessed 1 February 2013].

Direct Method of Standardization

The direct method of standardization is used when age–gender-specific mortality rates are known for the populations being compared to a standard population. These rates are then applied to the standard population to calculate the *expected numbers of deaths for each group* in the population, as if its composition (with respect to the variable being standardized for) were the same as in the standard population. They are then summed and divided by the total standard population to give a summary adjusted rate. Standardized death rates can be calculated for particular diseases. For example, if one is comparing lung cancer death rates in a number of countries to see whether there are differences that might be attributed to external factors such as air pollution patterns, the data for each city can be compared using standardized (cause-specific) mortality rates.

The direct standardization of rates is an important method of comparing mortality patterns between cities, districts, regions, and countries. Table 3.6 shows mortality rates from a range of countries with very different age distributions comparing mortality from NCDs in 2004. With age standardization, countries can be compared with key causes of mortality which illustrate the high rates of mortality from NCDs in developing and mid-level income countries. Age adjustment of rates is important for time trends and comparisons between countries and regions within countries.

Indirect Method of Standardization

When age–gender-specific mortality rates for the study population are not available or if the numbers in some age groups are too small, the indirect method of standardization is used. This method uses known age–gender-specific rates from a standard population to calculate the expected number of the same health event for the population being studied, given that population's distribution (Box 3.16). The expected number of deaths or cases thus calculated is then compared to the actually observed number of deaths or

BOX 3.16 Standardized Mortality Rates (SMRs) and Standardized Incidence Ratios (SIRs)

$$SMR\,(SIR) = O/E = \frac{Observed\ deaths\ (cases)}{Expected\ deaths\ (cases)} \times 100$$

cases. The ratio of observed to expected is then multiplied by 100 (or another decimal multiplier) to give the standardized mortality ratio (SMR), which now shows the comparisons free from confounding factors such as different age distributions.

The SMR thus allows for comparison of one national, regional, or other defined population group where the age–gender-specific rates are not available, to a selected standard population for which these specific rates are known. This same method is also used to calculate morbidity as standardized incidence ratios (SIRs) or other health-related observations.

Comparing mortality or morbidity rates in European countries is made accessible to all by the Health for All database. This compares rates of mortality, morbidity, health resources, utilization, lifestyle, and others. Data for all countries are standardized to the European population standard, so the reported rates are comparable.

Standardized mortality (incidence) ratios (SMRs or SIRs) are therefore the crude rate or the total number of deaths or cases occurring in the study group, compared to the expected number of deaths if that population had experienced the same death (or incidence) rates as the standard population. The standard population provides a strong base of comparison as it is larger in size, with less likelihood of random variation.

SMRs can be calculated for a specific population group at special risk and compared to a standard population to see whether it is vulnerable to higher rates. A group of people who have been employed in a certain industry and exposed to asbestos may, after a long latency period, develop mesothelioma. The SMR for a population of former asbestos workers in a 25-year follow-up study is seen in Table 3.7. Studies in the USA, the UK, and Italy followed the expected burden of mesothelioma calculated based on exposed population and degree of exposure, to document and project future expected deaths from this highly specific asbestos-induced disease.

In the UK, the SMR is used as the adjustment factor for allocation of funds to district health authorities. Following a lengthy examination of many alternatives, the SMR was believed to incorporate many variables affecting health, including age, gender, and socioeconomic and environmental factors. Populations living in areas with higher than expected mortality may have more disease or higher case fatality rates (CFRs) resulting from a greater prevalence of risk factors (genetic, environmental, and/or socioeconomic). Excess mortality may also be due to less access to or poorer quality of health care. Extra resources are made available on this basis to deal with the poorer health status of the population. This is a practical method of addressing regional differences in health, providing a high degree of equity in resource allocation. It takes into account greater need in some areas than in others. The SMR applies epidemiological methods to improve management practice in health.

TABLE 3.7 Mesothelioma Death Rates Among Former Asbestos Workers in Israel, 1950–1990

Study group (*n*)	4401
No. of mesothelioma deaths in study group	26
Expected deaths from national population rates	0.12
Standardized mortality rate (SMR)	26/0.12 = 216.7

Note: Expected deaths derived from applying age-specific mesothelioma mortality rates of total population of Israel to the study group.
Sources: Tulchinsky TH, Ginsberg GM, Shihab S, Goldberg E, Laster R. Mesothelioma mortality among former asbestos-cement workers in Israel, 1953–1990. Isr J Med Sci 1992;28:542–7.
Hodgson JT, McElvenny DM, Darnton AJ, Price MJ, Peto J. The expected burden of mesothelioma mortality in Great Britain from 2002 to 2050. Br J Cancer 2005;92;587–93.

POTENTIAL ERRORS IN MEASUREMENT

Data must be assessed as to their validity and reliability. They should also be considered for their biological plausibility (Box 3.17). These all affect the degree to which inferences can be made and generalizations drawn from the study sample.

Reliability

Reproducibility or reliability is the degree of stability of the data when the measurement is repeated under similar

BOX 3.17 Observation Measurement Issues in Epidemiology

- *Validity* – the degree to which a measure actually measures what it claims to measure.
- *Accuracy* – the extent to which a measure conforms to or agrees with the true value.
- *Precision* – the quality of being sharply defined.
- *Reliability, reproducibility* – the stability seen when a measure is repeated under similar conditions.
- *Instrumental error* – this includes all sources of variation inherent in the test itself.
- *Digit preference* – a consistent bias by observer rounding of numbers (e.g., to the nearest whole number).
- *Interobserver variation* – differences in observation between different observers of the same phenomenon.
- *Individual observer variation* – the same observer may record the same observation differently owing to changes within the observer, not the observed.
- *Bias* – an effect or inference that departs systematically from the true value.
- *Spurious* – an apparent but not genuine epidemiological relationship.

Source: *Adapted from Last JM, editor. A dictionary of epidemiology. 4th ed. New York: Oxford University Press; 2001.*

conditions. If the findings of two researchers carrying out the same test (such as the measurement of blood pressure) are very close, the observations show a high degree of interobserver reproducibility. However, it is common in medicine that even relatively objective measurements by different observers, such as radiologists' readings of the same X-ray or cardiologists' readings of the same cardiogram, show high degrees of variability. Instrument standardization, observer training in common standards, and standardization of recording observations are needed to ensure acceptable standards of reliability in any data set. Measuring the same patient at different times can produce different results (as in measuring blood pressure or blood sugar), such that standardization of conditions of recording or timing the test is essential to ensure comparable data. Standardization of a test requires, as part of quality control, sending samples tested in one laboratory to a reference laboratory to see whether the test results are the same.

There are three main types of bias: selection, information, and analytical bias. All other types are subtypes of these. It is worth noting that bias is a dynamic concept; that is, if no conclusion is drawn, there is no bias. This means that bias cannot be defined only based on material aspects. It is important to minimize sources of bias (Box 3.18).

BOX 3.18 Sources of Bias

The reliability of a data set may be compromised by systematic biases in the data collection or processing. Such biases include the following:

- *Assumption bias* – errors from faulty logic, premises, or assumptions on which the study is based.
- *Response bias* – systematic error due to differences between those who choose or volunteer for a study as compared to those who do not.
- *Selection bias* – error due to inclusion of those who appear and are included in a study, leaving out those who did not arrive because they had died, were cured without care, were not interested, and so forth.
- *Sampling bias* – error when sampling methodology does not ensure that all members of the reference population have a known and equal chance of being selected for the sample.
- *Observer bias* – error due to differences between observers; may be between observers (interobserver) or by the same observer on different occasions (intraobserver).
- *Detection bias* – systematic error due to faulty methods of diagnosis or verification of cases in a survey.
- *Design bias* – systematic bias due to faulty design of the study.
- *Information bias* – flaws in measuring exposure or outcome resulting in data being not comparable.
- *Measuring instrument bias* – faulty calibration, inaccurate measuring instruments, contaminated reagents, incorrect dilutions/mixing of reagents, flawed questionnaire.
- *Interviewer bias* – conscious or subconscious selection in gathering of data.
- *Reporting bias* – self-report selective reporting, suppressing, or exaggerating of information; e.g., history of STIs.
- *Publication bias* – editors and reviewers prefer positive results so that a distorted perception of an issue may occur.
- *Bias due to withdrawals* – loss of cases from the sample by withdrawal or non-appearance in follow-up.
- *Ascertainment bias* – error due to the type of patients seen by the observer, or in the diagnostic process affected by the culture, customs, or idiosyncrasies of the provider of care.

Source: *Adapted from Last JM, editor. A dictionary of epidemiology. 4th ed. New York: Oxford University Press; 2001.*

Validity

Validity refers to the degree that a measurement actually measures what it claims to measure. This includes the representativeness of the sample and the nature of the population from which the sample is taken. It includes the nature of the phenomenon being tested and whether the sampling method takes it into account, such as when a condition changes with age, does the sample take that into account, or whether the content of the testing, such as a questionnaire, truly reflects the nature of the phenomenon being studied. A set of findings from a study using white middle-class males or US nurses as subjects may not be generalizable to females or males of other ethnic or socioeconomic status, or populations with different sociocultural environments.

SCREENING FOR DISEASE

Screening for disease may be carried out on a mass basis of a whole population, as was commonly done in the past for TB. When done with a number of tests it is called *multiphasic screening*. Screening may target a group at special risk, such as blood lead screening among workers exposed to lead at their place of work or children living in the vicinity of a plant using lead.

Screening is an essential part of patient care when the caregiver routinely tests, for example, blood pressure, blood sugar, or blood lipids. Hypertension is common and undiagnosed in a high percentage of affected persons, with serious long-term effects such as strokes and other vascular diseases. Blood pressure testing is a simple procedure that should be carried out in all possible health visit situations to find those cases for whom preventive care programs can be life saving.

The *accuracy* of a test is usually measured in terms of sensitivity and specificity. Targeted screening may be required by law, as in the case of newborn screening for phenylketonuria (PKU), hypothyroidism, and other congenital disorders. The value of the screening test is defined with regard to its degree of sensitivity and specificity, as well as its costs and benefits for screening or not screening.

TABLE 3.8 Screening Tests: Validity, Sensitivity, and Specificity

Screening Test	Disease Present	Disease Absent	Total
Test positive	True positive (A)	False positive (B)	A + B
Test negative	False negative (C)	True negative (D)	C + D
Total	A + B	B + D	A + B + C + D

Note: Sensitivity = TP/TP + FN.
Specificity = TN/TN + FP.
Positive predictive value = TP/TP + FP.
Negative predictive value = TN/TN + FN.
True-positive rate (TP)
True-negative rate (TN)
False negatives (FN)
False positive (FP)

Sensitivity is the proportion of truly diseased people in the screened population who are identified as such by a screening test, and is sometimes called the *true-positive rate* (TP). *Specificity* is the proportion of truly non-diseased people who are identified as not having the disease; that is, it measures the probability of correctly identifying a non-diseased person with a screening test, or the *true-negative rate* (TN). A test that produces too many false positives or false negatives is not valid (Table 3.8).

Screening for cancer of cervix is still a life-saving procedure even though an effective vaccine against HPV is now being used. The interval and age of onset of testing are revised periodically, but the Pap smear test of the cervix has proven its value over many years in many countries. Breast cancer screening with mammography is somewhat controversial but still recommended regularly by many professional organizations. Screening for colorectal cancer is now accepted as essential for all people over the age of 50 at intervals of 5–6 years (see Chapter 5).

False negatives (FN) occur when a negative laboratory result appears in a person who has the condition for which the test is being conducted. The condition is present but does not show up on the initial screening test or data set. If screening for PKU is done too soon after birth, some cases may be missed and will only appear later. False negatives can compromise the effectiveness of the screening program.

False-positive (FP) results are those cases in which a positive laboratory result occurs in a person without the condition for which the test is being conducted. Not everyone with an isolated elevated reading of blood pressure has true hypertension. False-positive results must be checked because they cannot be excluded without confirmation by more specific testing, such as repeated blood pressure readings. Precision is the quality of sharp definition of the test. If a laboratory test for environmental contamination is accurate to parts per billion as compared to parts per million, then the precision is enhanced.

Screening for disease and risk factors is a common and necessary part of public health. In order to be valuable, screening requires a valid test and a significant condition with a high prevalence in the population. Screening for breast cancer, carcinoma of the cervix, and many other conditions is part of the armamentarium of public health and contributes to lowering mortality and improving survival rates for these diseases. Screening of newborns is important for conditions that are serious and treatable but uncommon (e.g., PKU) and those that are more common and treatable (e.g., congenital hypothyroidism) (see Chapter 6). PKU is manageable with a strict diet to prevent serious consequences of the abnormal biochemical condition. Screening for these and other birth disorders, cancers of the cervix and colon, and many other conditions is now accepted in standard clinical guidelines, while screening for breast cancer is recommended but is under review as to its cost-effectiveness.

EPIDEMIOLOGICAL STUDIES

Epidemiological methods of study are important, not only to define the extent of disease in the population, but also to look for specific risk or causal factors for the disease. Epidemiological studies permit analysis of a risk factor, a variable, or an intervention (such as a new vaccine or drug), allowing the testing of new hypotheses and innovations in medicine and public health.

Epidemiological studies are classified as observational or experimental (Figure 3.12). No intervention is made in an observational study, whereas an experimental study involves interventions.

Observational Studies

Observational studies are those where the population is studied, but nature is allowed to take its course. They may be descriptive or analytical. Descriptive studies are limited to describing the occurrence of a disease in a population, which is often the first step in investigation, as it may provide clues for more in-depth investigation. Analytical studies go further by looking for specific variables that may be causally associated with the disease.

Descriptive Epidemiology

Descriptive epidemiology uses observational studies of the distribution of disease in terms of person, place, and time. The study describes the distribution of a set of variables, without regard to causal or other hypotheses. Personal factors include age, gender, SES, educational level, ethnicity, and occupation. The place of occurrence can be defined by natural or political boundaries, and can also include such variables as location of residence, work, school, or

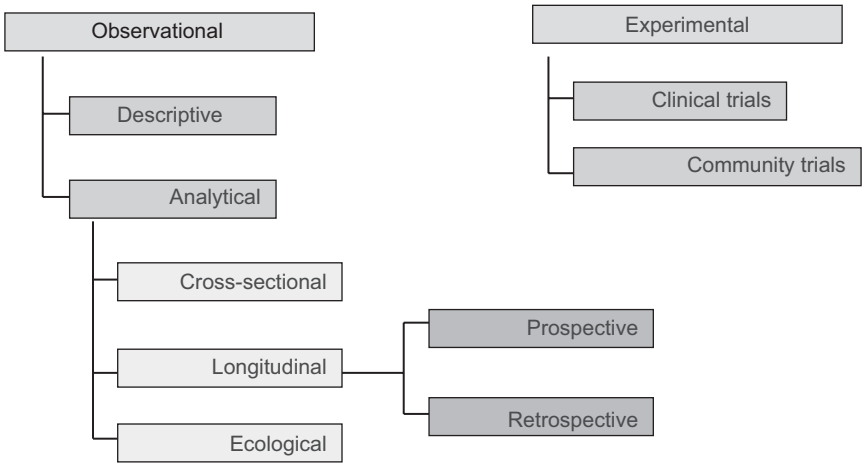

FIGURE 3.12 Classification of epidemiological studies. *Source: Abramson ZH, Abramson JH. Research methods in community medicine: surveys, epidemiological research, programme evaluation, clinical trials. 6th ed. Indianapolis, IN: Wiley; 2008.*

recreation. Time factors include time trends, which are generally divided into three types:

- *secular trends* – long-term variations
- *cyclic changes* – periodic fluctuations on an annual or other basis
- *epidemic disease outbreaks* – short-term fluctuations.

Time trends contribute to our understanding of the natural history of epidemics of acute infectious diseases such as measles or waterborne disease, as well as NCDs such as stroke or cancer. The study of a "natural experiment" when a public health situation is occurring may provide valuable experience and hypothesis for further investigation. Epidemiology also examines the frequency and distribution of potential health indicators and health-related events (such as smoking).

Natural experiments allow observation of the effects of events not in the control of the observer. Increases in legal speed limits are associated with increases in the incidence and severity of traffic collisions, and deaths as velocity increases. Fluoridation of community water supplies is associated with reductions in dental caries and poor dental health of children and elderly people. The observations are consistent and show a strong association, but are denied by ideologues as "not proven".

Laws on smoking restrictions are important in reducing this previously highly prevalent risk factor for CVD and cancer, but this cannot be demonstrated by usual epidemiological methods. Yet it was the good epidemiology that provided the strong association between smoking and these diseases which justified the legal restrictions imposed by many civil societies. Natural experiments are an important part of the evidence base for public health where in many circumstances more definitive epidemiological research methods such as RCTs are neither feasible nor ethical.

Analytical Studies

Analytical studies are concerned with establishing causes or contributory risk factors to disease, including social, economic, psychological, or political conditions that impinge on health. They help to define programs to intervene in order to reduce the burden of disease in the population. Analytical epidemiology has made vital contributions to modern medicine through identification of key risk factors, such as higher rates of lung cancer among smokers and higher rates of stroke among people with hypertension. Analytical studies may include cross-sectional (or prevalence), as well as retrospective, prospective, and ecological studies.

Analytical studies may be individual or group-based studies. Individual-based epidemiological studies collect information about individuals, and both the exposure and the outcome status should be known for each individual within the study. An ecological study is one in which the units of analysis are populations or groups of a population rather than individuals.

Ecological Studies

Ecological studies, also known as *group-based studies*, compare the mean (or summary) values of exposures and outcomes of different population groups. For example, a study analyzing the association between the GDP of different countries and the prevalence of malnutrition in those countries is an ecological study. However, conclusions from ecological studies should be drawn carefully, as the mean values may not be truly representative of the actual situation, and furthermore, because exposures and outcomes for individuals are not established. A group may have a high prevalence of a specific exposure (e.g., oral contraceptive use among women) and an outcome (e.g., prevalence of heart disease), but it is not known whether the individuals with a positive

exposure status are also those with a positive outcome. Drawing a conclusion from this apparent relationship is a bias termed an *ecological fallacy*. The association between aggregated variables based on group characteristics does not necessarily represent the association at the individual level.

Studies showing an apparent correlation between quality of drinking water and mortality rates from heart disease have not been substantiated as indicating a "cause–effect" relationship. It would be an inappropriate conclusion (ecological fallacy) to infer from this finding alone that exposure to water of a particular level of hardness necessarily influences an individual's chances of developing or dying of heart disease.

However, ecological studies are important for population health monitoring and for generation of hypotheses for further investigation and intervention. For example, comparison of SMRs for disease categories from routine mortality sets can identify regions with high rates of a specific disease, such as lung cancer or diabetes-related conditions, or motor vehicle accidents, which require follow-up, investigation, and possibly intervention even before more complete epidemiological studies can be carried out. Studies have shown higher rates of CVD mortality for African Americans compared to whites in the USA. However, further analysis shows that there are gradients for cardiovascular mortality for both whites and African Americans according to median family income, such that SES emerges as a more important factor than race.

Cross-Sectional Studies or Prevalence Studies

These studies examine the relationship between specific diseases and health-related factors as they exist in individuals in a population at a particular time. The population may then be divided into subgroups, with and without the disease, and the characteristics of each member of each group analyzed for different variables; for example, age, gender, region of residence, occupation, and social class. Comparisons of these variables may indicate a higher risk for disease in one population group than in an otherwise similar comparable population.

This type of study is relatively simple and easy to perform. However, it has some serious drawbacks resulting from the simultaneous measurement of both exposure and outcome. When investigating two variables (a presumed exposure and presumed outcome) it may be impossible to determine which one is the exposure and which is the outcome, as there is no information about a time relationship. For example, a cross-sectional study of body mass index (BMI) and blood pressure may find that high BMI correlates with high blood pressure, but will not be able to indicate whether people with high BMI had an increase in blood pressure or if people with high blood pressure became fatter. A cross-sectional study may fail to produce valuable information where the main studied exposure or outcome is only present during a short period. If the exposure is short, the recovery from the outcome condition is rapid, or its case fatality is high, it is unlikely that their assessment at one point in time will actually reflect all the exposures and outcomes.

Case–Control Studies

Case–control studies are observational studies of people with the disease (or other outcome variable of interest) and a suitable control group of people without the disease. These studies are retrospective, taking a known outcome status (e.g., disease status) and looking at the exposure status. They compare two similar population groups for their exposure outcomes, one with the disease or condition and the other without. An example is the study of the occurrence of a serious upper limb defect (phocomelia) in children born in Germany in the late 1950s, which showed that of those born with this defect, 41 out of 46 mothers had taken the medication thalidomide as an antinausea pill promoted for use during pregnancy, whereas none of the 300 control mothers with normal children had done so. This study was confirmed by studies in other European countries which had licensed thalidomide, which led to the FDA stopping approval for this drug in the USA, and later to its being banned in countries where it was already in use. Case–control studies are defined as retrospective (defining the outcome status and then looking at the exposure).

The odds ratio is commonly used to summarize findings of case–control studies. It is a ratio of the odds of exposure among cases to the odds of exposure among controls. Case–control studies may be vital to define the differences between the sick and the control groups in an epidemic or outbreak situation.

Case–control studies are ideal for the study of rare disease or conditions that are slow to evolve, as they permit the assembly of a group of cases of appropriate size for analysis, without requiring an extremely large study population. This presents an important advantage as it reduces the cost and time necessary for the study of such conditions. However, a case–control study is prone to various sources of bias, notably "recall bias", where people with (or without) a studied outcome may tend to better remember their exposure status. For example, a study of environmental exposures during pregnancy and fetus malformation may reveal a higher proportion of exposures among women who had an affected fetus because they were more aware and recalled all potential hazards that may have caused the severe adverse outcome of their pregnancies.

Cohort Studies

Cohort studies are also referred to as prospective, longitudinal, or follow-up studies. They examine a population that is initially free from the disease, dividing the population

into subgroups according to exposure to a potential risk factor. Such studies can yield the magnitude of risk or incidence rates of the disease under study. The relative risk (a ratio of risk of disease in the two groups; i.e., exposed and non-exposed) can then be calculated. Where risk cannot be determined, the rates of disease for each group (exposed and non-exposed) are determined and the rate ratio may be determined for comparison of risk.

The main disadvantages of cohort studies are the follow-up time they require (during which people may leave the study or be lost to follow-up, an important source of bias) and the relatively large study populations needed to ensure the appearance of a sufficient number of cases for analysis. Long follow-up and large samples usually imply high costs, and make cohort studies less suitable for the investigation of rare diseases or conditions that develop slowly. However, cohort studies present many advantages in terms of the reliability of the information collected, as all exposures may be assessed by the investigators at the beginning of the study and outcomes are identified as they appear during the study period, so that there is no doubt about time relationships.

Cohort (prospective) studies permit the observation of many outcomes from long-term follow-up of a selected population to ascertain morbidity and mortality data not readily available in the general population reporting systems. The British doctors' smoking habits study initiated by Richard Doll and Bradford Hill was carried on from 1951 to 2001, showing the harmful effects of smoking in terms of lung cancer, coronary heart disease, and early mortality. The Framingham Study, initiated in 1949, has provided a wealth of epidemiological information on risk factors for CVD in the population of Framingham, Massachusetts (see Chapter 5). Many epidemiological prospective studies follow selected population groups, such as the long-term prospective study of nurses conducted by Walter Willett at the Harvard School of Public Health, providing a major source of new information on the health of women. This is the largest cohort study of women, tracking over 120,000 nurses since 1976.

Retrospective or historical cohort analysis looks back at earlier records of groups with a specific disease and their earlier life experience. Factors such as smoking, birth weight, obesity, hypertension, or exposure to toxic substances (e.g., asbestos) are analyzed in relation to current morbidity and mortality from lung cancer, coronary heart disease, diabetes, and mesothelioma.

Observational studies of particular population groups have provided important public health advances over the past 50 years. A natural experiment is a situation in which naturally occurring circumstances result in two similar population groups, one exposed to a supposed causal factor and one not exposed as a study or control group. The term *natural experiment* is derived from John Snow's 1850 study of Londoners exposed to drinking water supplied by two different water companies, one group having high rates of cholera and the other low rates. This term is currently used in investigating epidemiological events, regarding each event as a unique situation for which relevant factors need to be defined and, to the extent possible, linked to the disease.

A cohort study of 68,444 adults exposed to the 9/11 terrorist destruction of the New York World Trade Center was made up of lower Manhattan residents, area workers, and passers-by enrolled in the World Trade Center Health Registry. The cohort was followed for 5–6 years and showed morbidity from post-traumatic stress syndrome and lower respiratory symptoms. The study showed that: "respiratory and mental illness are closely linked in individuals exposed to 9/11 and should be considered jointly in public health outreach and treatment programs" (Stellman SD, personal communication; Nair et al., 2012).

Experimental Epidemiology

Experimental studies are studies of conditions under the direct control of the investigator, conducted as closely as possible to a laboratory experiment. Experimental epidemiology involves changing a variable and measuring the effect in one or more population groups. Clinical epidemiology applies experimental epidemiological research methods to clinical problems and practice. It includes promoting the use of epidemiological knowledge in the clinical care of individual patients. Clinical epidemiology also contributes knowledge to the planning and operation of health care systems and clinical and community trials.

Controlled Trials

Controlled trials are epidemiological experiments designed to study an intervention (preventive or therapeutic). A clinical trial requires a random method of allocating the cases to the experimental or the control group, and then both groups are observed for change over time in relation to the condition being studied. Assignment to the treatment or the control group is by random selection. If the people in both the test and control groups do not know which group they are in, the study is called *blind*. If, in addition, the people judging the outcome are not aware whether the person tested is in the test or control group, the trial is called *double blind*. Furthermore, if those analyzing the data also do not know who was in each group, the study may be called *triple blind*. Blinding helps to avoid various biases which limit the value of a study. If the difference in outcomes is statistically significant for the control group and the treatment group, then the treatment is deemed to have been effective.

Although RCTs are considered the gold standard in clinical epidemiology, they are often not available for important policy issues and would be unethical to conduct because

denying the benefits of a known positive intervention would be unacceptable. They are also often difficult for policy-making generalization because of inherent limitations in the methodological limitations and resources available for the study.

Field Trials

Field trials follow people who are disease free in two groups, one with and one without a specific intervention, to determine whether the intervention affects the risk of developing the disease. They are often used to test new vaccines in susceptible populations. The field trial conducted by Jonas Salk of inactivated poliomyelitis vaccine in 1956 demonstrated its protective effect and safety in some 1.5 million American children, and the vaccine was subsequently adopted throughout the world. Field trials are part of the process of approval for new vaccines and medications.

There are many ethical traps in conducting such trials in developing countries without adequate transmission of information to subjects in field trials. Serious ethical breaches in such experiments are discussed in Chapters 4 and 15: the Tuskegee and Guatemala experiments with syphilis in the 1930s and 1940s stand as important warnings to overzealous research with inadequate protection and ethical clearance, as now required according to the Helsinki Declaration and more recent iterations of ethical standards in epidemiological research.

Community Trials

Community trials are conducted on whole communities to measure the effect of a risk factor or intervention. They cannot easily be randomized because the entire community is selected, and it may not be possible to isolate the community from changes going on in the general population. Community-based heart disease prevention programs have been undertaken in many settings, such as in North Karelia, Finland; in the USA, such as the Minnesota Heart Health Project, Pawtucket Heart Health Project in Rhode Island (CHAD project); in Kiryat Yovel, Jerusalem, Israel; and many others. These are difficult to evaluate, with a conflict between experimental design and community realities. Regional programs for prevention of heart disease cannot be isolated from time trends in the surrounding communities, limiting the interpretation of measured outcomes. Nevertheless, community trials are necessary in evaluating health interventions to reduce risks or adverse health outcomes. They often rely on performance or utilization indicators as proxies. For example, a village health worker program may lead to earlier and more frequent use of prenatal care or immunization coverage, but measurement of outcome variables may be hard to establish in field conditions, mainly because of a lack of reliable data.

ESTABLISHING CAUSAL RELATIONSHIPS

Classically, the search for causation in medicine and in public health is for the agent–host–vector relationship, with the agent being a specific causative organism. In infectious disease epidemiology, this has provided the scientific basis for immunology and control of vaccine-preventable diseases, and for sanitation to prevent transmission of foodborne and waterborne diseases. Criteria for attributing causation for communicable disease were established in the nineteenth century by Jacob Henle and Robert Koch (Box 3.19).

Criteria for causation include the strength of the association, biological plausibility, consistency with other investigations, and dose–response relationship. Biological plausibility is a test of the plausibility of a causal association based on existing biological or medical knowledge. Consistency with other investigations means that the findings are similar to those of other studies. The dose–response relationship is that in which a change in amount, intensity, or duration of exposure is associated with a change (increase or decrease) in a specified outcome.

Even in infectious disease control, the public health reality is often more complex than the single-causation model. TB deaths fell during the nineteenth century, presumably due to improved nutrition and living conditions, and were further reduced in the early part of the twentieth century before the antibiotic era by a combination of improved nutrition and symptomatic treatment. Mortality from measles dropped dramatically despite its endemicity (the continuing presence of a disease in a given geographic area) prior to the successful vaccine introduced in the 1960s. This can be attributed to rising standards of living and improved means of treatment of complications. Even today, the mortality rate from measles is seen to be affected by improving the nutrition of children and by vitamin A supplementation.

For NCDs, causation is even more clearly multifactorial, and a risk factor for one disease may also be a contributor to increased risk for another disease. Diet has been established as a major risk factor for coronary heart disease, as well as diabetes and hypertension. Diabetes is a major risk factor for coronary heart disease, stroke, renal, eye, and peripheral vascular disease. Nutrition is an important contributor to certain cancers, so that the multiple-factor causation of disease cannot be ignored.

Risk factors for disease are those aspects of personal behavior or lifestyle, occupational or environmental exposure, social and economic conditions, and inborn or inherited characteristics which, on the basis of epidemiological evidence, are known to be associated with health-related conditions considered important to prevent. Non-infectious diseases are often related to and exacerbated by a number of risk factors, so that measurement of the prevalence of risk factors, or intervening variables, is important to epidemiological assessment of the future risk of such diseases. The

BOX 3.19 Henle–Koch Postulates on Microorganisms as the Cause of Disease

- The organism (agent) must be shown to be present in every case of the disease and must be isolated, cultured, and identified.
- The organism must produce the disease when a pure culture is given to a susceptible animal.
- The organism must be recoverable from the animal.

Source: *Last JM, editor. A dictionary of epidemiology. 4th ed. New York: Oxford University Press, 2001.*

BOX 3.20 Criteria for Causation in Chronic Disease: The Evans Postulates

- Prevalence of the disease should be significantly higher in those exposed to the hypothesized cause than in controls not so exposed.
- Exposure to the hypothesized cause should be more frequent among those with the disease than in controls without the disease, when all other risk factors are held constant.
- Incidence of the disease should be significantly higher in those exposed to the hypothesized cause than in controls not so exposed, as shown by prospective studies.
- The disease should follow exposure to the hypothesized causative agent with a normal or log-normal distribution of incubation periods.
- A spectrum of host responses should follow exposure to the hypothesized agent along a logical biological gradient from mild to severe.
- A measurable host response following exposure to the hypothesized cause should have a high probability of appearing in those lacking this before exposure (e.g., antibody, cancer cell) or should increase in magnitude if present before exposure. This response pattern should occur infrequently in people not so exposed.
- Experimental reproduction of the disease should occur more frequently in animals or humans appropriately exposed to the hypothesized cause than in those not so exposed; this exposure may be deliberate in volunteers, experimentally induced in the laboratory, or may represent a regulation of a natural exposure.
- Elimination or modification of the hypothesized cause should decrease the incidence of the disease (e.g., attenuation of a virus, removal of tar from cigarettes).
- Prevention or modification of the host's response on exposure to the hypothesized cause should decrease or eliminate the disease (e.g., immunization, drugs to lower cholesterol, specific lymphocyte transfer factor in cancer).
- All of the relationships and findings should make biological and epidemiological sense.

Sources: *Evans AS. Causation and disease: the Henle–Koch postulates revisited. Yale J Biol Med 1976;49:175–95.*
Porta M, Greenland S, Last JM, editors. International Epidemiological Association. A dictionary of epidemiology. 5th ed. New York: Oxford University Press; 2008.

prevalence of smoking, as an example, may serve as an indicator of the future potential of lung cancer and CVD. BMI, blood pressure, and serum cholesterol levels measured in the community serve as indicators of risk for coronary heart disease (Box 3.20). These measurements indicate individual and community risk, and the potential effectiveness of health promotion programs.

NOTIFICATION OF DISEASES

Morbidity data are reported by doctors, usually based on compulsory reporting of specific infectious and non-infectious diseases. Some diseases such as plague, cholera, yellow fever, louseborne typhus, and louseborne relapsing fever are notifiable by international convention. Locally endemic diseases are notifiable under national and also state/provincial public health laws in order to monitor their prevalence and the impact of public health measures (see Chapter 4). Additional diseases reported routinely in other countries include waterborne and foodborne disease, chemical poisonings, botulism, leishmaniasis, septicemia, *Chlamydia trachomatis* (genital), gonococcal ophthalmia, and listeriosis. Other diseases or health events may be added to routine reporting (or to special surveys) according to endemic environmental conditions. Reporting of infectious diseases is one of the most important foundations of public health practice.

SPECIAL REGISTRIES AND REPORTING SYSTEMS

Special registries are used to establish a basis for the epidemiological study of vital health events pertinent to the population and clinical states important to population health. These include mandatory reporting and special registries and surveys. They are vital for monitoring the health of a population and providing epidemiological information to guide health policy, whether it is for an acute infectious disease challenge or a long-term chronic disease problem such as CVD or diabetes. The range of such reporting systems is necessarily very wide (Table 3.9), with recent additions including mandatory reporting of child and elder abuse. Priorities may vary from country to country, but the basic registry needs in health care include a range of conditions, including infectious diseases, cancer, birth defects, and hospital discharge information systems. Data from cancer, birth defect, and low birth weight registries can provide valuable clues about environmental exposures of public health importance.

Ideally, disease registries and reporting systems should be coordinated into unified health information systems. The USA has an effective network of such reporting systems, such as the Census Bureau, the Department of Health and

TABLE 3.9 Public Health Mandatory or Voluntary Reporting and Registries

Mandatory	Special Registries or Surveys
Vital events: birth, death, marriages, and divorces	Cancer registries
Notifiable infectious diseases, including STIs, HIV, and TB (see Chapter 4)	Chronic diseases registries
Birth weight and condition (Apgar score)	Neurological disorders registries
Birth defect registries	Diabetes registries
Congenital screening for PKU, hypothyroidism	Coronary heart disease
Abortions and other pregnancy events	Thalassemia
Hospital discharge information systems	Sickle cell disease
Battered children, partners/spouses	Mental illness – psychiatric conditions
Domestic violence and elder abuse	Nutritional status indicators surveys, e.g., NHANES
Motor vehicle accident injuries	Growth and development indicators
Air and water quality monitoring	Blind and partially sighted people
Environmental hazards and monitoring	Deaf and hearing impaired
Occupational safety and health hazards	Disability surveys
Animal disease monitoring	At-risk workers' groups
Vaccine and drug reactions	Behavioral risk factors surveys
Hospital infections and incident reports	Internet and news media obituaries
Poison control centers	Influenza – sentinel reporting centers
Injuries, trauma	Autism registries
Workers' compensation	Alzheimer's and other dementias
School absence	Toxic substance and poison control centers
Public health laboratories	Hazardous waste sites
Social security: Medicare, Medicaid, special categories (e.g., end-stage renal disease patients)	Psychiatric/mental health
Hospital discharge information systems	Cancer, leukemia, lymphoma, and transplant registries
Blood bank	Cystic fibrosis registries
Public health laboratories	Self-rated health status surveys
Veterinary public health surveillance	Sentinel sites for influenza reporting
Animal reservoirs and health	Behavioral risk factors surveys (e.g., smoking, teen pregnancies, car seat belt use)
Vaccine and drug reactions	Nutritional surveys (e.g., NHANES)
Hospital (nosocomial) infections	Growth and development indicators
Injuries	Health insurance systems utilization
Poisonings (e.g., poison control centers)	Performance indicators (e.g., GP immunization and preventive service coverage rates, hospital utilization)
Violence and trauma (i.e., emergency services)	

Note: STI = sexually transmitted infection; HIV = human immunodeficiency virus; TB = tuberculosis; PKU = phenylketonuria; NHANES = National Health and Nutrition Examination Survey; GP = general practitioner.

Roush S, Birkhead G, Koo D, Cobb A, Fleming D. Mandatory reporting of diseases and conditions by health care professionals and laboratories. JAMA 1999;282:164–70.

New York State Department of Health. Chronic Disease Registries; 1999. Available at: http://www.health.ny.gov/diseases/chronic/diseaser.htm [Accessed 11 January 2013].

Sources: Adapted from Declich S, Carter AO. Public health surveillance: historical origins, methods and evaluation. Bull World Health Organ 1994;72: 285–304.

Human Services, state health departments, and the CDC, which has a variety of surveillance systems and a regular weekly publication with periodic special reports on special surveys and routine reports of disease incidence and prevalence. Individual identification numbers, such as Social Security numbers, for each member of the population enable the use of data from related special registries. However, protective measures must be in place to ensure privacy and to prevent the misuse of these data for unethical purposes. Safeguard mechanisms can be built into data systems to protect the privacy of the individual. This is a particular problem in the USA, which has a large unregistered immigrant population, many of whom receive services from public programs, but who may be put in jeopardy by the threat of possible deportation by federal immigration authorities.

Linkages among data sets allow important epidemiological correlations to be studied. For example, linking data sets for cancer registries, vital records, pollution indicators, and hospital discharge information systems may enhance the investigation of specific medical conditions, such as monitoring longevity and hospital use for childhood cancer. Such links may also be used to compare morbidity and mortality patterns for specific conditions by comparing hospitalizations with mortality patterns.

A study by the Department of Health, based on an observation from routine death reports of 32 infant deaths in New York State over a 10 year period, found that none of the 24 hospitals where these deaths occurred had standing orders for vitamin K injection at birth, as recommended by the American Academy of Pediatrics since 1961. The Commissioner of Health initiated a decision by the State Board of Health for the adoption of mandatory vitamin K by injection as a routine for newborns. This was gradually adopted by all states and there are now zero deaths in the USA from Vitamin K Deficiency Bleeding (VKDB) previously known as Hemmorhagic Disease of the Newborn (HDN).

Mandatory care in most states now includes vitamin K along with antibiotic eye care and heel blood for newborn screening for phenylketonuria (PKU), congenital hypothyroidism, sickle-cell anemia, and many other inborn errors of metabolism to prevent Vitamin K Deficiency Bleeding (VKDB) (see Chapter 6 and Box 3.21). Birth defect registries are very important as there are many preventive interventions that can reduce birth defects, such as folic acid fortification, reduction of low birth weight in newborns, and intervention in cases of social deprivation associated with low education and social support for young single mothers. Monitoring the incidence of new cases and rates will help in evaluation of the effectiveness of interventions such as folic acid supplements before pregnancy and fortification of flour with folic acid (see Chapters 6 and 8).

The importance of records linkage may also be demonstrated by the following epidemiological example. Mortality from CVD has fallen dramatically in industrialized countries since its peak in the early 1960s. This decrease can be attributed to many factors, including changes in nutrition, smoking, and other risk factors, but also to improved medical care for hypertension and for acute coronary events, as well as long-term cardiac rehabilitation and care. The prevalence of the basic disease process may not have declined, but primary and secondary prevention is much improved. Studies linking hospitalization patterns with preventive action such as smoking education laws and CFRs for CVDs are helping to provide support for prevention and new modalities of care.

BOX 3.21 Identification of Vitamin K Deficiency Bleeding (VKDB) in a Review of Vital Records and Follow-Up Study in New York State

Studies of vital statistics registries may raise epidemiological questions or hypotheses for further investigation. Special surveys become important as the follow-up to initial findings. Intervention can then be planned on the basis of these investigations. An example review of vital statistics in New York State (1987) showed 32 infant deaths reported during the 1980s attributed to Vitamin K Deficiency Bleeding (VKDB), then called Hemorrhagic Disease of Newborne (HDN), a disease preventable by prophylactic vitamin K injections of newborns.

A study of the State Hospital Discharge Information system showed a substantial number of hospital discharges with the diagnosis of HDN (first to fourth diagnosis) during the same period. A case record review conducted of infant deaths with VKDB, then known as Hemorrhagic Disease of Newborn (HDN) as a diagnosis (first to fourth diagnosis). Two-thirds of the cases did not receive vitamin K at all, or not until after bleeding had already begun. None of the 22 hospitals in which these cases occurred had standing orders for vitamin K injections for newborns. Up to that time, five states had mandatory vitamin K requirements for newborns and is standard practice since first recommended by the American Academy of Pediatrics in 1961.

As a result, the New York State Department of Health adopted mandatory vitamin K prophylaxis for newborns. Record linkage between hospitalization data and the individual cases would have made such a study more readily achievable. This study led to adoption of mandatory vitamin K injection for all infants in New York State and subsequently in all US states. No cases of mortality from this condition were reported in 2011 and 2012. In 2013, 4 cases of late VKDB were reported in a childrens' hospital in Tennessee due to mothers refusal to give vitamin K to their newborns. Three of these children had intracranial hemorrhages. Vitamin K is not standard international recommended care for newborns.

Source: *Tulchinsky TH, Patton MM, Randolph LA, Meyer MR, Linden JV. Mandating vitamin K prophylaxis for newborns in New York State. Am J Public Health 1993;83:1166–8.*
Zipursky A. Prevention of vitamin K deficiency bleeding in newborns. Br J Haematol 1999;104:430–7.

DISEASE CLASSIFICATION

Because comparative statistics are vital in monitoring the health status of a population, it has been essential to develop internationally accepted standard nomenclature and a coding system in order to minimize differences in classification. The Bills of Mortality used in the seventeenth century defined 17 categories. Classification of disease by anatomic site or body system was initiated by William Farr at the Second International Statistical Congress in Paris in 1855.

After World War I, the League of Nations supervised revisions of the *International Classification of Diseases* (ICD), and since the 1948 sixth revision, the ICD has been updated at approximately 10-year intervals by the WHO. The tenth revision of the *International Classification of Diseases* (ICD-10) came into general use in 1993. The classification is broken down into many subcategories with coding to indicate precise disease and procedure groups (see Table 3.10 on the companion web site at http://booksite.elsevier.com/9780124157668). Similarly, a classification of mental health disorders has been developed (see Chapter 7).

HOSPITAL DISCHARGE INFORMATION

Admission to a hospital is a major medical event, no less important from an epidemiological point of view than the reporting of a death or an infectious disease. A hospital discharge data system is an informational, planning, budgeting, epidemiological, and quality control tool in modern health care. It involves gathering a basic data set on all hospital discharges, input of data into a central file on a regular basis, and processing the data for administrative and epidemiological purposes. This process requires a basic data retrieval form for all hospitalized patients and a system of reporting and analysis, preferably with computerized data retrieval.

Hospital statistics were originally promoted by Florence Nightingale in the nineteenth century as essential to improve outcomes of care. The Uniform Hospital Discharge Information System (UHDIS) evolved as a result of the growing recognition of the importance of hospital utilization in the economics of health care (Box 3.22). Introduced in the 1960s by the US National Center for Health Statistics (NCHS), it provided the basis for the development of diagnosis-related groups (DRGs), which have become the

BOX 3.22 Hospital Discharge Information Systems

- *Planning* – organizing based on admission and surgical rates, utilization by age and gender, diagnosis, length of stay, and "small area analysis" which compares practice patterns and use or excess and waste of resources; search for new methods to promote patient flow to alternative care facilities (e.g., minimal supervisory residential care, ambulatory, or home care).
- *Case-mix analysis* – make-up of the hospital case load, looking for common diagnoses or rare events which might be of epidemiological significance, or may have administrative and quality control importance. Case mix has become part of payment systems for hospital care in the USA and other countries.
- *Budgeting* – planning within the hospital and in relation to referral sources based on utilization patterns by diagnosis and department.
- *Quality of care monitoring* – determination of aberrant practice, complications, or outcomes (e.g., excess surgical rates, infections, mortality). Organisation for Economic Development and Cooperation (OECD) includes many measures of hospitalization as quality of care measures, including in-hospital case fatality rates for myocardial infarction, strokes, and cancer of the colon, and avoidable hospital admissions for asthma and asthma mortality rates.
- *Epidemiology* – tracing and mapping epidemics of communicable diseases and identifying localizations and sources; using "tracer conditions" to pick out medically and epidemiologically significant events such as strokes or diabetes mellitus; supplementing international, national, or regional mortality data.
- *Research* – through case finding of particular clinical events which may then be analyzed for related variables (e.g., incidence of coronary heart disease to compare with mortality patterns, intracranial hemorrhages, and administration of prophylactic vitamin K to newborns, or follow-up of patients with coronary artery bypass procedures).
- *Linkage with other registries* – linkage with death records, cancer, birth defects, or other special disease registries; relating hospitalization events to special disease registries, such as birth defects, cystic fibrosis, asbestosis, and mesothelioma; supplementing a cancer registry.
- *Economic analysis* – this is an essential aspect of modern health care and the use of hospital care and its alternatives, central to health economics; linked data from various registries and hospitalization data can provide data for important cost-effectiveness and other economic planning models.

Sources: *Dennison C, Pokras R. Design and operation of the National Hospital Discharge Survey: 1988 redesign. Vital Health Stat 2000;1(39). Organisation for Economic Co-operation and Development. Health policies and data: OECD health data 2012 – frequently requested data. October 2012. Available at: http://www.oecd.org/els/healthpoliciesanddata/oecd-healthdata2012-frequentlyrequesteddata.htm [Accessed 11 January 2013]. Centers for Disease Control and Prevention/National Center for Health Statistics. National Hospital Discharge Survey. 16 October 2012. Available at: http://www.cdc.gov/nchs/nhds.htm [Accessed 11 January 2013]. Department of Health and Human Services, Centers for Medicare & Medicaid Services. Federal Register, 11 May 2012. 42 CFR Parts 412, 413, 424, et al. Medicare Program; Hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and fiscal year 2013 rates; Hospitals' resident caps for graduate medical education payment purposes; Quality reporting requirements for specific providers and for ambulatory surgical centers; Proposed rule; 77(92):1–324.*

major mode of payment for hospitals in the USA and in some other countries since the 1980s. Use of the ICD allows for comparisons among data sets, regions, and countries. The National Hospital Discharge Survey (NHDS) was conducted annually from 1965 to 2010, using a national probability survey of 500 and later 239 US hospitals. It provides information on characteristics of inpatients discharged from acute-care short-stay hospitals to examine important topics of interest in public health (NHDS/NHCS, 2012). A central governmental professional unit is needed at the state level to plan, train, and supervise data retrieval, and to process and interpret the output data. Data provided by all hospitals provide a complete picture of the entire population using all hospital services, rather than just those services provided by an individual hospital in the region. This is necessary, as people residing in a hospital catchment area may be hospitalized in another region by referral or for emergency care.

Developing countries need assistance in developing basic registration systems of births, deaths, and other vital events. The WHO estimates that tens of millions of such events occur annually without registration or reporting. At the same time, the understaffed primary care services compile daily records with large amounts of indigestible data on ambulatory care utilization. Scarce financial and personnel resources should instead be focused on more significant and higher quality data associated with hospitalizations. Fewer centers are involved in hospital care than in ambulatory care, so that data retrieval is easier to control. Most importantly, the less common event of hospitalization is medically and epidemiologically more significant because it consumes 40–75 percent of health care financing. A UHDIS may be seen as a priority information system after the reporting of infectious diseases, mortality, cancer, and birth defects.

The three primary users of information flow in a hospital information system are clinical medicine, epidemiology, and managerial services. However, much of the development of information systems in recent years has been for managerial purposes. Good data should be easy to interpret for managers and clinicians alike. This requires informatics staff (knowledgeable of modern technology) to tailor the data reporting method so that the manager and others can analyze the data for their needs. The data should be in a manageable format and training should be provided for users of the system.

Hospital discharge provides a basis for epidemiological monitoring and control of diseases and simple research information. Analysis of hospital discharge data, especially mortality, surgical complications, and excessive length of stay, provides important indicators of efficiency and quality of care. Interregional variations in hospital utilization provide a clear premise for designing and implementing policies. With the increasing use of surgery, cancer care, and other medical care on an outpatient basis or with endoscopic methods, long lengths of stay in hospital are unjustified from both the patient welfare and economic points of view, which are important to the health insurance or health service system (Box 3.22).

Hospital discharge data studies permit case-mix studies, reveal trends in care patterns and patient safety conditions, and provide a basis for peer review within a hospital and between hospitals. They provide material for analysis and policy formation at the clinical level, as well as for hospital management and planning; for example, in the development of ambulatory care, reducing admissions and length of stay for services better provided on an outpatient basis.

The number of hospitalizations is reducing over the years, with rates varying by age group. Limitations of the data include factors such as lack of standardization of diagnostic criteria. Some patients do not reach a hospital, for economic or other reasons; they may have transportation problems, or may have died prior to admission. Others may be unaware of the existence of some health services or are simply afraid of them. Moreover, the denominator for rates is missing because the hospitals may not have a defined catchment population. Nevertheless, hospital discharge information is an important tool for planning, monitoring, and evaluating health services (Box 3.22).

Vast numbers of people use ambulatory care, generating too large a data set for effective monitoring. The number of ambulatory care visits may range from four to 10 per person per year, depending on the country. Ambulatory care data are of poorer quality because they are usually in broad categories of diagnosis, such as musculoskeletal and respiratory complaints, which comprise the bulk of visits. Ambulatory care can be monitored selectively through sampling or monitoring of representative sentinel centers to provide examples for wider replication. Specific components of ambulatory care should be monitored, such as infants and school-age children receiving immunizations, attendance for prenatal care, birth control services, screening for hypertension and diabetes, or breast cancer screening, as particular health goals. With increasing trends for ambulatory care surgery and medical care, linkage of such data with inpatient care is needed to ensure continuity of comparisons with previous patterns of care.

HEALTH INFORMATION SYSTEMS (INFORMATICS)

Information is needed for the management of any health system. It is vital to establishing objectives, developing programs, and managing the use of resources. Modern information technology, or informatics, provides the tools for analysis and policy formation to adjust the service. Informatics is as much a part of health care as the cardiograph or ultrasound machines. It provides the feedback, “imaging”, or cybernetics potential for management.

Dissemination of information is no less vital than its collection or interpretation in central offices. Reporting of vital

data is meaningless unless the data are processed and fed back to the service system in a regular, timely, and usable fashion or, in current computer terminology, in a user-friendly manner. Modern health information monitors the operation of a health care system, including component parts such as objects (hospital buildings), people (health personnel), services, policy (equity), finance, organization, administration, regulation, quality assurance, and health promotion. The component parts interact to support the system as a whole. Interaction is made possible through information and communications technology and driven by financing and organizational imperatives.

Health care services are a source of increasing expense to governments and individuals. As a result, governments throughout the world are recognizing the importance of health information for effective health services management and planning. The requirement for public accountability has led to the design of policies to ensure appropriate quantity, quality, and effectiveness of care with the best use of resources. This has created substantial requirements for information.

Public health informatics is the systematic application of information and computer science to clinical and public health practice, research, and learning. It includes the use of computerized medical and hospital records, the use of clinical and preventive care guidelines, and disease registry information retrieval.

Each country must develop its own health information system and uniform health information systems, such as that developed by the WHO European Region (Box 3.23). This system provides a timely (current or real-time) spectrum of vital statistics, demography, and key outcome measures, as well as data on health care resources and utilization. Each country should provide local, district, community or municipal, and regional health profiles. This information should be widely distributed and available for analysis and discussion to the media, the public, and health professionals. Data are of little value if locked away and unavailable for regular circulation and dissemination to a wide audience, who require this information in order to make an informed contribution to policy analysis and formation.

BOX 3.23 Functions of Health Information Systems

- *Monitoring* – of the health status of a population.
- *Comparisons* – using historical, regional, national, or international patterns and standards.
- *Assessment* – an overview of the health status of a population based on available data, the professional literature, field visits, and interviews with key health personnel and community representatives.
- *Evaluation* – monitoring use of resources, performance, and outcomes of programs as part of total quality management.
- *Prediction* – using current data to predict trends in disease ("modeling") and utilization patterns, costs, potential outcomes, program planning, policy formulation, and setting priorities.
- *Explanation* – data to understand disease patterns, risk factors, and service utilization of a population of a district and determine causal relations, or need for intervention.
- *Planning* – data are needed for planning responses to public health problems and monitoring the outcomes of interventions.
- *Payment systems* – diagnosis-related groups (DRGs) and case-mix systems of payment are now used widely in the USA and elsewhere to provide incentives for efficiency in care and short stay in hospital. This requires good home care and ambulatory care in hospital and in primary care settings.
- *Adaptation* – as new technologies (e.g., laparoscopy and robotic surgery) increase the effectiveness of care, hospital care patterns change; as science advances (e.g., discovery of *Helicobacter* as the cause of chronic peptic ulcer disease), much of the surgery done in previous decades is no longer performed.
- *Quality improvement* – early response to index cases of infectious diseases provides information critical to rapid response and management of longstanding diseases that recur, e.g., diphtheria after decades of its control, or new entities such as HIV in the 1980s, and many examples since. Patients in health care facilities are at risk of serious hospital-acquired infections or human error which cost many lives each year and prolong hospital stay. Monitoring and preventive systems help to avert these issues.

Precision is limited by the quality of the data, but even limited data are extremely important in epidemiology and for health planning. Some infectious diseases are reported less stringently than others, partly because of lesser concern by physicians, but also because the clinical presentation may be atypical, or some cases may be entirely subclinical. A clinical case of poliomyelitis may represent 100 subclinical cases. Many infectious diseases of public health importance (e.g., measles, rubella) are underreported because non-immunized, vulnerable children may not be brought to medical care despite mandatory reporting requirements, while some reported cases are unconfirmed by laboratory evidence. Nevertheless, reported cases are the basis for monitoring and policy formation. Awareness of the direction and magnitude of errors will enable the user to determine the validity of the data.

Making health information data available on a routine basis to providers and managers of services helps to promote an awareness of the overall operation of the health system in which they are involved. Information provides the basis for accountability, which implies that the provider of care or the manager of a health system is responsible for and must report on the results of his or her work, including unintended outcomes. Any system of service requires a system of

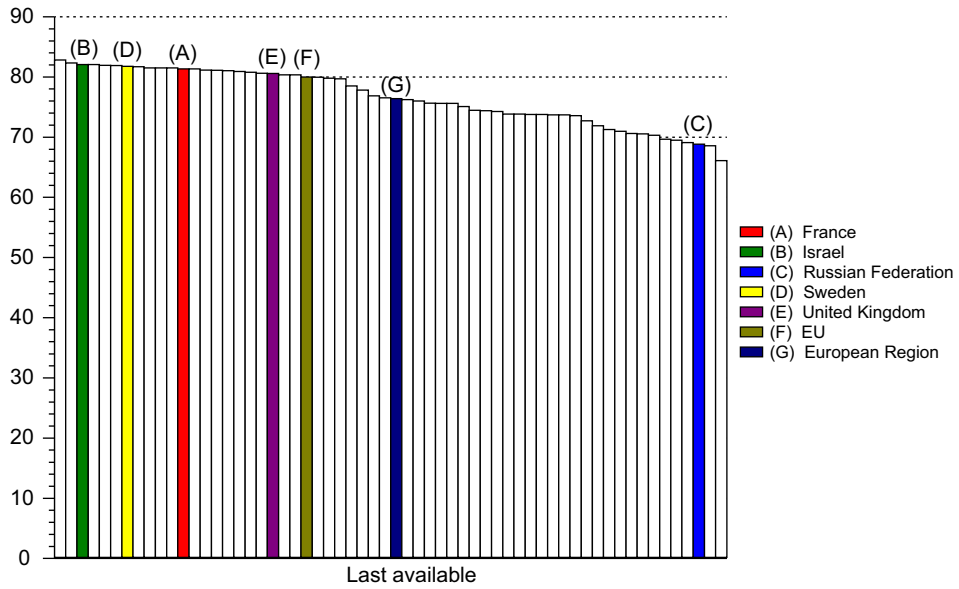

FIGURE 3.13 Life expectancy at birth, European Region, 1970 to 2010–2011. *Source: World Health Organization, European Region. Health for All database; July 2012. Available at: http://data.euro.who.int/hfadb/ [Accessed 2 February 2013].*

accountability in order to maintain standards and to provide the consumer with an assurance of quality care.

In a centrally managed system, reporting of services provided is part of the chain of command. In a decentralized system, such data may be derived from billing patterns from hospitals or physician payments. They are then transferred to the higher levels of the health service administration and used for decision making and planning. Those who provide the data should be informed of the outcome, including resultant operational decisions.

The United Nations Statistics Division is the primary agency responsible at the international level for collecting official national statistics related to population size and structure, birth, death, migration and social concerns globally, with updated country reports. The WHO Technical Committee on Information Systems emphasizes that the more active and innovative a health policy, the greater the need for information. Data collection and processing require planning, training, and continuing monitoring. While massive data banks are not helpful, well-selected and widely available information systems targeted to vital events in the health process can promote flexibility and relevance in the planning of health services. Other international organizations maintain vital statistics and socioeconomic data systems with regular reporting available online; these include the United Nations Children's Fund (UNICEF), the Organisation for Economic Co-operation and Development (OECD), the United Nations Development Programme (UNDP), US Census Bureau International, the European Union (EU), and regional offices of the WHO (Africa, the Americas, South-East Asia, Europe, Eastern Mediterranean, and Western Pacific).

WHO European Region Health for All Database

The WHO European Region makes available an outstanding database as a free service. It provides some 500 health indicators for all countries in the European region of WHO and is updated twice yearly. It can be accessed at http://www.euro.who.int/ under Publications and Data. It can be downloaded to a computer and unzipped to provide continuous access to up-to-date data on demographics, mortality, morbidity, lifestyle, resources, and utilization data, and presented as time trends or single-year comparisons of all countries in the region or as a single-year map. It is excellent for teaching purposes and the graphs and data can be downloaded to Microsoft PowerPoint or Word documents. An example is shown in Figure 3.13, which compares life expectancy at birth in 2010–2011 in all countries in the European Region of WHO and indicates selected countries (France, Israel, Russia, Sweden, the UK, EU member states, and the European average).

SURVEILLANCE, REPORTING, AND PUBLICATION

The publication and wide distribution of weekly summaries of specified reportable diseases are essential to maintain the viability of reporting and promote meaningful use of the data (Box 3.24). The CDC of the US Public Health Service publishes and widely distributes the *Morbidity and Mortality Weekly Report* (MMWR), reporting on national and international epidemiological events through surveys and special reports. The weekly report is supplemented by in-depth special reviews of important public health topics.

BOX 3.24 Factors Affecting the Value of Data

- *Relevancy* – Are the right data being collected? Are some data no longer useful?
- *Coverage* – Do the data help to identify high-risk groups?
- *Quality* – How good do data need to be to be useful? Limitations of data are a factor in decision making.
- *Acceptability* – Are the data collected acceptable in terms of design, cost, and ethical standards?
- *Timeliness* – How recent are the data? How long a time-series is needed to show temporal patterns?
- *Accessibility* – Are the data available to those who need them? Are the data suitable for publication? Are they published and distributed on the Internet and hard copy?
- *Usability* – Are the data in a usable format? Are they presented in a user-friendly manner (i.e., easy to access and use for non-specialists)? Can one generate summaries, graphs, and tabulations from the data?
- *Cost* – What does it cost to collect and process the data? Are the data available to students and researchers without prohibitive cost?
- *Validity* – To what extent do the data relate to the issue of concern?
- *Specificity and sensitivity* – Were the raw data collected using accurate measures (i.e., measures with a high capacity of detecting actual cases and determining non-cases as such)?
- *Data aggregation and reporting* – Are data reported by disease, category of service, social indicators, and region of residence? What is the population at risk?
- *Biological plausibility* – Is the observed or presumed causal association compatible with existing biological and medical science? Can it be explained from a biological perspective?
- *Equity* – Do the data show interregional and social class variation and inequity?
- *Dissemination* – Information obtained, collated, and analyzed must be organized and available to those who report the raw data, who need data to monitor health status, and who plan health services and health promotion needs of the population.

Source: *Last JM. A dictionary of public health. New York: Oxford University Press; 2007.*

The Department of Health and Human Services and Census Bureau publish frequent topical reports, as do the Agency for Healthcare Research and Quality and other agencies of government. The WHO publishes the *Weekly Epidemiological Record* (WER), which reports global, regional, and country epidemiological events and offers highly professional reviews of selected topics of infectious diseases internationally. *Eurosurveillance* is published by the European Center for Disease Prevention and Control, based in Stockholm and sponsored by the EU, and monitors infectious disease events in the EU and potential candidate countries. The OECD, UNICEF, and UNDP publish annual reports of high importance for the field of public health. The UNDP annual reports on progress in MDGs overall and by country are an important source of health-related data.

The UK Health Protection Agency publishes regular reports on infectious diseases and a wide variety of environmental and other publications of public health importance. Ministries of health often use online reporting and publication to keep the flow of information available to public health practitioners. The Public Health Agency of Canada publishes *Canada Communicable Disease Report*, as well as *Chronic Diseases and Injuries in Canada* for non-infectious diseases and related laboratory findings, in addition to Statistics Canada publishing annual updates on important economic, environmental health, and other databases. Many countries publish similar bulletins and annual reports vital to following trends in health status of their populations.

Reporting systems and publication of the data are both vital to epidemiological monitoring of infectious and non-infectious disease trends. Regular circulation to field personnel increases the sense of awareness and participation in epidemiological monitoring and shows that the reporting is put to good use. Awareness of the reported data helps local health providers and managers in managing their services more effectively (Box 3.25).

Providing ready access to historical and current data as the events unfold is vital to promote a sense of involvement and challenge for the achievement of goals, such as high coverage of immunization and rapid control of disease outbreaks. Linking data sets such as for hospitalization and ambulatory care with mortality data provides important material for studies of the health impact of interventions with comparison groups. One challenge in managing health systems is to monitor population health by linking multiple factors. Studying the impact of health promotion activities such as those of community health workers can provide a rationale for introducing new approaches to community health to improve patient education for diabetics, smokers, or young people at risk for intravenous drug use and suicide. Macrostudies into natural changes in the socioeconomic and physical environment include investigations assessing the impact of economic change on air pollution in California over the period 1980–2000 by linking multiple data sets (Davis, 2012), and monitoring complications from influenza vaccinations by studying Medicare claims (Burwen et al., 2012). Internet surveys of physicians can help researchers to understand doctors' attitudes to immunization for influenza or managing hypertension and help to elucidate quality of care with outcome data.

The Internet is clearly an essential tool for public health, for reporting and obtaining data, and for access to the world literature. Many resources such as the MMWR, WER, and *Eurosurveillance*, as well as major journals, are available online free, at least as abstracts and as full articles for some publications (Public Health Reviews at www.publichealthreviews.eu). CDC

BOX 3.25 Evidence- and Best Practice-Based Public Health

Evidence-based evaluation of policies to improve health and reduce inequalities, prioritization, and providing resources for these policies requires four basic types of information:

- a detailed assessment of the magnitude and impact of health problems in the population, including information on the causes of loss of health in the population in terms of both diseases and injury, and risk factors or broader determinants
- information on health expenditure and health infrastructure (a national system of health accounts) detailing the availability of resources for health improvement and what the resources are currently used for
- information on the cost-effectiveness of available technologies and strategies for improving health
- information on inequalities in health status, health determinants, and access to and use of health services (including both prevention and treatment services).

Performance-based measures have become essential elements of public health policy and implementation strategies. These are generally based on professional consensus criteria determined by Delphi methods of consultation. These may be translated into "gold standards" and health targets. They may be used for performance monitoring and indeed administrative payment systems to encourage their complete implementation. Examples of performance indicators for payment include immunization coverage, Pap smears, and mammograms for patients registered with British general practitioners.

The concept of health targets has become an essential element of US public health policy with *Healthy People 2020* at the federal level with state compliance with such measures. When reviewing policy issues in public health, currently accepted practices used in other countries with recognized stature in this field should be taken into account, as well as recommendations by respected international health agencies such as WHO, UNICEF, and others.

Source: *Brownson RC, Fielding JE, Maylahn CM. Evidence-based public health: a fundamental concept for public health practice. Annu Rev Public Health 2009;30:175–201. http://dx.doi.org/10.1146/annurev.publhealth.031308.100134.*

provides regular and special reports, as do WHO, UNICEF, UNDP, EU, OECD, and other international agencies. These are available online, free of charge. Newsgroups enable convenient and immediate discussions by professionals on particular topics, such as Promed for almost daily current infectious disease reporting from around the world (see Chapter 4). Similarly, the Internet permits literature searches and access to interest groups on virtually any topic in health. This allows people to be in contact with and to obtain support from many others in their field. The WHO home page (http://www.who.int/en/) provides access to its component departments and regional offices.

BOX 3.26 Assessing the Health Status of the Individual

- Current chief complaint
- Personal data – age, gender, ethnicity, education, marital status, children, living situation
- Occupational history
- Family history
- Personal history
- Functional inquiry – systems review
- Summary of risk factors – family history, hypertension, diabetes, smoking, sedentary lifestyle, high-fat diet, occupation, alcohol use, stress, other
- History of the present illness
- Physical examination
- Differential diagnosis
- Other medical problems
- Investigation: laboratory, cardiographic, imaging, other
- Presumptive or working diagnosis
- Treatment and its effects
- Definitive diagnosis
- Management of other medical problems
- Follow-up management and monitoring
- Counseling regarding long-term health needs

ASSESSING THE HEALTH OF THE INDIVIDUAL

Physicians and other health professionals are trained to assess the health of the individual patient seeking care (Box 3.26). This involves more than dealing with the chief complaint, requiring a history of the present illness, as well as a wider review of body functions, family and occupational history, physical examination, and laboratory and imaging tests.

Defining a differential diagnosis and treatment for a presumptive diagnosis allows for follow-up of a patient to observe the course of the disease, the outcomes of diagnostic tests, and the effects of intervention. Caregivers must take into account the effects of the process on the patient, the family, and the community. Providers must also be concerned about costs of care, alternative methods of looking after the patient to meet changing needs, and promoting early and maximum recovery. Continuous monitoring and re-evaluation are key parts of the process. There are many parallels in care of the individual and care of the population.

ASSESSMENT OF POPULATION HEALTH

Health service administration is being increasingly decentralized in many countries, and the concept of healthy cities/municipalities is becoming more widespread. These developments have increased the need for and value of health profiles at the community, county, and district levels. This type of health profile provides management with regular monitoring of the health situation, including resources, utilization, morbidity, and mortality. This application of

modern health informatics at a community level does not require advanced computer capacity or skills. Annual reports in a standard format using all existing data sources can be brought together in a user-friendly manner to provide valuable health status monitoring.

District or community health information systems increase the potential for local health authorities and communities to have greater power in determining local health policy. National health authorities need to provide guidance on health targets and resources that may be used flexibly to meet local needs. But supervision and regulation by national health authorities are essential to ensure that resources are well used and that targets are being met, as well as to reduce inequalities between regions.

The WHO European Region has developed a user-friendly computer program for 1000 health indicators, including sociodemographic, mortality, morbidity, health resources, utilization, and lifestyle indicators. These can readily be produced in tabular or graphic form with time trends and mapping capability. The program is accessible free of charge to anyone with a personal computer, Internet access, and modest computer skills via http://www.euro.who.int/hfadb.

As with individual health assessment, evaluation of the health status of a population is based on the accumulation of a portfolio of observations and data from a variety of sources and their interpretation, with comparisons to international, national, or regional patterns or standards. Community health assessment (CHA) begins with identification of the main health problems or chief complaints as understood by key health professionals and the community, or from regular community health profiles.

Information should be derived about the community's SES, the resources available for health care, how they are distributed, and how services are utilized, as well as morbidity, mortality, and other "outcome" measures that help to describe or compare health status (Table 3.11). Health measures include how care is provided, how it governs or monitors itself, and how the system is accountable for its component services. The knowledge, attitudes, beliefs, and practices (KABP) of the people and health providers and the way in which society addresses risk factors for ill-health may also be important determinants of health status.

Gathering the data necessary for monitoring the system itself should be part of the standard functions of a health system. This provides for accountability in use of public resources and maintains a self-correcting feature of the system. CHAs help to point out health risk factors at the population level, and if carried out in a timely and regular fashion, changes can be made without inordinately long waiting periods and without any unnecessary increase in morbidity or mortality.

The CHA is part of the health planning process; it may be designed to monitor the impact of an intervention program meant to deal with a particular health problem, such as coronary heart disease, or a set of risk factors for disease, such as smoking. The CHA is also part of program evaluation, especially in community trials, with an evaluation protocol based on a multiphasic approach and data from many sources.

Defining the Population

The population served by a health system must be defined in terms of age and gender distribution. This is one of the key factors in the planning of health care services, as different age groups have different needs. Women, children, and the elderly utilize more health services and institutional care than the population in general. The demographic pyramid is an excellent graphic summary of the population distribution. The health status of elderly people is affected by the major chronic diseases and the associated disability and mortality patterns. While increasing longevity is associated with a healthier elderly population, the demand for care still grows with age. The elderly, and increasingly the very elderly (those over 85), are high users of health services, including institutional care in hospitals and long-term facilities.

Socioeconomic Status

Health is affected by standards of living and therefore analysis of income and its distribution is a component of the process of assessing the health status of a population. The national average income is often represented by the gross national product (GNP) or gross domestic product (GDP) per capita; for instance, the average of the total production of goods and services of a nation. Real income may vary by state or district, ethnic group, educational levels, gender, or family size. These and many other factors may affect the distribution of wealth in the population.

Living conditions as reflected in housing standards, density of housing, and crowding (people per room or per square meter) are dependent on family income. Services, such as electricity, running water, indoor toilet and bathing facilities, as well as other service facilities in the home (e.g., refrigerators, toilets, baths, stoves, central heating and air conditioning), are also important measures of health-related socioeconomic conditions. Adverse economic conditions prejudice health status in measurable ways. In developing countries, the poverty–disease–malnutrition cycle affects children, women, and the elderly predominantly, reducing potential for economic growth. Even in industrialized countries, there is unevenness in the patterns of income and of health status; the health status of the upper social class is much better than that of the unskilled workers for many health indicators. Where there are large gaps between the rich and the poor, such as in the USA, there is poorer health status than in countries with smaller social gaps, such as Japan and the Scandinavian countries.

Educational level of parents is an important factor in family health. In the case of the father in a family, level of

TABLE 3.11 Evaluation of Population Health of a Community, District, State, or Country

Factor	Topics	Example Indicators
Geography	Climate, topography, density, urban/rural	Tropical, temperate, mountainous, desert, distance from medical facilities
Demography	Vital statistics	Population size, age/gender, urban/rural
Socioeconomic	Ethnic, cultural, religious practices Community, family economic status	Per capita and family income, education, literacy (women), employment, religious affiliation, social attitudes, occupations
Nutrition	Supply, affordability, use of major food groups Food safety and quality Food fortification	Undernutrition and overnutrition Risk group identification Monitoring child growth patterns, anemia
Environment and occupational	Water, air, waste and sewage disposal, toxic wastes, radiological hazards Industrial or agricultural toxic materials	Ambient air pollutants, bacteriological and chemical qualities of community and recreational water, radiation and radon levels, lead levels in soil, water
Public health infrastructure	Organization, training and deployment of public health functions and personnel	Legal and regulatory functions Schools of public health Research capacity in epidemiology, public health
Health care system	Organization Prepaid coverage Finance total and internal allocation	Decentralized administration and finances Integration of local services and finances Total resources; % GNP and per capita (US $) spent on health care; % population with full, partial, or no health benefit insurance
Health resources	Expenditures per capita Hospital beds per capita Long-term care facilities Clinics Personnel, doctors, nurses per capita	Expenditure by type of service, preventive, curative, hospital Acute care beds per 1000 population Special hospital beds per 1000 population Long-term care facilities per 1000 population Doctors and nurses per 1000 population
Community and home care	Post and pre hospital care at home Outreach services to chronically ill Day centers for elderly and handicapped Patient guidance for individuals and groups	Diabetics
Health care utilization	Hospitals, general, chronic, and mental Ambulatory care Preventive services	Admissions and days of care per 1000 population Physician visits per person per year Immunization coverage at age 2 years Ambulatory surgery, home care measures
Process (quality) of care	Professional care standards Accreditation by external agency Peer-review mechanisms Records review Mortality case review Clinical guidelines	Criteria for surgery, second opinion Immunization and child health monitoring rates Correction of deficiencies from accreditation Departmental reviews of caesarean, infection rates Maternal and infant mortality case by case reviews Computerized medical records
Health outcomes	Morbidity Mortality Functional/physiological status "Tracer conditions" – common, treatable or preventable diseases to indicate system failure	Infectious and chronic disease incidence/prevalence Infant, child, maternal, age–gender-specific mortality rates by cause, cardiovascular disease, trauma Anemia of infancy, pregnancy, blood lead levels Lower limb amputation rates
Costs and benefits	Examine specific diseases, procedures, services or health promotion	Cost–benefit of second dose of measles vaccine, bicycle helmets, air bags in cars, antismoking campaigns, e.g., smoking among teenagers
Knowledge, attitude, beliefs, practices (KABP)	General population Risk groups Patients Patients' families Health providers	Diet, smoking, eating, moderate alcohol use, exercise Diabetes, hypertension Birth control, rights of women AIDS/STI-related issues

Note: GNP = gross national product; AIDS = acquired immunodeficiency syndrome; STI = sexually transmitted infection.

education is often a direct determinant of income. In the case of the mother, education relates to income, but even more strongly to successful health care of infants and children. Mothers with higher levels of education, as measured by years of school attendance, are more likely to absorb new knowledge regarding self-care in pregnancy and care of the infant in areas such as nutrition, immunization, and routine baby care. Better educated women tend to have fewer pregnancies, not only because of knowledge of the need for and methods of birth control, but also because of greater self-awareness and different life goals. Ethnic, cultural, political, and religious beliefs and practices have important implications for health, in such areas as the status of women, mental health, family structure, nutrition, substance use and abuse, and birth control and abortion. These beliefs and practices can affect attitudes towards issues such as national health insurance and the funding of health care.

Studies on regional variation in health indicators in the UK show large differences between deprived and non-deprived regions of the country, and between Scotland and northern England on the one hand and southern regions of England on the other. Figure 3.14 shows a comparison of standardized values for life expectancy at birth, mortality, cancer incidence, "limiting illnesses", current smokers, alcohol consumption, childhood obesity and drug use for men and women for three relatively deprived northern regions of England compared to the English average.

Nutrition

Appropriate nutrition, overnutrition, and undernutrition are fundamental determinants of the health of a population. Overnutrition and obesity place a heavy burden of morbidity and mortality on the health system, with such diseases as diabetes, coronary heart disease, hypertension, and stroke, and their complications. Undernutrition in the form of gross malnutrition is rare in the industrialized countries, but extremely common in many developing nations. In all societies there are groups at risk for overt or subclinical malnutrition, such as iron-deficiency anemia, iodine deficiency, vitamin D and osteoporosis, and other essential minerals or vitamins. A society that acts to prevent malnutrition in vulnerable groups is acting on behalf of the vulnerable groups in the population and indicates the well-being of that society. Public health and economic measures to promote good quality of food and its accessibility to the population, fortification of basic foods, school lunch programs, and meal services for the elderly and chronically ill are health promotion programs that show the level of organized community responsibility for its members (see Chapter 8).

Special surveys, such as low birth weight or nutritional status conditions, are needed to provide nutrition status data. Monitoring of nutrition status, discussed in detail in Chapter 8, is of fundamental importance to population health evaluation. Periodic large-scale national surveys, such as the NHANES, initiated in 1971 in the USA, provide meaningful information on nutrition status in the country. Within the USA, the surveys provide vital information for adjusting recommended dietary allowances and national, state, or local nutrition programs. This information is of great importance for the food industry, which is obliged to follow federal government standards of labeling and content of packaged and processed foods.

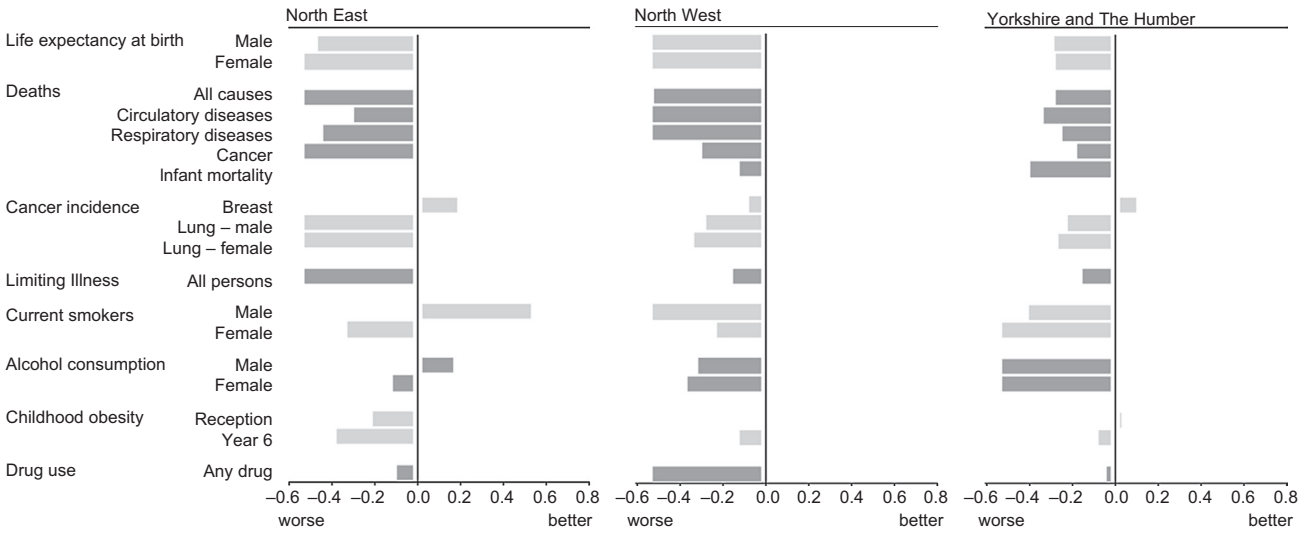

FIGURE 3.14 Health indicators for three deprived regions of England compared to England average, 2006–2008. *Source: Ellis A, Fry R. United Kingdom. Office for National Statistics. Regional trends, no. 42, 2010 edition – Regional health inequalities in England 8 Jun 2010. Available at: http://www.ons.gov.uk/ons/search/index.html?content-type=Article&pubdateRangeType=allDates&newquery=stroke+mortality+by+regions&pageSize=50&applyFilters=true [Accessed 3 January 2013].*

Environment and Occupation

Safety of community water, management of solid and toxic wastes, air and noise pollution, and ambient air standards are all factors in the health of the community. Organized public health has traditionally focused on these issues, but they remain public policy issues in virtually all countries and internationally. Healthy societies are dealing with these issues with a very high degree of public awareness, sometimes overcoming strong economic interest groups to force improved attention to the environment by governments, communities, and businesses.

Environment includes housing, recreation, schools, businesses, parks, urban and rural planning, and many other aspects of community life that are addressed in "healthy community" initiatives. Employment of children and work in hazardous industries are health issues. Societies that tolerate toxic and dangerous work settings create health hazards that are preventable, but costly to treat. Unemployment, job insecurity, loss of health insurance with change of employer, job-related injury or disease, and low income levels for many workers all contribute to poor health (see Chapter 9). Where health insurance is related to employment, as in the USA, health protection can be a major factor in relation to losing or changing place of employment.

The development of the New Public Health has moved national agendas and local authorities with major roles in improving the health of populations. The idea of community diagnosis and community-oriented primary care has played an important part in this process. It is of vital importance in developing countries where the infrastructure for prevention and primary care remain weak. In countries in transition from the Soviet system of health care, reform should address the imbalance between excessive expenditure on hospitalization and inadequate development of primary care and health promotion. Countries in transition should address high rates of mortality from CVD and trauma (see Chapters 11 and 13).

HEALTH CARE FINANCING AND ORGANIZATION

The way in which a nation finances and organizes health care is an important aspect of health status evaluation. Where there is universal coverage of the population, either through health insurance or through a state-operated health care program, the population in principle has equity in access to care. Financial access, however, does not guarantee actual access because the distribution and supply of services are important variables in utilization. Financing and organization of health services are related issues, discussed in Chapters 10–13, that must be recognized as part of the process of assessing the health status of the population of a country or region. Assurance of access to medical and hospital care does not necessarily ensure that appropriate or effective services are provided.

How services link facilities of different levels of intensity of care and costs is a basic issue in health reform in many countries. The way in which preventive care is provided to special groups in the population (such as infants, children, adults, the elderly, and the chronically ill) and how these services fit together as a holistic entity, interacting to serve the community, are important in determining the status of health and health costs of a community or a country.

Health Care Resources

While overall expenditures for health are important determinants of the level of health care available, no less important is how these resources are spent; that is, what the internal financial allocation is within total health. The major resources for health care are in primary care services, hospitals, and long-term care facilities. All countries have limited health financial resources for health expenditures, so that to a great extent one aspect of the health system can only grow at the expense of another.

Hospitals are the largest segment of the health care system in terms of expenditures and may consume more than 50 percent of total expenditures. The supply of hospital beds is, therefore, a central factor in the health care economy. The number of hospital beds per 1000 population is a key indicator for health economics. The hospital bed-to-population ratio varies widely, from 2.5 to 16 care beds per 1000 in OECD countries, with most countries having reduced hospital bed supplies rapidly since the 1980s.

Age distribution of the population affects morbidity and therefore hospitalizations; countries with a high percentage of elderly people may need more hospital facilities, as well as alternative care services, such as home care and long-term institutional care services. Innovations in health care organization are influencing health planning, with many developed countries reducing acute care hospital admissions and length of stay by a variety of incentive and management systems (see Chapters 11–13). Health planning requires facing up to political and other pressures to sustain or even increase levels of hospital bed-to-population ratios beyond real need, at the expense of other more appropriate alternative services. The absence of organized home care programs is an indicator of inadequate planning to address the needs of the elderly and chronically ill in a society.

The ratio of medical doctors per 10,000 population also varies widely. A high ratio may indicate an overpopulation of specialists and a lack of primary care services, while a low ratio may indicate a need for training more physicians. Countries in Eastern Europe have high doctor-to-population ratios and lower ratings on health status indicators (such as SMRs for trauma) than countries with fewer doctors. Nurse-to-population ratios are also equally variable, but

typically, many countries that have high levels of physician-to-population ratios have relatively low numbers of nursing personnel. The number of nurses registered to practice often overstates the actual supply because many nurses never practice following graduation, work only part time, or stay in the profession for only a short period.

Excessive supply of medical doctors, inequitable distribution, relative shortages of nurses, inefficient development of community health programs, and inefficient use of community health workers are important issues in many countries (see Chapter 15). These all have economic and health outcome implications, requiring continuous review and reassessment in each country, and application of lessons learned from other countries.

The organization of health services, discussed in Chapters 10–12, is an important factor in the efficiency and quality of care. Community health services are a hallmark of provision of primary care to address population health needs, while many health systems in the past especially emphasized hospital and other institutional care in their norms and financial incentives.

Utilization of Services

Rapid cost increases have fostered a search for efficient ways of organizing and financing health services. In the USA, the development of the DRG method of payment for hospital services has reduced hospital length of stay. Health maintenance organizations (HMOs) have been successful in providing comprehensive care with less hospitalization and fewer hospital beds than traditional fee-for-service practice. Policy makers and the business community have therefore begun to focus on "managed care" systems to meet the need to extend insurance coverage and to control costs.

While supply of services is important, actual utilization patterns are also a valuable part of the overall evaluation program. Hospital care is a key issue because of its dominance in the economics of health care. Monitoring hospital performance indicators can play an important role in determining the effective functioning of the health care system.

Surgical and other procedure rates are continuing issues in health systems management. For instance, age-standardized hysterectomy rates varied widely among Canadian provinces in 2010, from 512 per 100,000 in Prince Edward Island to 311 per 100,000 in British Colombia, and varied by a factor of 4 within Ontario on a county-to-county basis (2008–2009). A study of this phenomenon indicates that if all provinces achieved the hysterectomy rates of British Columbia, there would be 3700 fewer hysterectomies with a cost saving of $19 million per year (Canadian Institute for Health Information, 2010). A study conducted in Saskatchewan showed that the introduction of mandatory second opinions resulted in dramatic reductions in hysterectomy rates. Appendectomy rates in Germany are up to three times higher than those in other countries, with no epidemiological explanation.

Studies abound in the USA showing differential utilization of health services by African American and white populations for coronary heart bypass procedures, for localized compared to radical surgery for lumps in the breast, and for mammography and other services currently considered to be of benefit to the patient. These differences generally are primarily due to differences in health insurance coverage, but other socioeconomic or ethnic variables may also be responsible. Excess surgical procedures, for example, caesarean sections, are a widespread problem in countries where fee-for-service is the method of payment, but the amount of surgery is also related to the number of surgeons and fee-for-service payments.

Health Care Outcomes

While it is clear that health status is affected by many social and economic factors, the general state of the country's health is often described by epidemiological indicators, such as mortality and morbidity rates as indicators of health status. Epidemiological information on communicable and non-communicable diseases helps to determine a potential for intervention and alteration of the natural history of the disease.

Outcomes can include morbidity, mortality, and physiological and functional measures (Box 3.27). They may also include measures of self-assessment of health status; risk behavior such as smoking or engaging in unsafe sexual practices; or knowledge, attitude, and beliefs of health-related issues. These measures may be part of the evaluation of the health status of a population or a program meant to cause change.

Outcome indicators include a variety of measures from routine data sources and special surveys. DALYs and QALYs (described earlier) attempt to quantify mortality and quality of life measures for comparisons and for analysis of specific interventions. In addition, physiological or functional indicators such as activities of daily living measure patient performance. Special surveys for clinical signs of undernutrition such as anthropometric measures (growth and body size) should be supplemented by biochemical-level and hematological surveys to establish patterns of undernutrition. Special surveys of nutrition status and disability, school performance, and other indicators of functional status are important aspects of health status evaluation (see Chapter 8).

Quality of Care

The quality of care (see Chapter 11) is part of evaluation of health in any population. Assessment of how available funds are spent to address the health problems specific to that

BOX 3.27 Outcome Indicators of Health Status of a Population

Outcome is a variable with a value which varies according to the outcome or the effectiveness of an intervention (Last, 2007), taking into account independent variables, such as more general changes occurring in the same time-frame. Examples include the following.

Mortality-related indicators
- Infant and child mortality rates (IMRs)
- Maternal mortality rates (MMRs)
- Crude mortality rates (CMRs)
- Age-specific mortality rates
- Cause-specific mortality rates – infectious, non-infectious
- Case fatality rates as a measure of the success of medical care
- Life expectancy (LE) at ages 0, 1, 65, and other ages
- Standardized mortality rates (SMRs) – total specific
- Years of potential life lost (YPLL) – a measure of the impact of mortality on different age groups to reflect relative impact of diseases or conditions on the population
- Quality-adjusted life years (QALYs) – an adjustment of life expectancy by inclusion of chronic conditions with impairment, disability, or handicap
- Disability-adjusted life years (DALYs) – a measurement based on adjustment of life expectancy and includes the estimated effect of long-term disability.

Morbidity outcome indicators
- Incidence of vaccine-preventable disease
- Incidence of waterborne disease
- Incidence of foodborne disease
- Incidence/prevalence of tuberculosis
- Incidence/prevalence of STIs/AIDS
- Incidence of malaria, other tropical diseases
- Prevalence of non-infectious diseases – cardiovascular diseases, diabetes, cancer, trauma
- Prevalence of disabling conditions
- Prevalence of risk factors.

Behavioral indicators
- Knowledge, attitudes, beliefs, practices regarding risk factors – smoking, alcohol and drug use; unsafe sexual practices; high-risk behavior regarding motor vehicles, violence, drug use, suicide
- Compliance with immunization, preventive care, medical treatment and advice, physical fitness, suitable weight.

Physiological indicators
- Nutritional status – growth patterns of infants and children; body mass index of adults; dietary patterns
- Hematological and biochemical indicators (blood sugar; cholesterol; lipids; vitamins A, B, C, D); anemia among infants; children, and women; iodine status; environment.

Functional indicators
- Work and school absence
- Psychomotor function
- Work capacity
- School performance
- Fitness test performance
- Activities of daily living (ADLs)
- Cognitive capacity.

population is part of the CHA. The findings of such evaluations are meant to affect resource allocation and address unmet needs. Health care is increasingly being evaluated by managers of health insurance programs, whether as health maintenance organizations or veterans' health services and Medicare of the US federal government, or by international organizations (such as WHO, UNICEF, OECD, and UNDP), seeing health as an economic investment, and international comparisons, as in the Human Development Index (HDI) and Health for All database. Data systems for epidemiological studies and for population health monitoring include the most basic reporting systems of infectious diseases, vital statistics, and special disease registries such as birth defect registries, special surveys such as NHANES on nutrition status (see Chapter 8), and hospitalizations as seminal health events or "tracer conditions" to provide vital material to study and compare the effectiveness of health systems, and indeed individual provider performance.

Other important indicators of quality health systems include health system responsiveness and patient or population satisfaction. Responsiveness is a measure of ease of access and comfort level of clients with "consumer-friendly" and psychologically supportive facilities and staff for the population served.

Practices in prescription drug use may indicate utilization much beyond accepted clinical guidelines, as in the use of proton pump inhibitors (PPIs) in the treatment of acid-related dyspepsia and peptic ulcers by the UK NHS. These drugs are important but overused, according to National Institute for Health and Care Excellence (NICE) standards in the UK (see Chapter 15): expenditure on PPIs by the NHS was estimated at €595 million (euros) in England in 2006 and €4.5 billion in the USA in 2009 on one PPI, whereas less costly methods are just as or more effective (Cahir et al., 2012). Such analysis of data sets on prescription drug use is of great importance to the economic survival of health systems, permitting limited resources to be used to better effect for unmet health needs.

Self-Assessment of Health

Data on self-assessment of health are used along with household expenditure and nutrition surveys to provide information on the health-related experiences of selected samples

of the population, sometimes by household interviews and by telephone surveys. These may yield estimates of poverty, illness, or inequality for small areas for which no or few other data are available. Reliability of recall and reporting is limiting, but this method does provide important information that cannot be measured in other ways. Health surveys are vital to monitoring population health and self-assessment is an important component of ongoing monitoring, and to measure inequalities within a health system.

Costs and Benefits

Analysis of costs and benefits is reviewed in more detail in Chapter 11 on economics and health policy, and will be mentioned here only briefly. Evaluation of the health status of a population requires examination of the choices made in resource allocation in a particular geographic area. This is of concern not only to the planner, but also to the provider of health care and to the public. If priorities in resource allocation promote highly technological medicine, then primary care may lag behind in resources, and the health status of the population may be compromised. Cost–benefit analyses can contribute to establishing priorities within a health care system (see Chapter 11).

Effects of Intervention

The adoption of *Haemophilus influenzae* vaccine for infant immunization will result in an almost immediate drop in *H. influenzae* meningitis and pneumonia, in the same way as adoption of a two-dose policy for measles vaccination will lead to a very rapid reduction in measles morbidity and mortality. Other interventions in public health affect an epidemic curve more slowly, as smoking reduction actions lead to reduced hospitalization and mortality from coronary heart disease.

Many interventions in preventive medicine and public health are complementary, so that a doctor's advice to quit smoking and antismoking legislation mutually reinforce the same message. The natural history of disease is affected by many sociological and economic factors as well as medical or public health interventions. The dramatic reduction in coronary heart disease mortality, but not necessarily morbidity, is attributable to improved medical care, preventive medical care, and wider public health activities related to improving knowledge, attitudes, and practices for lifestyle change. These themes were discussed in Chapters 1 and 2, and will recur in coming chapters of this book as part of the continuously evolving New Public Health.

Qualitative and Quantitative Research Methods

Public health research capacity is important to investigate how diseases are generated by causative agents, and in the context of contributory factors, how the social, physical, or policy environment influences people's perceptions and behavior. Research methods in epidemiology rely on quantitative studies based on centuries of population data analysis.

Quantitative studies are important for new epidemiological and clinical research. They are the basis for analysis of routinely collected health information such as births, mortality and morbidity rates, and associated factors. They also investigate the utilization of health services, such as short- and long-term hospitalization by cause, and many others such as registries of birth defects, cancer, diabetes, asthma, neurological disorders and other diseases, and socioeconomic data.

Quantitative research uses questionnaires and surveys, including telephone and electronic mail surveys, to provide objective evidence of population health, and its associated factors such as nutrition, smoking, diet, physical activity, self-defined health status, activities of daily living, and many other measures of health and social well-being. Some surveys study age, gender, and ethnic groups for biological factors by, for example, BMI, micronutrient levels (e.g., vitamin D), blood lipid levels, and dietary intake. These are basic to monitoring population disease as cornerstones of public health.

Quantitative research yield data analyzed as rates, proportions, associations, and multifactorial correlations. Quantitative surveys emphasize structure, consistency, precisely worded questions, and analysis methods to quantify experiences and produce measurable outcomes. Quantitative studies generate or use existing databases for analysis which can aid understanding and add precision in evidence of disease risk factors that have become part of modern epidemiology and public health, such as smoking and cholesterol, the reduction of which has led to declines in cardiovascular and cancer mortality (see Chapter 5).

Qualitative research methodologies developed by social sciences are valuable in the direct observation of behavior and attitudes, and have been especially important in exploring issues related to human sexuality, strategies for managing complex public health issues such as the AIDS pandemic, malaria control, and many other public health challenges.

Qualitative research is increasingly related to health issues. The social sciences (psychology, sociology, and anthropology) are important in studying human behavior and the societies in which they live, but with increasing difficulty in trying to explain human behavior in quantifiable, measurable terms alone. Although qualitative research also starts with research questions, these may change with the experience of addressing people in an open fashion in their own communities. This helps to generate knowledge of social influences and processes by understanding what they mean to people. Qualitative research methods are valuable

for exploration, with open-ended collection of information by questionnaires, interviews, and focus groups to develop hypotheses for further study using quantitative methods. These types of study supplement quantitative research, or provide new hypotheses and issues for quantitative research to provide important information on the policy alternatives for decision making, and to modify intervention programs.

Clinical observation and analysis is a form of qualitative methodology with exploratory epidemiology that has contributed greatly to development of the field. The observations of Peter Panum of measles in the Faroe Islands in the 1840s made an enormous contribution to infectious disease epidemiology. Observations of a large number of cases of infant cataracts by Australian ophthalmologist Norman Gregg in 1941 led to the discovery of rubella syndrome. The observation in 1979 by pathologist Robin Warren in Adelaide, Australia, of small, curved, organism-like objects in crypts of gastric biopsy specimens led to the discovery of *Helicobacter pylori* as the cause of chronic peptic ulcer disease in the early 1980s, and the Nobel Prize in 2005 (see Chapter 1). In the early years of the HIV/AIDS pandemic, qualitative research provided clues for educational and behavioral interventions that were the only tools available until the advent of ART in the 1990s.

Quantitative and qualitative methods, in principle, both start with a research question as a study hypothesis but differ in their methods of data collection, analysis, and interpretation. Researchers working with behavioral aspects of health serve to generate hypotheses or modifications for quantitative studies or trial interventions. Qualitative researchers should be familiar with methods of quantitative research, and vice versa. In the era of webs of causation, with multiple factors in play, quantitative research provides greater precision and statistical strength to determine causal relationships. Qualitative research provides valuable exploration to elucidate questions which can add to our understanding of the epidemiology of a multifactorial causation, especially regarding compliance with best practices. Both methods are vital to progress in public health (Table 3.12).

The emphasis in qualitative research is on exploration. It relies on the synergy between design and discovery, and thus is valuable for program evaluation. This research helps investigators to elucidate and understand how the social, physical, or policy environment influences people's perceptions and behavior. It does this by focusing on both verbal and non-verbal language using an unstructured interview format so that participants can answer for as long and as openly as they choose.

Important clues to public health issues can be revealed by talking to people. For example, studies on the use of low-cost insecticide-treated nets (ITNs) to prevent malaria in sub-Saharan Africa showed cultural and beliefs to be important in their uptake, including information on their benefit, seasonality of use, and many other factors that could only be determined by interviews and community participation focus groups (Binka and Adongo, 1997). Another study report on this issue (Alaii et al., 2003) states:

"… findings from our anthropologic studies early in the trial indicated that the study population would accept and use ITNs. After introduction, an array of social and cultural issues associated with the ITN studies became apparent. While the majority of these problems could be addressed during the trial they illustrate the shifting roles of communication, time, and the social system in the diffusion process. Individuals seek information at various stages of the diffusion process to decrease uncertainty about its expected consequences. The decision leads to either rejection or adoption of the innovation and success or failure of the intervention."

In another example, research focusing on high birth rates among indigenous adolescent women in rural Mexico would require quantitative surveys to provide relevant data such as the percentage of women pregnant in the age groups 15–17 and 17–19, the probability that a woman will use a contraceptive method, frequency of abortions, or the risk of her dying from pregnancy. Qualitative research would be able to elucidate factors such as misinformation regarding contraception, parental or partner opinions about adolescent pregnancy, and beliefs and problems regarding accessing prenatal and postnatal care. Qualitative research methods can operate independently or complement quantitative instruments by either proceeding or preceding them, depending on the study goals.

Qualitative research is guided by the research problem and community responses in less formal questionnaires or discussion with community residents and key people, which can fuel further research questions. A conceptual framework is often applied to keep the research directed and dictates the combination of questions asked such as ones based on experiences, behaviors, opinions, values, concerns, or knowledge. Qualitative research should be dynamic, using questions and approaches that evolve as new insights are gained. Approaches to data collection can take the form of words, images, and observations; observation, in-depth interviews, and focus groups are the fundamental approaches to qualitative research. Other methods, such as documentary research and videotaping, can also play an important role in gaining participants' perspectives.

Entering the community by acknowledging and consulting with "gatekeepers" or leaders of the potential research site population helps in accessing members of the community. It also facilitates follow-up, such as identifying local people to work with, presenting oneself and the research to key stakeholders, and recruiting participants. Researchers often visit common meeting places, chat with potential participants, and then select a sample purposively based on readiness of individuals to participate, as well as their demographic characteristics to represent a defined subgroup. Sampling can be varied and, depending on strategy,

TABLE 3.12 Quantitative Versus Qualitative Research

Quantitative Research	Qualitative Research
Methodological Approaches	
Define the issue to be examined – case for action	Define the issue to be examined – case for action
Theory or question driven	Theory or question driven
Deductive process to test prespecified concepts, constructs, and hypothesis that make up a theory	Inductive process of observation to formulate a theory, or hypotheses
Objective in observing effects (interpreted by researchers) of a program, problem or condition	Interviews and focus groups use semi-structured but open-ended questions/formats
Sampling representative of population size, composition, randomization crucial	Describes a problem or condition from the point of view of those experiencing it
Surveys, structured interviews, observations, and reviews of records or documents numeric information	Time expenditure lighter on the planning end and heavier during the analysis phase
Fixed response options use numbers to define relationships via closed-ended answers, experimental, empirical means	Sample size and composition less formal, structured for exploration
Data collection: surveys with closed answers	Interpretive "experience near"
Statistical tests used for analysis	Sampling – selection of sample of people with direct familiarity with the population and research question
Specificity and reliability key issues	Text-based, and not numerical
Analysis: turning beliefs, behaviors, or attitudes into numbers to support hypotheses	Analysis of observed interactions, behaviors, and attitudes
Conclusions in keeping with the findings, limitations and plausibility given the literature and knowledge of the topic	No statistical tests
	In-depth information on fewer participants
	Conclusions in keeping with the findings, limitations of the study, more research questions indicated, and policy implications
Research Questions	
Precisely worded questions, structured response options	Interview skills require well-trained personnel
Aim to quantify information/data and produce measurable outcomes	Unstructured or semi-structured response options, room for follow-up questions
Structured by hypothesis	Aim to explore and gain insight into behavior and perceptions
Less in-depth but more breadth of information across appropriate sample size	How people interpret and experience their interactions and perceptions and/or attitudes
Place emphasis on structure	Open-ended or semi-fixed structure: discovery and exploration, synergy between design and discovery
Statistical tests used for analysis	Methods include focus groups, in-depth interviews, and reviews of documents for types of themes
Can be valid and reliable: largely depends on sample, measurement device, or instrument used	Can be valid and reliable: largely depends on skill and rigor of the researcher
Time and cost expenditure heavier on the planning phase and lighter on the analysis phase	More in-depth information on a few cases
Reliability, uniformity, objectivity, and freedom from bias are paramount	Less generalizable
More generalizable	Generate hypotheses for future research or policy decisions
Generate further research and policy guidelines, standards	

Centers for Disease Control and Prevention. CDCynergy "Lite". Evaluation. Available at: http://www.cdc.gov/healthcommunication/cdcynergy/evaluation.html [Accessed 3 January 2012].
US Department of Energy. Differences between qualitative and quantitative research methods. Available at: http://www.orau.gov/cdcynergy/soc2web/Content/phase05/phase05_step03_deeper_qualitative_and_quantitative.htm [Accessed 3 January 2012].
Sources: Feldman B. Personal communication; 2007.

may select homogeneous, heterogeneous, extreme, or typical participants. Pilot testing often follows to assess how well the objectives of the study are fulfilled, and provides the opportunity to circumvent any constraints and obstacles before study initiation.

One-to-one, or in-depth interviewing allows participants to play an active role in determining the direction of the interview. Questions follow the flow of conversation and the interview has a conversational quality. The interviews can take the form of unstructured informal conversations, or can be semi-structured or structured. They generate empirical data as participants talk freely about their experiences and beliefs. This is an effective approach when inquiring about sensitive information and when assessing an individual's opinions and perceptions rather than understanding community norms and customs. In-depth interviews can highlight the differences between individuals, elicit detailed information, and also provide a forum for follow-up questions.

In the 1960s, the NHANES began to study the US population health and nutrition behaviors and the links between dietary habits and NCDs. By the 1980s, epidemiological evidence showed that personal health behavior was a major risk for premature morbidity and mortality from many diseases including lung cancer, CVD, and HIV, and health promotion became an established part of public health. In 1984, the CDC established behavioral surveys with standard questionnaires administered through telephone surveys to monitor established risk factors in 15 states of the USA. These surveys supplement other important epidemiological monitoring systems, such as vital statistics, disease registries, and health systems monitoring, with counterparts in other countries.

FROM HEALTH INFORMATION TO KNOWLEDGE TO POLICY

Internal review boards (IRBs) are research monitoring bodies or committees, sometimes called Helsinki Committees, whose approval is required for research funding and publication purposes. IRBs require that all precautions are taken so that participants are not exposed to harm by the study, and that the project is scientifically sound. They also require that follow-up care is provided with referrals, that a researcher/practitioner is clear about his or her role boundaries, and that appropriate information and support are available.

Consent requires that participants are informed that research is not therapeutic. Some situations do not require consent when it is made clear that participants understand the study. Confidentiality must be maintained (e.g., the secure storage of tapes and transcripts), using as few details about participants as possible. This is to prevent anxiety and distress, exploitation, misrepresentation, and identification of participants in published papers. Validation for respondents refers to the process whereby researchers review the results of the study with the participants before the findings are published.

Information is the basis for planning, organizing, managing, and providing high-quality care. The process begins with basic vital statistics and the epidemiology of infectious and non-infectious diseases to identify and quantify the health needs of the population. It extends into health information systems to manage and monitor the functioning of the health care system. Surveillance of health events at national, regional, and community levels depends on building information systems and linking data to provide community health profiles. This process is fundamental to monitoring and managing health systems. It requires clear policy to ensure that information systems do not exist to serve only those who process the data at national levels, but are returned to the community level and linked with other data sources in readily usable formats (Box 3.28).

SUMMARY

Epidemiology and related sciences have made enormous contributions to defining the causes of disease and articulating their risk factors, and translating them into effective public health policy saving millions of lives. Information is widely available in the form of health statistics and published data of all kinds, today more than ever on the Internet. The sophisticated methods and data sets available provide a wide array of information allowing the continuous development of information technology and monitoring systems for health policy and the management of health facilities and health systems.

Health policy formulation requires seeking the appropriate information and making intelligent use of it. Educating health workers in coordinating information and streamlining data will help them to understand the relevance and impact of their actions. Information systems and the flow of properly organized and disseminated data are vital for management. They are as important to the functioning of the system as an intelligence service is to a military operation. The vast and expensive mechanism of a health service operates in the dark without a continuously monitoring information system and applied research methods of epidemiology.

Translation of knowledge into practice in many cases moves with glacial speed. Delayed implementation of established preventive interventions such as weight loss and prescription of beta-blockers and antihypertensive medications costs many needless premature deaths. These practices no longer require research to demonstrate efficacy and effectiveness; what is at issue is how to ensure that they reach all those in need. The vast majority of cardiovascular deaths could be eliminated through measures that have already been demonstrated in etiological studies (Ness, 2013).

Throughout the world, health care systems are under critical scrutiny because of concerns over costs, accessibility, appropriateness, quality, and outcomes of care. The

BOX 3.28 Evidence-Based Public Health and the Burden of Proof

The Hippocratic Oath specifies: do good and do no harm. It has found expression in the precautionary principle, a contemporary redefinition of Bradford Hill's case for action; when in doubt about the possible presence of a hazard, the burden of proof is shifted from showing presence of risk to showing total absence of risk. This creates a dilemma in public health and in clinical medicine suggesting that the normal evidence required for action is without validity. It implies that any possible risk of an intervention outweighs the risk of non-intervention.

Great care is warranted when introducing new public health interventions, but the weight of evidence must include not only epidemiological studies but policies derived from Delphi consultative procedures and successful experience of the intervention in large population groups over long periods, without substantive evidence of harmful effect.

A balance between the precautionary principle, the experience of "good public health practice" and epidemiological evidence is often a delicate judgment, but is nonetheless essential for policy in this field. Last's definition of *evidence-based public health* is wise: "application of best available experience in setting public health policies and priorities. The evidence comes from official vital and health statistics and from peer reviewed publications in epidemiology, sociology, economics and other relevant disciplines".

Failure to act on best practices and cumulative evidence can be an ethical and indeed a legal problem (see Chapter 15), where inordinate delay in implementing scientific and practical positive experience with public health interventions can allow serious morbidity and mortality to go unchecked when they are preventable.

The time lag between adequate scientific evidence and positive experience with good public health practices can be very long, and measures that can save or improve the quality of life for large numbers of people are delayed in implementation due to lack of political motivation, priorities, and active or passive resistance by professional or lobby groups with other agendas.

Delays in the adoption of a two-dose policy for measles vaccination and slow implementation in some developing countries have cost millions of lives. The implementation of folic acid fortification of flour has been slow, despite overwhelming evidence and positive experience in over 60 countries showing that folic acid fortification prevents birth defects and late pregnancy terminations with low cost and great safety. The banning of DDT in the 1960s due to legitimate environmental concerns without replacement of equally effective insecticides contributed to the resurgence of malaria, again costing millions of lives. Keeping up with scientific and best public health practices is an important responsibility of public health in balance with due precaution.

As Brownson et al. (2009) point out, "An array of effective interventions is now available from numerous sources including the *Guide to Community Preventive Services*, the *Guide to Clinical Preventive Services*, *Cancer Control PLANET*, and the *National Registry of Evidence-based Programs and Practices*: Second, to translate science to practice, we need to marry information on evidence-based interventions from the peer-reviewed literature with the realities of a specific real-world environment. Finally, wide-scale dissemination of interventions of proven effectiveness must occur more consistently at state and local levels."

Jacobs et al. (2012) address the "free online resources in the following topic areas: training and planning tools, US health surveillance, policy tracking and surveillance, systematic reviews and evidence-based guidelines, economic evaluation, and gray literature. Key elements of EBPH are engaging the community in assessment and decision making; using data and information systems systematically; making decisions on the basis of the best available peer-reviewed evidence (both quantitative and qualitative); applying program-planning frameworks (often based in health-behavior theory); conducting sound evaluation; and disseminating what is learned."

Sources: *Last JM. A dictionary of public health. New York: Oxford University Press; 2007.*
Coughlin SS, Barker A, Dawson A. Ethics and scientific integrity in public health, epidemiological and clinical research. Public Health Rev 2012;34: Epub ahead of print. Available at: www.publichealthreviews.eu [Accessed 10 January 2013].
Brownson RC, Fielding JE, Maylahn CM. Evidence-based public health: a fundamental concept for public health practice. Annu Rev Public Health 2009;30:175–201. http://dx.doi.org/10.1146/annurev.publhealth.031308.100134.
Jacobs JA, Jones E, Gabella BA, Spring B, Brownson RC. Tools for implementing an evidence-based approach in public health practice. Prev Chronic Dis 2012;9:110324. doi: http://dx.doi.org/10.5888/pcd9.110324. Available at: http://www.cdc.gov/pcd/issues/2012/11_0324.htm

effectiveness of a health system is frequently on the political agenda. Quality assurance and accountability are critical in the operation of any health system. Health expenditures must be increasingly justified in terms of their need and cost-effectiveness, policy formulation, strategies, and priorities, taking into account economic, sociological, and political factors.

Curbing the soaring costs of health care is a necessity and not a matter of choice for governments and individuals if the WHO policy of Health for All is to be achieved. One means of reaching the goals and objectives of this policy is to develop an efficient health information system. Knowing the population, the epidemiological patterns of its diseases, and its health care services and utilization, are all part of the monitoring and feedback systems essential to allow the health system to evaluate health status and to keep pace with changes. They are therefore essential elements of the New Public Health.

NOTE

For a complete bibliography and guidance for student reviews and expected competencies please see companion web site at http://booksite.elsevier.com/9780124157668

BIBLIOGRAPHY

Abramson, Z.H., Abramson, J.H., 2008. Research methods in community medicine: surveys, epidemiological research, programme evaluation, clinical trials, sixth ed. Wiley, Indianapolis, IA.

American College of Epidemiology, http://acepidemiology.org/ (accessed 06.01.13).

American Public Health Association, http://www.alpha.org (accessed 03.01.13).

Breslow, L., 2006. Health measurement in the third era of health. Am. J. Public Health 96, 17–19.

Brownson, R.C., Fielding, J.E., Maylahn, C.M., 2009. Evidence-based public health: a fundamental concept for public health practice. Annu. Rev. Public Health 30, 175–201. http://dx.doi.org/10.1146/annurev.publhealth.031308.100134.

Cahir, C., Fahey, T., Tilson, L., Teljeur, C., Bennett, K., 2012. Proton pump inhibitors: potential cost reductions by applying prescribing guidelines. BMC Health Serv. Res. (12), 408. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3529111/ (accessed 08.08.13).

Canadian Institute for Health Information, 2010. Health Care in Canada 2010. CIHI, Ottawa. Available at: https://secure.cihi.ca/free_products/HCIC_2010_Web_e.pdf (accessed 08.08.13).

Centers for Disease Control and Prevention, http://www.cdc.gov/ (accessed 03.01.13).

Centers for Disease Control and Prevention, 2008. National Center for Chronic Disease Prevention and Health Promotion. Behavioral Risk Factor Surveillance System – BRFSS history. CDC, Atlanta, GA. Available at: http://www.cdc.gov/brfss/history.htm (accessed 03.01.13).

Centers for Disease Control and Prevention, National Health and Nutrition Examination Survey (NHANES). Available at: http://www.cdc.gov/nchs/nhanes.htm (accessed 03.01.12).

Centers for Disease Control and Prevention. Public Health Then and Now: Celebrating 50 Years of *MMWR* at CDC. Available at: 1961-2011. MMWR Morb Mort Wkly Rep Suppl 2011;60(04):15-21. In: http://www.cdc.gov/mmwr/preview/ind2011_su.html (accessed 20 November 2013).

Centers for Disease Control and Prevention. CDC's vision for public health surveillance in the 21st century. MMWR Morb Mort Wkly Rep Suppl 2012;61:1-40. Available at: http://www.cdc.gov/mmwr/pdf/other/su6103.pdf (accessed 20 November 2013).

Centers for Disease Control and Prevention. Notes from the Field: Late Vitamin K Deficiency Bleeding in Infants Whose Parents Declined Vitamin K Prophylaxis — Tennessee, 2013. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6245a4.htm (accessed 18 November 2013).

Coughlin, S.S., Barker, A., Dawson, A., 2012. Ethics and scientific integrity in public health, epidemiological and clinical research. Public Health Rev., 34. Epub ahead of print. Available at: www.publichealthreviews.eu (accessed 10.01.13).

Ellis A, Fry R. United Kingdom. Office for National Statistics. Regional Trends, No. 42, 2010 Edition – Regional health inequalities in England 8 Jun 2010. Available at: http://www.ons.gov.uk/ons/search/index.html?content-type=Article&pubdateRangeType=allDates&newquery=stroke+mortality+by+regions&pageSize=50&applyFilters=true and http://www.ons.gov.uk/ons/rel/regional-trends/regional-trends/no–42–2010-edition/regional-health-inequalites-in-england-and-wales.pdf (accessed 03.01.13).

Eurostat, Causes of death_statistics. Available at: http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Causes_of_death_statistics (accessed 09.01.13).

Epidemiology, Gordis L., 2008. fourth ed. WB Saunders, Philadelphia, PA.

Green, L., Ottoson, J., Hiatt, R., Garcia, C., 2009. Diffusion, dissemination and implementation of evidence based public health. Annu. Rev. Public Health 30, 151–174.

Health Metrics Network, http://www.who.int/healthmetrics/en/ (accessed 03.01.13).

International Epidemiologic Association, November 2007. Good epidemiologic practice: IEA guidelines for epidemiologic practice (GEP). Available at: http://webcast.hrsa.gov/conferences/mchb/mchepi_2009/communicating_research/Ethical_guidelines/IEA_guidelines.pdf. (accessed 22.12.12).

International Society for Infectious Diseases, Promed-mail. Available at: http://www.promedmail.org/ (accessed 09.01.13).

Institute of Medicine, 2002. The future of the public's health in the 21st century. National Academies Press, Washington, DC.

Joint Commission, 2013. Sentinel events. . Available at: http://www.jointcommission.org/sentinel_event.aspx. (accessed 10.01.13).

Kozak, L.J., DeFrances, C.J., Hall, M.J., 2006. National hospital discharge survey: 2004 annual summary with detailed diagnosis and procedure data. Vital Health Stat. 13, 1–209.

Last, J.M. (Ed.), 2007. A dictionary of public health. Oxford University Press, New York.

Lee, L.M., Thacker, S.B., 2011. The cornerstone of public health practice: public health surveillance, 1961–2011. MMWR Morb. Mort. Wkly. Rep. Suppl. 60 (04), 15–21. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/su6004a4.htm?s_cid=su6004a4_w (accessed 03.01.13).

MacDonald, P.D.M., 2011. Methods in field epidemiology. Burlington, MA: America Public Health Association Press/Jones and Bartlett Learning; 2012. Available at:. World Health Organization. World health statistics, 2011, Geneva: WHO. (accessed 03.01.13) http://www.who.int/whosis/whostat/EN_WHS2011_Full.pdf.

Martinson, M.L., 2012. Income inequality in health at all ages: a comparison of the United States and England. Am. J. Public Health 102, 2049–2056.

Murray, C.J.L., Richards, M.A., Newton, J.N., Fenton, K.A., Anderson, H.R., Atkinson, C., et al., 2013. UK health performance: findings of the Global Burden of Disease Study 2010. Lancet 381, 997–1020.

National Center for Health Statistics, 2011. Health, United States. with special feature on socioeconomic status and health. Department of Health and Human Services, Hyattsville, MD 2012.

Needleman, J., Buerhaus, P., Pankratz, S.V., Leibson, C.V., Steven, S.R., 2011. Nurse staffing and inpatient hospital mortality. N. Engl. J. Med. 364 (11), 1037–1045.

Nolte, E., McKee, M., 2012. In amenable mortality – deaths avoidable through health care – progress in the US lags that of three European countries. Health Aff. 31, 2114–2122.

Organisation for Economic Co-operation and Development, 2011. Health policies and data: health at a glance. Available at: http://www.oecd.org/health/healthpoliciesanddata/healthataglance2011.htm. (accessed 08.12.12).

Organisation for Economic Co-operation and Development, OECD health data 2012 – frequently requested data. Available at: http://www.oecd.org/els/healthpoliciesanddata/oecdhealthdata2012-frequentlyrequesteddata.htm (accessed 03.01.12).

Tulchinsky, T.H., Ginsberg, G.M., Ishovitz, J., Shihab, S., Fischbein, A., Richter, E.D., 1998. Cancer in ex-asbestos cement workers in Israel, 1953–1992. Am. J. Ind. Med. 35, 1–8.

World Health Organization, The global burden of disease: 2004 update. Available at: http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf (accessed 09.01.13).

World Health Organization, 2011. World health statistics, 2011. WHO, Geneva. Available at: http://www.who.int/whosis/whostat/EN_WHS2011_Full.pdf (accessed 03.01.13).

World Health Organization, January 2013. European Region. Health for All data set. WHO, Copenhagenhttp://data.euro.who.int/hfadb/ (accessed 13.06.13).