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Chapter 15

Health Technology, Quality, Law, and Ethics

Learning Objectives

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

1. Describe responsibility for and methods of assessing and regulating technological developments in health care;
2. Describe methods of health facility accreditation and peer review;
3. Describe the concept of total quality management;
4. Identify and discuss ethical and legal issues in national health systems;
5. Apply ethical considerations to health issues in his or her home setting.

INTRODUCTION

Management of a production or a service system requires attention to the quality of personnel as much as to the system in which they work. Their motivation and sense of participation, the scientific and technological level of the program, and the legal and ethical standards of individual providers and of the system as a whole, are all important to the quality of care provided and equity of health status achieved.

Quality is the result of input and process, and is measured by outcome or performance indicators as well as perception of the service by the patients, the staff, and the community as a whole. Input refers to the institutional and financial resources for education, human resources, supplies, medications, vaccines, diagnostic capacity, and services available. Process refers to the use of those resources, including peer group expectations of professionalism. Outcomes generally include measures of morbidity, mortality, and functional status of the patient and the population. Defining and measuring achievements of national health objectives and targets, the methods of financing services, and the efficiency of organization help to determine quality. Training, supply, and distribution of health personnel are all determinants of access to and quality of care. Continuous and adequate availability of essential preventive, diagnostic, and treatment services, as well as accountability and internal methods of promoting standards, are all elements of the quality of a health service for the individual, the population as a whole, and groups within the population with special needs.

The content and standards of service are assessed through organized review by professional peers within an institution, and from outside. Peer review within an institution and external evaluation by accreditation or governmental inspection, based on cumulative evidence and the recognized current "state of the art", contribute to accountability and improved quality of care. Continuous quality improvement (CQI) among health care teams and organizations includes regular practice assessments, evidence gathering, remediation, and re-evaluation, which will be discussed later in this chapter. The perception of the services by the community, along with the knowledge, attitudes, beliefs, and practices of health, are all vital to improvement of health status.

Health-related technology is also in a continuing state of change. Systematic review and absorption of new scientific knowledge, technology, and innovations are essential to promote and renew health care methods. Public health serves in a regulatory role to assure high-quality care to the individual and the community. New technology, whether in the form of diagnostic procedures, new drugs, devices, or vaccines, or new types of health personnel, requires evaluation for effectiveness and appropriateness to the system.

Technology assessment also involves epidemiological and economic aspects of effectiveness. Failure to continuously monitor developments and to assimilate those that are demonstrably successful is an ethical and management failure which tragically costs many millions of lives from preventable diseases yearly, such as in delayed adoption of well-proven vaccines or tobacco restriction legislation. This is due to political failure even more than professional weakness, and constitutes one of the saddest ethical dilemmas of public health: failure to convince policy makers of the prime importance of health promotion and disease prevention in the health sector.

Ethics and law in public health reflect the values of a society. They inevitably evolve as they face dramatic social, economic, demographic, and political changes; new health challenges; and new technological and scientific possibilities for improving health. Ethics are the foundation of the value systems of a society and thus of its health concepts.

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Biblical sources articulated values of the Ten Commandments, Sanctity of Human Life, Improve the World, along with the Hippocratic Oath of physicians to "do good and do no harm". Modern definitions of public health and bioethics emerged from lessons learned from the horrors of eugenics and genocide in the twentieth century with humanistic precepts of "Universal Human Rights" and "Health for All" in the recent era (see Chapters 1 and 2).

The law is both permissive and restrictive. It sets the basic responsibilities, powers, and limitations of public health practice, with legislation and court decisions. Innovations in the technology of medical care and public health are powerful forces contributing to increased longevity, quality of life, and economic growth, but they also bring challenges to implementation impeded by additional costs of the health system and slow adaptation in countries with the greatest need. These are challenges to national and international political, organizational, and economic systems to address health with the full potential for saving lives. Determining standards of "good practice" is a continuing process with the rapid development of new knowledge, technology, and experience.

The law is a dynamic process involving old and new legislation, court decisions, and new issues not previously faced, often following rather than anticipating public health issues. Public health has had both positive and negative ethical experiences and continues to face new issues with changing population needs, technology, science, and economics.

INNOVATION, REGULATION, AND QUALITY CONTROL

Health care technology has advanced with an increasing stream of innovation since the seventeenth-century epidemiological discoveries of Lind on scurvy (1747) and smallpox

TABLE 15.1 Health Care Innovations from the Seventeenth to the Twenty-First Centuries

Period	Selected Highlights of Scientific, Technological, and Organizational Innovations in Health
17th century	Biological basis of disease (Descartes), circulation of blood (Harvey), microscope (Leeuwenhoek)
18th century	Thermometer, lime juice supplements (Lind, 1756), vaccination (Jenner, 1796), surgical anatomy (Hunter), clinical sciences (Sydenham)
19th century	Miasma theory vs germ theory; inventions of stethoscope (1816), blood transfusion (1818), anesthesia (1842), hypodermic syringe (1852), ophthalmoscope (1851), laryngoscope (1855), pasteurization of wine, beer, milk (1860s), cholera vaccine (1879), X-ray (1895), blood pressure cuff (1896); sanitation, municipal health departments, chlorination and filtration of community water supplies, antisepsis, Braille printing, hygiene in obstetrics, nursing, microscopic pathology, pathological chemistry, microbiology, vaccines, X-ray, national health insurance, syringes, well-child care, aspirin (1899), Bismarkian social insurance (1881)
1900–1930	Electrocardiogram (1901), Flexner report on medical education, salvarsan, insulin (1922), blood groups, vitamins, conquest of yellow fever, vitamin B, vaccine for diphtheria (1923), tetanus vaccine (1924), electroencephalogram (1924), iron lung respirator (1927), Social Security Act (1935), cost–benefit analysis, food fortification (iodized salt, flour with vitamin B complex), improved work safety
1931–1945	Mandatory fortification of milk, salt, and flour in USA (1941), Pap test (1942), penicillin (1928), streptomycin, randomized clinical trials, antimalarial drugs, vector controls, dialysis machine (1945)
1946–1960	Contact lens (1948), DNA double helix (1953), heart–lung bypass machine (1953), ultrasound (1955), cardiac pacemaker (1958), Salk polio vaccine (1955), kidney transplant (1959), advances in vaccines, antihypertensives, psychotropic drugs, cancer chemotherapy, prepaid group practice, UK National Health Service (1948), Medicare in Canada (1946–1971)
1961–1980	Oral polio vaccine (Sabin), hip replacement (1962), oral rehydration therapy, measles vaccine (1964), coronary bypass (1964), Medicare, Medicaid (1965), mammography (1965), portable defibrillator (1965), measles–mumps–rubella vaccine, cost-effectiveness analysis, open heart surgery, pacemakers, organ transplantation, computed tomography (CT), eradication of smallpox (1972), health maintenance organizations (HMOs), diagnosis-related groups (DRGs), district health systems
1981–2000	Health promotion (1987), magnetic resonance imaging (MRI), positron emission tomography (PET), endoscopic surgery, *Helicobacter pylori* and chronic peptic ulcer disease (1982), managed care, *Haemophilus influenzae* b (Hib) vaccine, statins (1987), poliomyelitis eradication campaign (1982), local eradication of beta-thalassemia, pandemic of HIV (1981 onward), AZT antiretroviral approved (1987), robotic surgery (2000)
2001–2013	Millennium Development Goals (MDGS 2000) with substantial progress achieved, managing emergencies of mass terrorism and natural disasters, new vaccines (HPV), managing epidemics of measles and influenza, new diagnostic technologies, flour fortification to prevent birth defects, HIV still deadly but effective treatment and control measures, new treatments for hepatitis C, robotic surgery, nanotechnology, scientific advances with great potential benefit, Affordable Care Act (2010), Accountable Care Organizations

Source: Adapted from Health United States 2009. Special Feature: Medical technology. Introduction and timeline. 2009. Available at: http://www.ncbi.nlm.nih.gov/books/NBK44737/#specialfeature.sec1 [Accessed 15 December 2012]. See Historical Markers in Chapter 1.

vaccination by Jenner (1796), to the dramatic innovations of the end of the twentieth century (Table 15.1). The pace of innovation is rapid, creating the need for regulation, quality control, and technology assessment.

National governments are responsible for assuring that pharmaceuticals, biological products, food, and the environment are regulated to protect the public. In some countries, these responsibilities are divided among ministries of trade, industry, commerce, health, and environment. In a federal system of government, there may be a division of responsibility among federal, state, and local government, but with the national government often providing national standards and leadership in this area.

Government regulation and control are meant to protect the public health. The US Food and Drug Administration (FDA) is responsible for enforcing the Food, Drug and Cosmetic Act, the Fair Packaging and Labeling Act, sections of the Public Health Services Act relating to biological products for control of communicable diseases, and the Radiation Control for Health and Safety Act. The FDA is a Division of the Department of Health and Human Services (DHHS). State governments have the authority to supervise pharmacies and their products, which may be marketed across different states. All national governments have departments responsible for conducting supervision of food, drugs, and medical devices, often relying on international standards.

Drugs and devices include all drugs, diagnostic products, blood and its derivatives, biologicals, veterinary medicines, and medicated premixed animal products. All manufacturers and distributors are required by law to register these products with the national authority in order to be allowed to market or import them. All countries need to govern the food, drugs, vaccines, and cosmetics regulated for production, importation, marketing, and use within their jurisdiction. Organizations within each government must be responsible for assuring the consumer that foods are pure (unadulterated) and wholesome, safe to eat, and produced under sanitary conditions; that drugs and medical devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that labeling is truthful, informative, and not deceptive.

National authorities such as the FDA, under legislation and regulations, govern both domestic and imported products. They establish and enforce standards, or adopt external agency standards as a "gold standard", meaning that products meet high standards of safety and efficacy. The FDA also monitors and inspects contents manufacturing standards under good manufacturing practices (GMPs), which includes regular accreditation of a manufacturer's facilities, staffing, planning, and monitoring capacity. Testing of products is carried out to assess safety, potency, and toxicity using accepted reference laboratory procedures as published in the compendium *Official Methods of Analysis of the Association of Official Analytical Chemists.*

When federal, state, or local investigators, sometimes known as *consumer safety officers*, detect through laboratory monitoring or observe conditions that may result in a public health hazard, and violation of food and drug laws and regulations, they issue a written report to the manufacturers with recommendations for correcting the conditions. In more blatant cases, the authorities may issue urgent recall or seizure orders for products in violation of standards constituting a danger to public health, such as contaminated products, lead-painted children's toys, or contaminated foods causing foodborne disease outbreaks, which occur not infrequently in imported and domestically produced foods in the USA. The Los Angeles County Department of Health inspects restaurants regularly and places a prominent placard in the window giving a grade A, B, or C to the restaurant for sanitation and safety. Those given D ratings may be closed until specified faults are eliminated, or a restaurant may be closed permanently. State governments require restaurants to list calorie and salt content of foods on their menus as part of the public health efforts to reduce obesity.

Supervision of food standards may also fail, as occurred in Israel in 2004 when total absence of vitamin B_1 in a soy-based baby formula imported from Germany resulted in three deaths and permanent brain damage to other infants due to severe beriberi. This episode led to criminal charges in 2008 of negligence resulting in death against the owners of the company that imported or produced the foods and staff members of the Ministry of Health. Animal foods in 2007 and infant milk products imported from China in 2008 were found to be contaminated with melamine, which was meant to mimic protein content but was toxic in combination with other chemicals used. The infant formula caused serious illness in some 300,000 Chinese babies and six deaths.

The FDA and its counterparts in each country are responsible for regulation of:

- *food* – foodborne illness, nutritional content, labeling, dietary supplements
- *drugs* – prescription drugs and generics, over-the-counter products
- *medical devices* – pacemakers, stents, contact lenses, hearing aids
- *biologics* – vaccines, blood products
- *animal feed and drugs* – for livestock, pets
- *cosmetics* – safety, labeling
- *radiation-emitting product*s – cell phones, lasers, microwaves
- *combination products.*

New drugs and biological products for human use are required to pass rigorous review before approval for marketing is granted. Applications are submitted by the manufacturer or sponsor with acceptable scientific data including test results to evaluate the safety and effectiveness of the

product for the conditions under which it is being offered. All manufacturers of drugs are required to be registered with the FDA and to meet its requirements for each drug produced and marketed, including the reporting of adverse reactions and labeling criteria. Manufacturers are required to operate in conformity with current GMPs, which include stringent control over manufacturing processes, personnel training, computerized operations, and testing of finished products. The FDA publishes guidelines to help manufacturers to familiarize themselves with current standards. The *United States Pharmacopoeia*, *National Formulary*, and *WHO Model Formulary 2008* are the official listings of approved products.

Medical devices are also regulated by the FDA. Thousands of products for health care purposes require premarket approval, ranging from basic articles such as thermometers, tongue depressors, and intrauterine devices (IUDs), to more complex devices such as cardiac monitors, pacemakers, breast implants, and kidney dialysis machines. These products are subject to controls of GMPs, labeling, registration of the manufacturer, and performance standards.

Monitoring for efficacy and potential hazards has been strengthened since the 1970s as a result of findings of long-term carcinogenic and mutagenic effects of estrogens, and toxic effects of chloramphenicol on bone marrow. The drug thalidomide, widely used as an antinauseant and sleeping pill for pregnant women in Europe, Canada, and Australia in the 1960s, was not approved by the US FDA. This drug was found to cause large numbers of serious birth deformities leading to its being banned in most countries. Controls of blood and blood products have been strengthened since the transmission of human immunodeficiency virus (HIV), hepatitis B, and hepatitis C by contaminated blood products in the 1980s. The responsibility of this regulatory function is well illustrated by the 1995 criminal conviction of several senior health officials in France for failing to stop the use of blood products contaminated with HIV in the mid-1980s. Concern regarding possible carcinogenic effects of silicone breast implants led to legal action and greater controls of all implantable products. A balance between safety and well-regulated approval of new products requires a highly professional and motivated regulatory agency, well-developed procedures, and well-trained staff.

The concepts of standardization of GMPs for pharmaceutical products and written protocols for good medical practice or good public health practice are accepted norms based on best available evidence of current scientific knowledge and experience. Recommended immunization schedules, water quality, ambient air standards, food fortification, and screening programs for early stages of diabetes are examples of accepted practice that have become recommended standards of public health practice, paralleling qualitative measures developed in clinical care.

APPROPRIATE HEALTH TECHNOLOGY

The concept of intermediate technology pioneered by Dr Ernst Schumacher in the 1960s proposed the development of simple and inexpensive technology for developing countries such as India to promote local economic development. Environmentally sustainable development and sources of energy, energy conservation, and reductions in toxic and harmful emissions are encouraged. In recent years ideas have included small loan systems for rural entrepreneurs in developing countries, and the use of simple cell phones for communication, farm produce marketing, cash transfers in remote areas without banking services, and many others. Now called appropriate technology, this topic has gained adherence in the health field in the search for low-cost and simple techniques for preventing and managing common illnesses.

Appropriate technology is defined by the World Health Organization (WHO) as the level of medical technology needed to improve health conditions in keeping with the epidemiological, demographic, and financial situation of each country. All countries have limited resources and so must select strategies of health care and appropriate technology to use those resources effectively to achieve health benefits. Improved water pumps, solar energy, rainwater collection and water reservoirs, sanitary latrines, fly traps, insecticide-impregnated bed nets, biogas from animal waste, improved home cooking stoves, and many other simple devices can make enormous differences in local sustainable agriculture, economic growth, and living conditions. Cell phones are now used to monitor health conditions such as hypertension, diabetes control, weight and body mass index, and other non-communicable conditions, and to transmit imaging from remote areas to specialists in medical centers who can provide test readings online. Simple, affordable, portable information technology can effectively support public health programs, even in resource-poor environments.

The topics discussed in the growing literature and meetings of the International Society of Technology Assessment in Health Care represent the dynamic field of technology assessment. The issues range from economic evaluation of pharmaceuticals to modeling approaches, measures of quality of life, technology dissemination and impact, and outcomes measurement. The range of issues also includes finance and health insurance, health care in developing countries, informatics, telemedicine, technologies for the disabled, screening, and cost-effectiveness. Evaluations in the scrutiny of both high- and low-technology services based on a combination of clinical, epidemiological, and economic factors are necessary. As health costs rise, disabling conditions increase and populations age, medical innovation proceeds at a rapid rate, and both client and community expectations in health care continually rise.

In developing countries, the training and supervision of traditional birth attendants (TBAs) for prenatal preparation and normal deliveries are important ways to reduce maternal mortality in rural areas, as discussed elsewhere, and an important Millennium Development Goal (MDG) which will not be met by 2015. Community health workers (CHWs) in well supervised and supported programs are essential to provide preventive care to underserved rural poor populations with a defined package of services that can be tailored to meet specific local needs, such as immunization, child growth monitoring, nutrition counseling, and malaria and TB control.

A major example of appropriate technology has been the WHO initiatives to promote national drug formularies (NDFs) as a consensus list of essential drugs that are sufficient for the major health needs of a country, eliminating unnecessary duplication and combined products on the commercial market. The WHO calls on all member states to ensure the availability and rational use of drugs and vaccines, and supports states wishing to select an essential list of drugs for economic procurement. Assistance with drug regulatory agencies, legislation, quality control, information, supply, and training is offered to help the member countries. Standard reference laboratories, the *International Pharmacopoeia*, and the *WHO Drug Bulletin* promote international standards and provide guidance to member states. The *WHO Model List of Essential Drugs* is a valuable tool to improve quality and cost management in national health systems.

Cochlear implants are now routinely used for children with congenital or other loss of hearing, as well as in elderly people. In August 2013, a new cell phone application was announced which photographs the eye and can be used to diagnose cataracts, macular degeneration (AMD), and other eye pathology, for interpretation by experts far away and to enable arrangements to be made for appropriate intervention to prevent blindness, which is common in developing countries. Other applications allow for monitoring of blood sugar of diabetics, hypertension, exercise, dietary management, and other aspects of health. In the same month, a camera, computer, and auditory device allowing blind people to "see and read" was demonstrated. The costs of such devices are initially high but will fall with advances in computing and other technical developments.

In both developing and industrialized countries major causes of death include cardiovascular diseases (coronary heart disease and stroke), along with respiratory diseases, cancer and injuries, all amenable to preventive and curative medical care. The key preventive measures for these are: healthful diet, reduced obesity, smoking cessation, exercise and physical fitness, hypertension management, aspirin, immunizations and other low-cost and highly effective medications such as statins. These are all low-cost self-care measures that can be promoted by local, state, and national governments, private advocacy organizations, and individuals in their families and communities. The principles of low technology, cost-effectiveness, and sound health policy converge in addressing these fundamental issues.

Priority Interventions in Low- and Medium-Income Countries

Disease control priorities for low- and medium-income countries are an important challenge for public health. Selection has often been based on individual initiatives due to strong advocacy in international organizations by donor countries, organizations, or individuals. In 1993, two landmark documents attempted to apply a logical system to such considerations: one was the World Bank's now classic *World Development Report: Investing in Health* and the other was *Disease Control Priorities in Developing Countries*. The *World Development Report* defined cost-effective clinical and public health cluster programs essential to improving health outcomes for low- and middle-income developing countries. The programs focus on those diseases that contribute heavily to the burden of disease and are amenable to relatively inexpensive interventions. The report defined interventions most able to reduce the burden of disease in low- and middle-income countries using clinical and public health interventions, as summarized in Table 15.2.

The 1993 *World Development Report* provided policy makers and public health practitioners with a concept and tools for assessing cost-effectiveness of available interventions for the major health problems in the developing world. It also provided useful measuring tools in the form of disability-adjusted life years (DALYs) to calculate the burden of disease and the cost-effectiveness of interventions to address them. This World Bank report addressed clinical interventions that would reduce DALYs lost by 24 percent in low-income countries and 8 percent in middle-income countries, including treatment of TB, with directly observed therapy, short course (DOTS); integrated management of the sick child; prenatal and delivery care; family planning; treatment of STIs; and limited care for pain, infections, and trauma as resources permit. It also addressed public health interventions, which would reduce DALYs lost by 8.2 percent in low-income countries and 4 percent in middle-income countries, expanded immunization with vitamin A supplements; tobacco and alcohol control; AIDS prevention; and school health including deworming. Together, the total reductions would be 32 percent for low-income and 12 percent for middle-income countries (Table 15.2).

These estimates have been refined by numerous studies conducted over the subsequent two decades. The second edition of the *Disease Control Priorities in Developing Countries* (2006) incorporates important changes in the technologies available. The concept of viewing priorities with an economic epidemiology model is still applicable, and has increased in importance (Box 15.1).

TABLE 15.2 World Bank Model for Priority Cost-Effective Health Interventions in Low- and Middle-Income Developing Countries

Service Type	Burden of Disease Averted (%)	
	Low-Income Countries	Middle-Income Countries
Public health interventions		
EPI-plus immunization (DPT, polio, measles, BCG, hepatitis B, yellow fever, vitamin A)	6.0	1.0
Other public health programs (family planning, health, and nutrition education)	NA	NA
Tobacco and alcohol control programs	0.1	0.3
AIDS prevention program	2.0	2.3
School health program (including deworming)	0.1	0.4
Subtotal (public health)	8.2	4.0
Clinical interventions		
Treatment of tuberculosis (short course)	1.0	1.0
Integrated management of the sick child	14.0	4.0
Prenatal and delivery care	4.0	–
Family planning	3.0	1.0
Treatment of STIs	1.0	1.0
Limited care: pain, trauma, infection plus as resources permit	1.0	1.0
Subtotal (clinical care)	24.0	8.0
Total	32.2	12.0

Note: Low-income = < US$350 gross national product (GNP) per capita; middle income = > US$2500 GNP per capita. Cost per immunized child = US$14.60 (US$0.50 per capita) and US$27.20 (US$0.80 per capita) in low- and middle-income countries, respectively.
DPT = diphtheria–pertussis–tetanus; BCG = bacille Calmette–Guérin; AIDS = acquired immunodeficiency syndrome; STI = sexually transmitted infection.
Note: The World Development Report was an innovative basis for follow-up work, as reported in Jamison DT, Breman JG, Measham AR, Alleyne G, Claeson M, Evans DB, et al., editors. Disease control priorities in developing countries. 2nd ed. Disease Control Priorities Project. Washington, DC: World Bank; 2006.
Source: Adapted from World Bank. World development report. Investing in health. New York: Oxford University Press; 1993.

BOX 15.1 Disease Control Priorities in Developing Countries

- Average life expectancy in low- and middle-income countries increased dramatically since the 1960s, while cross-country health inequalities decreased.
- Improved health has contributed significantly to economic welfare since the 1960s.
- Five critical challenges face developing countries (and the world) at the beginning of the twenty-first century:
  - Rapid demographic growth
  - HIV pandemic improved but still rampant
  - Persistent malaria, TB, diarrhea, pneumonia
  - Micronutrient malnutrition for mothers and infants
  - NCDs
  - Possible pandemics.
- Cost-effective interventions include:
  - Interventions to reduce neonatal mortality (50 percent of total child deaths)
  - Treatment of HIV-positive mothers, treatment of sexually transmitted infections
  - Controlling tobacco use, particularly through taxation
  - Lifelong medical management of risk factors in individuals at high risk for heart attacks or strokes, using aspirin and other drugs, would benefit tens of millions of individuals.
- Reform of health services and systems is needed, including:
  - Provider incentives
  - Provider focus on selected intervention to gain experience
  - Strengthening surgical capacity at district hospitals
  - Targeting limited resources to diseases affecting the poor, e.g., TB in low-income countries
  - In middle-income countries, public finance (or publicly mandated finance) of a substantial package of clinical care for all.
- Generation and diffusion of new knowledge and products underpinned the enormous improvements in health in the twentieth century and need to be applied for the control of NCDs, HIV, TB, and neglected populations.

Note: HIV = human immunodeficiency virus; TB = tuberculosis; NCD = non-communicable disease.
Source: *Adapted from Jamison DT, Breman JG, Measham AR, Alleyne G, Claeson M, Evans DB, et al., editors. Disease control priorities in developing countries. Chapter 1, Investing in health, Table 1.1. 2nd ed. Washington, DC: World Bank; 2006.*

As the MDGs are reaching their endpoint in 2015, follow-up global health targets will need to recognize the vital importance of non-communicable diseases (NCDs) in developing countries. The global consensus on MDGs, set out by the United Nations (UN) in 2001, indicates progress in the epidemiological understanding of realities in low-income countries and the need for consensus over common targets. Since then, attention has been directed towards the epidemiological shift to NCDs, which are the most common causes of death in low- and medium-income countries. Thus there is a double burden of infectious, nutrition, maternal, and child priorities, alongside the NCDs. The increasing adoption of vaccines such as *Haemophilus influenzae* type b (Hib) and rotavirus alongside the standard

diphtheria–pertussis–tetanus (DPT), poliomyelitis (polio), and measles–mumps–rubella (MMR) vaccines provides new possibilities to control the major infectious disease killers of children. New technologies such as the advent of antiretroviral treatment for HIV have led to startlingly successful improvements in the quality of life and longevity of HIV/AIDS patients, and the prevention of onward transmission of HIV from mothers to babies and sexual partners. The WHO and many other global health stakeholders continue this work and produce analyses to contribute to policy making based on economic epidemiological evidence. This work affects policy, slowly but importantly.

In 2003, the Bellagio Study Group on Child Survival estimated that the lives of 6 million children could be saved each year if 23 proven interventions were universally available in the 42 countries in which 90 percent of child deaths occurred in 2000. The MDGs set out in 2001 provided targets for economic, educational, and environmental improvements, with three specifically focused on health: reducing child mortality; reducing maternal mortality; and control of HIV, TB, and other diseases. While important progress is being made, some of these targets will not be achieved by 2015. The global public health infrastructure will need to be expanded in content and strengthened in order to implement lessons learned in childhood routine immunization, safe maternity care, and nutritional security (see Chapter 16).

In medium- and low-income countries the difficulties are much more severe because of limited resources for health and the weak infrastructure of facilities and human resources in many countries. The key issues relate to NCDs, as in developed countries, so the interventions most needed address cardiovascular diseases, cancer, and injury, as well as diarrheal diseases, malnutrition, vaccine-preventable diseases, HIV, TB, malaria, and neglected tropical diseases. Efforts should be focused on low-cost interventions such as smoking reduction, vitamin and mineral fortification of foods, HIV, TB, and malaria control, along with maternal and child health protection.

Priority Selection in High-Income Countries

As discussed in Chapters 5 and 13, high- and middle-income countries also face complex health challenges, including aging populations, health costs, rapid development of new drugs and technologies, high rates of NCDs, and the rising prevalence of obesity and diabetes. Selection of priorities for health care expenditure from public and private sources has become a major focus of managing health systems.

In the industrialized countries, technological advances in the medical and public health fields have been major contributors to increasing longevity but also rising health costs. This situation has led to pressures for greater selectivity in adopting costly innovations without adequate assessment of benefits and costs. Many countries have adopted more cautious policies with regard to financing high levels of expansion of new technology in the field of medical equipment, clinical procedures, or medications. Organized assessment of technology is now an essential feature of health management at the international, national, and local levels of service delivery. The major responsibility for technology assessment is at the national level, even with decentralization of service management.

With available resources being limited, health systems must choose interventions to be selected and how health systems are to be organized for efficiency and effectiveness while meeting public expectations. The US Patient Protection and Affordable Care Act (PPACA, more generally called ACA or "Obamacare") is undertaking reform measures to promote efficiency and prevention to reduce per capita health costs and to include more people in prepaid health care (see Chapters 10 and 13). These include preventive measures as recommended by Healthy People 2020 and implementation committees for selection of cost-effective measures to reduce morbidity and mortality to reduce health costs. The range of services to be promoted includes smoking cessation, increased physical activity, weight loss, healthy dietary practices, cancer screening, and many others that have not been previously accessible to those living in poverty and with no or limited health insurance. There is an emphasis on vaccination for children and adults.

The WHO promotes the widespread use of basic radiological units (BRUs) to increase access to low-cost, effective, diagnostic X-rays, especially in rural areas in developing countries. BRUs are hardy, relatively inexpensive pieces of radiological examination equipment that can be used in harsh field conditions for simple diagnosis of fractures and respiratory infections. The WHO estimates that 80 percent of all diagnostic radiology can be performed adequately using simple, safe, and low-cost equipment, supported by training of local people to operate and maintain the equipment. This is a consensus view of leading radiologists and clinicians helping the WHO to develop model equipment and training material.

The WHO *World Health Report* of 2009 focused on health technology assessment, stating:

"Technology continues to transform the medical care system and to improve length and quality of life – but at substantial cost. It is almost inconceivable to think about providing health care in today's world without medical devices, machinery, tests, computers, prosthetics, or drugs. Medical technology can be defined as the application of science to develop solutions to health problems or issues such as the prevention or delay of onset of diseases or the promotion and monitoring of good health."

Appropriate technology in the health field is becoming increasingly complex, laden with economic, legal, and ethical issues. Professional and public opinion demands make this a highly sensitive area of health policy, but responsible management of resources requires decision making that includes consideration of the effectiveness, costs, and alternatives of any new technology (Box 15.2). Failure to adopt

BOX 15.2 Health Technology Assessment

Questions that form the basis of technology assessment for a medical innovation include the following:

- Is it safe and cost-effective for the stated purpose?
- Is it a new service, or does it replace a less efficient intervention which can be phased out of service?
- What is the need it addresses?
- Where is it in the order of priorities of development of the facility?
- Does it duplicate a service already available in the community?
- Does it make medical sense (i.e., does it help in diagnosis and treatment for the patient's benefit)?
- What are the alternatives?
- What are the resources needed in terms of supplies, staffing, and upkeep?
- Can the facility afford it?
- What could otherwise be done with the resources it requires?

Sources: *Adapted from Kass N. Public health ethics: from foundations and frameworks to justice and global public health. J Law Med Ethics 2004;32:232–42.*
Sullivan SD, Watkins J, Sweet B, Ramsey SD. Health technology assessment in health-care decisions in the United States. Value Health 2009;12:S39–44. Available at: http://www.ispor.org/htaspecialissue/Sullivan.pdf [Accessed 14 December 2012].
Velasco-Garrido M, Busse R. Policy brief: Health technology assessment: an introduction to objectives, role of evidence, and structure in Europe. Geneva: WHO on behalf of the European Observatory on Health Systems and Policies; 2005. Available at: http://www.euro.who.int/__data/assets/pdf_file/0018/90432/E87866.pdf [Accessed 22 October 2012].

new innovations can result in obsolescence, while excessive expenditures for hospitals and medical technology prevent a health system from developing more cost-effective preventive approaches, such as improved ambulatory care, or supportive care for the chronically ill.

HEALTH TECHNOLOGY ASSESSMENT

Technology adoption can be a highly emotional and controversial issue, in advocacy of new cancer treatments or in criticism of managed care or national regulatory agencies, but spending limited national resources on some devices or medications of unproven value or inappropriately long hospital stays denies resources needed for other aspects of health care. A society must be able and willing to pay for medical innovation or improving quality of life by medical and public health interventions. Underfunding of a health system can deny these benefits just as misallocation of resources does, and this is a political issue even more than a professional one.

Medical and health technology assessment is the process of determining the contribution of any form of care to the health of the individual and community. It is a systematic analysis of the anticipated impact of a particular technology in regard to its safety and efficacy as well as its social, political, economic, legal, and ethical consequences. The technology may be a machine, a vaccine, an operation, or a form of organization and management of services. Analysis should include cost–benefit and cost-effectiveness studies (see Chapter 11) as well as clinical outcomes and other performance indicators.

Pressures from medical professionals, manufacturers of new medical equipment, and the public for adoption of new methods can be intense and continuous. Care must be taken that the specialists involved in committees for assessment are not those who may directly or indirectly benefit from the exploitation of technology, and who therefore may have conflicts of interest. Assessment must be multidisciplinary, involving policy analysts, physicians, public health specialists, economists, epidemiologists, sociologists, lawyers, and ethicists. The available information needs to include evidence from clinical trials, critical analysis of the literature, and the economic effect of adopting the technology on allocation of resources.

Medical technology varies in complexity and cost, not only to produce but in its utilization. Medical technology that is inexpensive to supply and administer is known as low technology or *low-tech*, while high technology or *high-tech* refers to costly and complex diagnostic and treatment devices or procedures.

At the low-tech end of the technology scale, oral rehydration therapy (ORT) was developed in the 1960s for oral replacement of fluids and electrolytes lost in diarrheal disease, particularly in children. It has been described as one of the greatest medical breakthroughs of the twentieth century. The introduction and wide-scale use of ORT for prevention of dehydration from diarrheal diseases throughout the world has saved hundreds of thousands of lives. Use of insecticide impregnated bed nets and reintroduction of DDT in household spraying along with vector control and improving diagnostic tools are low-tech but effective and key tools in malaria control.

Advances in endoscopic surgical techniques since the 1990s, and in robotic surgery since 2000, have greatly improved patient care by reducing trauma, discomfort, and length of hospital stay and endoscopy has become the surgical approach of choice for many procedures. Since reports of the first 100 operations performed in France in 1990, endoscopy has spread rapidly to all parts of the world. It is now recognized by surgeons worldwide as a safer, less traumatic and more effective alternative to traditional invasive surgery. Although the operating time is longer, patients are discharged from the hospital within several days and return to work shortly thereafter, compared to the long hospital stays after more invasive surgical procedures in the past. Following traditional abdominal surgery, a patient may acquire infections and require intensive care initially and a recovery period of many weeks.

Endoscopic surgery for cholecystectomy and esophageal, colorectal, hernia repair, renal, orthopedic, and other forms of surgery which previously were carried out with the patient remaining in hospital for many days are now done on a not-for-admission basis. Not-for-admission surgery has become standard practice in hospitals, extending the range of outpatient surgery and the comfort of patients who can return to their own homes to recuperate and return to regular activities much sooner. Fewer complications arise and patient comfort and economic implications are important. As a result, fewer hospital beds are needed for postoperative care than previously thought necessary, while surgical and ambulatory care facilities may need expansion to accommodate the growing elderly populations needing surgical interventions but requiring shorter recovery. This innovation is now accepted as the standard of much of modern surgical care and shows that simple organizational changes can save money and improve patient safety and comfort.

The bacterium *Helicobacter pylori* was first identified as the cause of peptic ulcers of the stomach and duodenum in 1982 (Robin Warren and Barry Marshall, Nobel Prize 2005). This discovery led to effective diagnosis and rapid, inexpensive treatment of chronic peptic ulcer disease. This has resulted in elimination of a major component of surgical procedures for chronic peptic ulcer diseases as well as a reduction in gastric cancer (see Chapter 4). Surgery for gastrectomies, vagotomies, and other outdated forms of treatment are now virtually gone, contributing to a decreased need for hospital beds even for an aging population. This and many other innovations in medical care have led to a growth in the use of ambulatory care for many forms of surgical, medical, and mental health care, along with much shorter length of hospital stay than in previous times. All of these factors have led to greater emphasis on ambulatory, outpatient, and home care services.

The dissonance between high-tech and low-tech procedures may lead to serious consequences in any health system. Choices require well-informed analysis of benefits, costs, alternatives, ethical considerations, and political consequences before limited health care resources are allocated between hospital-based high-tech medicine and low-tech primary care.

High-tech procedures are usually applied in hospital settings in the context of other highly specialized care for seriously ill, often terminal, patients. Computed tomography (CT), invented in the 1960s, quickly proved to be an extremely valuable diagnostic tool. Advances in CT, magnetic resonance imaging (MRI), and subsequent imaging techniques have proven to be cost-effective and lifesaving, replacing less efficient and more dangerous invasive procedures. The CT and MRI scans allow the clinician to reach a rapid diagnosis of many lesions before they can be detected by other invasive and dangerous diagnostic techniques, at stages where the lesions are subject to earlier and more effective interventions. Imaging technology is advancing rapidly and promising inexpensive new systems for long-distance transmission of imaging to medical centers may provide enormous benefits to people living in rural or developing countries. Recent advances in low-intensity CT screening of long-term heavy smokers for lung cancer have recently been added to recommended and potentially effective and cost-saving practice and may change the outlook for this disease in the coming decade (US Preventive Services Task Force, 2012 Flahault and Martin Moreno, 2013).

Technology assessment also examines methods of preventing and managing medical conditions. Treatment protocols or clinical guidelines are based on decision analysis of accumulated weight of evidence. Published clinical studies are assessed in meta-analyses, using statistical methods to combine the results of independent studies, where the studies selected meet predetermined criteria of quality. This provides an overview from pooling of data, but also implies an evaluation of the studies and data used. Clinical guidelines are part of raising standards of care, but also contribute to cost containment. Many countries form professional study groups to carry out meta-analyses on important health policy issues and new technologies.

Technology Assessment in Hospitals

There is considerable variance among countries, hospitals consume between 40 and 70 percent of total national health expenditures, with pressures for increased staffing and novel medical technology being a continual inflationary factor. Industrialized countries have all reduced their acute care hospital bed supplies and length of stay so that their expenditures for hospital care have fallen to between 30-40 percent of total health expenditures. Shorter stays and older patients have resulted in a drift towards intensive care, especially for internal medicine patients. Medical innovation is a continuing process with new diagnostic and treatment modalities reaching the market.

Hospitals no longer live in splendid isolation in the medical economy. A national or state government needs regulatory procedures to rationalize distribution of medical technology. The "certificate of need" is a form of technology assessment that has been used in the USA since the 1960s to assess and regulate the development of hospital services to prevent oversupply and costly duplication of services. It attempts to establish and implement the use of rational criteria for diffusion of expensive new technology. Whether this has had a lasting impact on restraining the excesses of high-tech medicine is arguable. This regulatory approach was limited to the hospital setting and failed to stop the development of high-tech medical services such as ambulatory for-profit CT, imaging, and in vitro fertilization centers.

Many countries have adopted national technology assessment systems to review topics as far-ranging as guidelines for acute cardiac interventions; liver, heart, and

lung transplantation; minimal access surgery; and beam and isotope radiotherapy. Other technology assessment guidelines include diagnostic ultrasound, sleep apnea, molecular biology, prostate cancer, MRI, and new medications for inclusion in a national health system's approved basket of services.

Despite the limitations of this approach, where governments do not directly operate health care services, governmental regulation is necessary to prevent inequities in services by excessive development in some geographic areas at the expense of others, or by overexpansion of the institutional sector of health care at the expense of primary care. Regulatory mechanisms are essential in health care planning to restrain excessive and inappropriate use of high-tech services, but need augmentation by fiscal incentives to promote other essential services.

Hospitals everywhere face serious problems of hospital-acquired infections, which occur in about 5 percent of all hospitalizations. Healthcare-associated infections (HAIs), including multidrug-resistant bacterial infections, cause long lengths of stay, high costs, and most importantly, unexpected deaths and serious disabilities. Prevention of hospital-acquired infection requires ongoing training, staffing, and organization. The Centers for Disease Control and Prevention (CDC) defines HAIs as "infections caused by a wide variety of common and unusual bacteria, fungi, and viruses during the course of receiving medical care". Some of the preventive measures are simply promoting frequent hand washing by caregivers and visitors, and immunization of staff members against influenza and pneumonia, which can be problematic if there is staff resistance to influenza vaccination.

Training and routine supervision of cleaning staff are also vital, as are strict infection control measures for isolation rooms, strict protocols for catheter care, surgical suite sterility, surgical site infections, central line associated bloodstream infections, ventilator-associated pneumonias, catheter-associated urinary tract infections, and *Clostridium difficile*-associated disease. Guidelines for their control in surgical dialysis, pediatric, outpatient, and other vulnerable departments are available from CDC. The benefits of preventive procedures for this problem include cost estimates ranging from US$5.7–6.8 billion (20 percent of infections preventable) to US$25.0–31.5 billion, yet 70 percent of HAIs are preventable by well-known methods such as frequent and careful hand washing by medical and nursing staff, catheter and infusion care, and other similar measures (CDC, 2012).

Technology Assessment in Prevention and Health Promotion

Technology assessment of preventive care programs includes evaluation of the methodology itself, along with the costs and measurable benefits, as in reduced burden of disease. DOTS is the standard management of sputum-positive and sputum-negative TB, at low cost for DALYs saved. The coexistence of HIV and other complications has created multidrug-resistant tuberculosis (MDR-TB), which is difficult and costly to treat and cases constitute a source of continuing spread of the disease. A 2012 meta-analysis of cost-effectiveness of MDR-TB treatment in Estonia, Peru, the Philippines, and Russia shows it to be cost-effective and best carried out on an ambulatory basis (Fitzpatrick and Floyd, 2012).

Wide use of available and effective vaccines such as Hemophilus influenza b (Hib), pneumococcal pneumonia, influenza and rotavirus reduce hospitalizations and mortality from respiratory and diarrhoeal diseases among children, the elderly and other age groups. Vaccine prices generally fall after their initial period of use as manufacturing costs are lessened by improved methods or by bulk purchase contracts, as occurs in the public sector. For example, in 2012 MMR vaccine cost US$19.33 per dose if purchased through the CDC, but US$52.73 per dose if purchased in the private sector in 10 packs of single-dose units of the vaccine. A combined diphtheria, tetanus, acellular pertussis (DTaP) vaccine cost US$15.00 when purchased through CDC, while the same vaccine purchased with hepatitis B and inactivated polio vaccine (IPV) cost US$52.10 per dose. But the combination saves repeated visits and loss of compliance for that reason. The new human papillomavirus (HPV) cervical cancer vaccine cost US$130.27 per dose for the series of three doses per person, while the vaccine against diarrhea-causing rotavirus, approved in 2006, cost US$106.57 per dose for the recommended three doses (CDC, 2012).

The WHO recommends the inclusion of rotavirus vaccination in a country's immunization program, but the costs of the current generations of rotavirus vaccines are high in comparison to the budgets for vaccines for prevention of childhood illnesses in many developing countries. Many cost-effectiveness studies have shown this vaccine to be highly beneficial and it could help to reduce the very high global burden of disease of over 500,000 child deaths and 2 million hospitalizations occurring annually (Tu et al., 2011).

Vaccine programs must take into account transportation and administrative costs and expenses of ordering, storing, inventory control, cold chain, insurance, wastage, and spoilage. Multiple vaccines in one dose are less costly and less inconvenient for all. Examples include DTaP plus polio and Hib, or MMR (see Chapters 4 and 6). There is a need for implementation of legal protection of manufacturers from excessive litigation judgments while protecting the interests of the public and individuals who may have reactions to vaccines.

In 2012, the reappearance of pertussis and diphtheria raised concerns about immunization coverage and

efficacy. Public opinions on vaccination may not be as supportive as in previous years. Mothers who oppose pertussis immunization for their children, such as occurred in the UK during the 1980's, leave their children vulnerable to a serious and often deadly disease, which has recurred since 2010.

The WHO estimates the cost of all immunization activities in all 117 low- and middle-income countries for the period 2006–2015 to be US$75 billion, while low-income countries would need US$35 billion. The rate of adoption of currently available and new vaccines will be determined by governmental decisions in each country, although external aid – such as that of the Global Alliance for Vaccines and Immunization (GAVI), an international public–private consortium to promote vaccination – is a valuable resource. The United Nations Children's Fund (UNICEF) is concerned about supply problems as well as costs, but the key issue relates to political decisions, funding, and capacities of national immunization systems.

Despite an excellent vaccine having been available since the 1960s, measles epidemics continue to occur in the industrialized countries. In the 1900s global deaths from measles were in the order of 1 million people per annum. Two major epidemics of measles occurred in Canada in the early 1990s, despite high rates of immunization coverage. Following this, a 1993 Delphi conference of experts from 31 countries reached a consensus recommending a two-dose measles immunization policy. Measles eradication has been set as a goal by the WHO and 90 percent reduction in cases and fatalities has been achieved since the 1990s. However, measles elimination requires coverage of 95 percent of children and two doses of a measles-containing vaccine (preferably MMR).

Measles reappeared as a widespread disease in Europe in 2010–2013 with tens of thousands of cases, many hospitalizations, and some deaths. It spread to the Americas, brought by travelers, and resulted in modest sized outbreaks, including the UK in 2012–2013. Eradicating measles by 2020 is projected to cost an additional discounted US$7.8 billion and avert a discounted 346 million DALYs between 2010 and 2050. As new vaccines enter the field, it is important to evaluate their effectiveness, costs, and the benefits to be derived.

The cost of the hepatitis B vaccine initially was over US$100 for an immunization schedule of three doses but has come down dramatically to less than US$1 per dose in developing countries for bulk purchases. However, in the USA, the price of vaccination per dose is estimated at US$41 if given by a general practitioner, US$15 if administered through an existing childhood immunization program, and US$17 if given through the school medical system. This is a standard vaccine covered by public and private health insurance systems. The vaccine is a cost-effective method to prevent liver cancer and the long-term effects of chronic hepatitis.

Screening and education for thalassemia in high-prevalence areas have nearly eradicated the clinical disease but not its carrier status in Cyprus, southern Greece, and other countries. Newborn screening and case management for phenylketonuria, congenital hypothyroidism, Tay–Sachs disease, and many other genetic diseases have been shown to be far less expensive than post-facto treatment of severely developmentally delayed and dependent children born with these diseases (see Chapter 6).

The success of Papanicolaou (Pap) smear screening in reducing cancer of the cervix mortality since the 1960s has been dramatic. The discovery of causation of cancer of the cervix by HPV strains led to development of an effective vaccine, which has been in use since 2006. Recent evidence shows that male circumcision can reduce transmission of HPV as well as HIV and other sexually transmitted diseases, and it is being adopted as an effective intervention in countries with high rates of both HIV and cancer of the cervix, such as in sub-Saharan Africa.

The drastic reduction in cancer of the cervix provides a powerful demonstration of the effectiveness of public health screening and other measures to control this major malignant cause of death in women. Screening for cervical cancer by Pap smears is recommended annually for high-risk groups, and every 2 or 3 years for other adult women (Box 15.3). Screening will remain vital for many years to come as the HPV vaccine comes into general use, and as its cost is reduced, but its protective effect for individual and herd immunity will not replace the need for ongoing screening for this very common cancer. HPV vaccine is also being recommended for all boys to prevent oral and anogenital cancers and HPV transmission to girls.

Routine mammography screening for breast cancer every 1–2 years is recommended by the US National Cancer Institute for women over the age of 40 and for younger women with high-risk factors (e.g., previous cancer, family history, genetic markers). Cost-effectiveness analysis is now an essential part of decision making in health policy and priorities. While there is controversy over the frequency of routine testing, mammography remains a mainstay in women's health and contributes to early case finding and falling mortality rates from breast cancer. Figure 15.1 demonstrates differences in utilization of mammography among US women in the age group 50–64 years within the previous 2 years, by insurance status. US women with private insurance (mostly through place of employment) had over 70 percent compliance, those with public insurance (primarily Medicaid) averaged about 60 percent compliance, while those with health insurance had average compliance rates of about 45 percent during the period 1993–2010. The UK National Health Service (NHS) invites women between the ages of 50 and 70 for screening every 3 years;

BOX 15.3 Technology for Prevention of Cervical, Colorectal, Liver, Stomach and Lung Cancers

Cancer of the cervix is the second most common cancer among women worldwide, with about 500,000 new cases and 250,000 deaths worldwide annually. Approximately 80 percent of cases occur in low-income countries, where cervical cancer is the second commonest cancer in women (WHO, 2012).

In the USA, and other industrialized countries, the incidence and mortality of cancer of the cervix have been going down steadily since the introduction of Papanicolaou (Pap) smear testing. Cervical cancer incidence declined during the period 1999–2008 by 2.3 percent per year and mortality declined by 1.9 percent per year an estimated 12,170 cases of invasive cervical cancer diagnosed in the USA with 4220 deaths in 2012.

Prevention of cancer of the cervix has until recently mainly focused on Pap smears to detect the disease while still in a precancerous (cancer in situ) phase, and this procedure reduced rates dramatically over the latter part of the twentieth century. The newly developed and highly effective vaccines against key strains of human papillomavirus (HPV) is now being used in routine immunization of young girls and more recently boys as well. The high cost of the vaccine precludes its rapid diffusion to most parts of the world but its use is spreading and being included in immunization programs funded by donor agencies in sub Saharan Africa. The vaccine should, in principle, also be used by adult women, in addition to continuation of routine Pap smear testing.

In the past decade, evidence of HPV as the cause of cancer of the cervix and the presence of HPV in uncircumcised men has brought circumcision back to professional and public debate. Reports from Africa of reduced risk of acquiring HIV among circumcised men have brought new attention to adult male circumcision, which is now actively promoted many sub-Saharan African countries.

The technological breakthroughs of the Pap smear in the 1950s, HPV testing in the 1990s, and the HPV vaccine in the 2000s should also include prevention by male circumcision. Visual inspection of the cervix and cryotherapy can treat precancerous cervical lesions in areas of developing countries as part of community health worker programs.

Colorectal cancer, the 7th leading cause of death in high income countries, is amenable to prevention by early screening using colonoscopy and fecal occult blood (FOB) testing. Screening is recommended for all persons over age 50 at 5 year intervals along with annual FOB testing. Where there is a family history of colorectal cancer or polyps, routine screening should begin earlier. Increasing use of screening and improved medical care are resulting in improving survival and declining mortality rates.

Stomach cancer is 10th leading cause of death in upper middle income countries. Prevention relies on early treatment of chronic peptic ulcer disease caused by Helicobacter pylori infection. This is readily diagnosed by a simple breath test and completely cured by low cost antibiotics. Increased awarenss and access to these services would enhance long term trends of reducing mortality from stomach cancer.

Liver cancer is 8th leading cause of death in upper middle income countries due to the global prevalence of hepatitis B and helaptitis C. Hepatitis B is now falling due to widespread vaccination in childhood. Hepatitis C is now the major cause of liver cancer affecting hundreds of millions of persons worldwide. There is still no vaccine currently available, but screening and treatment is now used in the industrialized countries and will become more widely used as simpler, less costly treatments with less side effects are becoming available.

Early detection of lung cancer with spiral low dose tomodensitometry for smokers is recently being recommended by many professional bodies.

More basic cancer preventive measures such as smoking cessation, healthy diets, regular exercise, and moderate alcohol use are discussed in chapter 5.

Sources: *World Health Organization. Sexual and reproductive health. Cancer of cervix. Available at: http://www.who.int/reproductivehealth/topics/cancers/en/ World Health Organization. The top 10 leading causes of death (2011). Available at: http://who.int/mediacentre/factsheets/fs310/en/index1.html*
Centers for Disease Control and Prevention. Cervical cancer trends 2012. Available at: http://www.cdc.gov/cancer/cervical/statistics/trends.htm [Accessed (13.12.2012)].

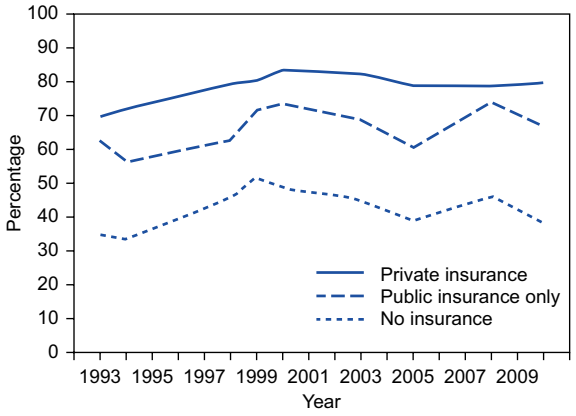

FIGURE 15.1 Self-reported percentage of women aged 50–64 years receiving a mammogram in the past 2 years, by health insurance status, USA, 1993–2010. *Source: Centers for Disease Control and Prevention. QuickStats from the National Center for Health Statistics: Percentage of women aged 50–64 years who reported receiving a mammogram in the past 2 Years, by health insurance status — National Health Interview Survey, United States, 1993–2010. MMWR Morbid. Mortal. Wkly. Rep. 2013;62:651. Available at: http://www.cdc.gov/mmwr/pdf/wk/mm6232.pdf (accessed 12.1.14).*

with an average of 75 percent respond to the invitation, of whom 4 percent are referred for further testing (UK Cancer Research, 2012) and as in most industrailized countries breast cancer mortality rates are falling impressively (see Chapter 5).

Health promotion in reducing exposure to HIV and cigarette smoking has been shown to be very cost-effective despite its low-tech or non-technological methodology, involving primarily group or mass education. Hypertension screening and case management is low-tech but highly effective in preventing strokes and blindness.

Low-tech innovations have had an important impact in reducing death and injury. These include mandatory use of car seat belts (introduced since the 1970s and 1980s in many countries), children's car seats, air bags, and bicycle and motorcycle helmets. Iodization of salt, vitamin A supplementation, and food fortification prevent large numbers of clinical cases of severe retardation, death, and blindness at low cost per child protected.

TABLE 15.3 Examples of High-Tech and Low-Tech Health Problem Solving

Problem	High Tech	Low Tech
Birth defects	Surgical repairs, rehabilitation	Folic acid fortification of flour, vitamin supplementation before and during pregnancy
Infectious diseases	Treatment – antibiotics	Vaccination, sanitation, handwashing, infection control in hospitals, health facilities, and nursing homes
Breast cancer	Screening – mammography	Nutrition, self-examination, routine medical examination
Colon cancer screening	Colonoscopy	Nutrition, vitamin D supplements; fecal occult blood testing
Acute myocardial infarction, primary, secondary prevention	Coronary angioplasty, stent, bypass surgery, heat transplantation	Antiplatelet thrombosis treatment (e.g., aspirin, intravenous streptokinase, beta-blocker); rehabilitation; diet, exercise, smoking cessation
Gallstones	Lithotripter, abdominal cholecystectomy	Endoscopic surgical removal
Head injuries	Intensive care	Helmets for bicycle riders and motorcyclists, seat belts in front and rear of motor vehicles
Thalassemia	Transfusions, chelating agents; prenatal diagnosis, amniocentesis, chorionic villus biopsy	Screening, education, counseling
Dehydration	Infusions	Oral rehydration
Neural tube defects	Surgery, pregnancy termination	Folic acid fortification of flour and grain products, supplements for women of fertile age
Liver cirrhosis, liver failure, cancer	Liver transplant	Hepatitis B vaccine, risk reduction activities among intravenous drug users, screening blood donors
Cancer of stomach	Surgery, chemotherapy	Dietary change, cure of *Helicobacter pylori*-generated gastric ulcers
Cancer of cervix		Pap smear screening; visual inspection and cryotherapy; human papillomavirus vaccine

Education for reducing risk factors for the cardiovascular disorders is far less costly than the premature deaths and high medical costs of patients suffering stroke and congestive heart failure. Health education, condom and needle supply, and screening of blood donations are the most important effective community health measures against the spread of HIV. Table 15.3 shows a comparison of high-tech and low-tech approaches, which often complement each other, to selected health problems.

Technology assessments represent the current consensus derived from reviews of published studies and exchange of views of highly qualified clinicians, epidemiologists, and economists within a context of technology assessment. They may change over time as new data or innovations are reported, and this possibility should be kept in mind in such discussions. Technology assessment mobilizes information and critically analyzes many aspects of medical technology to build a wide community consensus to influence policy decisions. Public opinion, political leadership, and administrative practice, as well as the scientific merit of a case are all factors in developing a consensus.

Technology Assessment in National Health Systems

Technology assessment requires an organization within the framework of national regulatory agencies. The FDA serves this purpose as a statutory body within the US Public Health Service. Sweden, Canada, Australia, the UK, the Netherlands, Spain, and other countries also have technology assessment advisory or regulatory agencies established by national governments to monitor and examine new technologies as they appear. Sweden has a widely representative national Swedish Council for Technology Assessment in Health Care which has an advisory role to the national health authorities.

The processes used in traditional systems to regulate food and drugs for efficacy, safety, and cost are more recently being applied to new medical devices and procedures. The unrestricted proliferation of new procedures presents serious dilemmas for national agencies concerned with financing health care and controlling cost increases. Non-governmental health insurance shares this concern, as does industry, which bears much of the

cost of health insurance through negotiated, collective bargaining, "voluntary" health insurance in the USA. Most industrialized countries have national health services or national health insurance and are thus vitally interested in health costs and technology assessment. Many industrialized countries maintain technology assessment and cost-control activities. In the USA, the Agency for Healthcare Research and Quality (AHRQ) maintains oversight and studies related to clinical information, including evidence-based practice, outcomes and effectiveness, comparative clinical effectiveness, risks and benefits, and preventive services.

In Canada, the Health Protection Branch of the Federal Department of Health reviews medical devices and drugs and, with consent of the provincial governments, approves new medical procedures. Concern by governments over the cost implications of new procedures led to this practice. Since 1988, a network of government and professional bodies has formed a non-profit agency for technology assessment (Canadian Agency for Drugs and Technologies in Health, CADTH). This supports the provincial administration of health insurance in resisting professional, commercial, or political pressures to add untested technology or procedures to the health system as covered benefits. A comparison of rates of procedure performance between provinces shows very high discrepancies, as high as two-fold, in procedures such as coronary artery bypass graft or prostatectomy. Control of acquisition of high-tech equipment by national or state authorities is essential to prevent expenditures on high-cost equipment without adequate assessment.

DISSEMINATION OF TECHNOLOGY

The rapid spread of high-tech medical equipment has played a substantial role in escalating health costs. A comparison of the number of MRI scanners per million population in member countries of the Organisation for Economic Co-operation and Development (OECD) (Table 15.4) showed Japan and the USA with the highest number at 43.1 in 2010 (23.2 in 2000–01) and 31.6 (15.4 in 2000) per million, respectively, while the median was 10.5. Canada ranked fourteenth among the 20 OECD countries with 8.2 MRI scanners per million. Comparing CT scanners showed that Japan had the highest number at 97.3 while the median was 15.6. Canada was in eighteenth place among the 28 OECD countries reporting in 2010 with 14.2 CTs per million population. However, it should be noted that countries with the most machines have lower productivity per machine. The USA has far fewer examinations per machine than other countries (OECD, 2012).

The use of endoscopic surgery has spread worldwide since the 1990s. Health professionals become almost instantly aware of new developments from the news media as well as professional diffusion of information at conferences, in exchange visits, in published articles, and most dramatically via the Internet. National policy to foster the introduction of appropriate new technology requires a careful program of regulatory and financial incentives and disincentives to encourage or discourage diffusion of new methods of prevention as well as of treatment and community health care. Kidney transplantation has become a cost-effective and patient-friendly alternative to long-term dialysis both in hospital and at home. The key limitation is

TABLE 15.4 High-Tech Medical Equipment Units, Selected Organisation for Economic Co-operation and Development Countries and Years, 1986–2010 (Rate per Million Population)

	CTs				MRIs			
Country	1986	2000	2005	2010	1986	2000	2005	2010
Japan	27.5	84.4[a]	92.6	97.3[c]	0.1	23.2[a]	40.1	43.1[c]
USA	12.8	25.1[a]	32.3	40.7[d]	0.5	15.4[a]	26.7	31.6
Israel	–	5.7	6.6	9.2	–	1.4	1.7	2.0
Germany	6.9	12.2	15.4	17.7	0.7	4.9	7.1	10.3
UK	2.7	5.4	7.5	8.2	0.3	5.6	5.4	5.9
Canada	–	9.8[b]	11.6	14.2	–	2.5	5.7	8.2
France	4.7	7.0	10.0	11.8	0.5	1.7	4.8	7.0

CTs = computed tomography scanners per million population; MRIs = magnetic resonance imaging units per million population.
Notes:
[a] *1999*
[b] *2001*
[c] *2008*
[d] *2011.*
Source: Organisation for Economic Co-operation and Development. Health policies and data: OECD health data – 2012 data; frequently requested data. Available at: http://www.oecd.org/health/healthpoliciesanddata/oecdhealthdata2012-frequentlyrequesteddata.htm [Accessed 13 October 2012].

the shortage of donors. The same can be said for liver transplantation, which has also been shown to be cost-effective in terms of DALYs saved from chronic liver diseases such as cirrhosis and hepatitis B and C. Heart transplantation has spread among major centers in western countries.

The black market in organs for transplantation has become an international scandal of exploitation of poor people in low-income countries, and is the subject of police investigation in many countries, but it is difficult to control.

Bone marrow transplantation is now used widely and is effective in saving the lives of many people with malignant and non-malignant hematological disorders. Stem cell therapy, by introducing new adult and embryonic stem cells into damaged tissue to treat disease or injury, is becoming feasible for a wide variety of conditions including cancer, type 1 diabetes mellitus, Parkinson's disease, Huntington's disease, celiac disease, cardiac failure, muscle damage, and neurological disorders.

Limitation of new techniques or procedures to selected medical centers allows the passage of time to fully assess the merits and deficiencies of new technology before general diffusion into the health care system. Such limitation, however, is fraught with the danger of depriving the population of benefits of new medical technology, and the possibility of restraint of trade to the economic advantage of selected providers. Current advances in robotic-assisted surgery will expand during the coming decade for brain, bone, joint, prostate, and other surgery, and need to be assessed with regard to patient care benefits, costs, and the economics of capitalization of such innovations. Stem cell therapy is already widespread for some malignant conditions, and with advances in genomics and molecular biological technology it is very likely to become a major therapeutic intervention for many more conditions in the coming years. The effects of new technology on insurance and managed care systems are necessarily involved in decision making as to inclusion of new procedures in their service plans.

Publication in the professional literature is an accepted method of establishing the scientific merit of a treatment or an intervention. Too rapid diffusion of a medical practice can lead to disillusionment and confusion as to the merits of a particular medical procedure, as happened during the 1960s and 1970s with anticoagulant therapy for acute myocardial infarction and gastric freezing for peptic ulcers. Reviews of the literature should be critical and should assess the scientific merits of published data, as well as the sources of funding. Well-controlled large-scale clinical trials are vital to establish the relative values of alternative therapeutic approaches, as are meta-analyses of multiple studies.

Dissemination of information about new medical innovations in the popular media is almost immediate. Many major newspapers and television networks have well-informed medical reporters and commentators who have access to electronic medical journals as quickly as do medical specialists in each field. News magazines may carry special articles on new innovations, creating instant demand for them as benefits in a health program. This ready access to information has both benefits and dangers.

In the USA, health insurers have led the way in developing technology assessment and information synthesis, and in evaluating the costs and benefits of new procedures. The process is affected by public opinion, as well as by court decisions. A landmark decision against a health maintenance organization (HMO) in 1993 awarded US$29 million in damages to the family of a terminal breast cancer patient who died following refusal of the HMO to authorize a bone marrow transplant, which was at the time an experimental procedure. Denial of new technology may lead to increases in malpractice suits. In countries with limited financial resources, selection of technological innovations in health care that can benefit patient care or the public health requires a careful balance in order to use limited resources well, and to gain from the application of appropriate new health care technology.

Payment systems by national or private insurance systems are crucial to introduce and control diffusion of technology. Block budgets for hospitals have been more effective in Canada than in the USA in restraining the proliferation of high-tech equipment. This has led to criticism of the limited access of Canadians to medical technology, such as CT, MRI, and advanced cancer therapies. In the USA, universal application of the diagnosis-related group (DRG) payment system for Medicare, Medicaid, and most private insurance had the effect of increasing ambulatory surgery very dramatically, from 16 percent of all surgery in 1980 to 80 percent in 2008 of all surgical procedures in community hospitals (i.e., non-federal short-stay hospitals or 85 percent of all hospitals in the country). Inpatient surgical procedure rates declined from 85 percent in 1980 to 35 percent in 2008. Although the rate of visits to hospital-based surgery centers remained largely unchanged in the USA from 1996 to 2006, the rate of visits to private ambulatory surgery centers increased by about 300 percent.

HMOs and managed care organizations are paid on a per capita basis and have a strong incentive for cost containment. They have developed procedures and medical guidelines for investigation and intervention that seek to reduce unnecessary procedures. At the same time, HMOs are very active in promoting preventive care and non-hospital care insofar as this is compatible with good patient care.

Coronary bypass procedures decreased in frequency in the USA between 2001–02 and 2007–08. In the USA, such procedures are less frequently carried out in women and African Americans, because of lesser access to health insurance for African Americans and possibly because of biases in terms of case assessment criteria in women. Cardiac invasive procedures increased dramatically since the 1980s

in most industrialized countries, but with wide variation in their use. The benefits of aggressive invasive management of cardiovascular diseases remain controversial, but many such procedures have proven beneficial in reducing mortality rates and improving quality of life.

Critical analysis of the need for surgery has resulted in lower tonsillectomy and radical mastectomy rates along with the increased use of outpatient procedures. Tonsillectomy, a routine procedure until the 1960s, is now performed infrequently since it was found to be of little medical value. Cataract surgery is now largely done on an ambulatory basis. The technology of home care has come to play an important role in early discharge of patients from the hospital, as has the wide use of cancer chemotherapy and radiation therapy on an outpatient basis.

DIFFUSION OF TECHNOLOGY

Innovations in health care through scientific and technological advances are continuing, with exciting breakthroughs being made in effective new treatments and public health interventions, and this requires health authorities, practitioners, and the public to maintain constant awareness of the current state of the art. Diffusion of new technology or adaptations from basic science advances may begin slowly, and then reach a "tipping point", at which time a dramatic change of trend occurs and it becomes the new standard or fashion.

Those with economic interests in the product try to advertise and promote sales, while practitioners are ready to try new methods to help their patients, but those who must pay for services may ask for evidence of effectiveness, safety, added value over present and known methods, and benefit to the length or quality of life of the individual. This can become a highly charged debate when those responsible for adopting new measures in national health plans must weigh one proposed addition against another, each with its ardent professional, community, or business promoters. The new HPV vaccine approved by the FDA in 2006 for prevention of cancer of the cervix is an example.

The HPV vaccine is recommended for preteen girls at the age of 11–12 years and also for females aged 13–26 to offset future sexual exposure to HPV-infected males and since 2012 recommended routinely for teenage boys as well. The two competing main manufacturers of HPV vaccine are naturally interested in increasing their market and market share, and willing to reduce prices. The cost has been lowered substantially for use in developing countries if purchased in bulk, but costs are still prohibitive unless funded by international donors. Competing low-cost manufacture in India has encouraged the two main manufacturers to lower prices to seek broader markets. In 2011, one manufacturer lowered its price dramatically to US$5 per dose, a 67 percent reduction in the current lowest public price. This has allowed GAVI to adopt an HPV strategy for developing countries, where 88 percent of cervical cancer deaths occur, with 275,000 deaths of relatively young women each year (GAVI, 2011, 2012).

Pioneering projects promoting visual examination of the cervix and local cauterization of abrasions by trained nurses and community health workers are meant to increase access to care in traditional villages remote from medical centers. The duration of immunity and whether booster doses will be required are still not known. Policy makers need to consider whether the same money would have greater benefit if used to provide pneumococcal pneumonia and rotavirus vaccine for children in developing countries, which would quickly save hundreds of thousands of lives. It is likely that the wonderful new public health technology that is the HPV vaccine will be absorbed quickly into public health practice at least in the industrialized countries, and is now being introduced by international donor agencies in sub-Saharan Africa.

QUALITY ASSURANCE

Quality assurance is an integral part of public health function and involves ensuring the quality of both health practitioners and facilities. It is an approach that measures and evaluates the proficiency or quality of services rendered. Hospital accreditation is a long-standing method of quality assurance, providing many generations of health providers in North America with first hand experience of quality assurance in community hospitals and long-term care facilities, as well as ambulatory and mental health services. Hospital accreditation has contributed to improvement in standards of facilities and patient care throughout Canada and the USA and has provided a working model for replication or adaptation internationally.

Adverse Events and Negligence

Iatrogenic diseases are adverse events that occur as a result of medical management and result in measurable disability. Negligent adverse events are those events caused by a failure to meet standards of care reasonably expected of the average physician or other provider of care. Hospital-acquired infections, anesthesia mishaps, falls, and drug errors are the most common iatrogenic events.

Iatrogenic disease is a major cause of morbidity, prolongation of hospitalization, and even death. Hospital-acquired (nosocomial) infections are estimated to occur in 7–10 percent of hospital cases in Britain and the USA. Primarily these are caused by urinary, respiratory tract, and wound infections. It is becoming more common that infections involving organisms previously responsive to antibiotics are now resistant to many antibiotics and difficult to treat. Infection control in hospitals is therefore an essential part of hospital organization. Because hospitals are increasingly being paid by DRGs, any secondary event prolonging

hospital stays may have adverse financial effects on the hospital. In the USA, recent decreases in Medicare reimbursements for nosocomial infections reflect this trend to provide financial incentives to improve hospital infection control. There is, therefore, a strong financial as well as professional interest in reducing hospital-acquired infections.

A classic study of 32,000 hospitalizations in New York State carried out by a Harvard University team showed that 3.7 percent of hospitalized patients suffered adverse events or injuries caused by medical mismanagement which resulted in measurable disability. Of these, 28 percent were due to negligence, so that 1.03 percent of all hospitalizations involved medical negligence leading to measurable injury. Of the total of some 100,000 adverse events in the study group, 57 percent recovered within a month and 7 percent had severe injury. Some 14 percent or 14,000 people with adverse events died as a result; 51 percent of these deaths were due to negligence. A 1999 report of the US National Institute of Medicine estimated that between 44,000 and 98,000 people die annually in the USA from medical errors occurring in hospitals, but these data are considered to be overestimated in some studies. Adverse drug events (ADEs) result in 700,000 emergency department visits and 120,000 hospitalizations annually, with US$3.5 billion spent on extra medical costs. CDC estimates that at least 40 percent of the costs of ambulatory (non-hospital setting) ADEs are preventable.

A 2008 report by the Office of Inspector General of the US DHHS reported that 13.5 percent of Medicare beneficiaries experienced adverse events and that for 1.5 percent of beneficiaries, these adverse events contributed to their deaths. An additional 13.5 percent of beneficiaries in the sample experienced temporary harm as a result of their medical care, bringing the total percentage of beneficiaries experiencing instances of care-related harm to 27 percent. Nearly half (44 percent) of these adverse or temporary harm events were preventable.

Hospital-acquired infections cause 99,000 patients deaths in the USA every year (AHRQ, 2009). Higher rates are seen among the elderly and the poor. Rates are lower in teaching hospitals than in community hospitals. About 20 percent of the events were related to drug reactions or dosage errors. Less than 3 percent of those injured brought civil litigation for the negligence. The search for "bad apples" – that is, unethical, criminal, or incompetent health providers – is necessary, but not sufficient to stem the problems created by the health system itself. Prevention requires organized activity. Investigation of adverse events helps to identify methods of prevention and to protect the patient's rights. A program of measures to reduce hospital infection must be based on epidemiological analysis of recorded events in the search for common causes and preventable factors.

Organized surveillance and control requires a ratio of one infection control practitioner per 250 acute care beds, a trained hospital epidemiologist, and routine reporting of wound infections to practicing surgeons (CDC, Hospital Infection Program). Computer-aided medication dispensing, as well as automated and other safety systems are critical elements in minimizing morbidity and mortality resulting from preventable human errors. In response to the high frequency and cost of medical litigation, many states in the USA have enacted legislation to restrict court awards for medical negligence. Proposals for alternatives to the tort system of medical malpractice compensation include arbitration and mediation, an administrative system similar to that used for workers' compensation, and a no-fault system of compensation, such as exists in New Zealand, Sweden, and Finland. In a no-fault system the complainant need not prove negligence on the part of the provider, but only that he or she suffered an adverse event which is compensable at standard rates depending on the degree of disability. In the USA, federal legislation provides compensation for vaccine injuries, and three states have enacted restricted no-fault systems for birth-related neurological injuries.

In addition, there is greater emphasis on the adoption of failsafe mechanisms, such as introducing warning systems in anesthesia machines to alert the anesthetist if oxygen flow in the patient's tubing falls below a safe point. This system was tested in Boston hospitals and found to reduce adverse anesthetic events to zero cases over a 3-year period. Vitamin K injection was made mandatory for all newborns in New York State, as was already the case in some other states, when a study showed deaths from hemorrhagic disease of the newborn in cases where vitamin K was not administered.

Inappropriate medical practice patterns are an equal, or even larger problem for health systems. Comparisons of surgical rates within the USA for coronary bypass procedures, hysterectomies, and caesarean sections show wide variation between different areas of the country. The costs of excess surgery not only are economically wasteful but also involve risks for the patient from the surgery itself or anesthesia mishaps, infection, pain, and discomfort, with legal and ethical questions of unwarranted interventions not for the benefit of the patient. Health systems are increasingly required to evaluate and control excess surgical, investigative, or other medical procedures, not only for financial reasons but also for protection against litigation and infringement of patients' rights.

Licensure and Certification

The requirements that society establishes for allowing an individual to practice medicine, and any health profession, are vital to maintaining and improving the quality of care (see Chapter 14). These standards require defining the training and experience needed by the individual, examination

procedures, and recognition for continued education and maintenance of competence. This requires a statutory base and national bodies operating under a national authority, separate from the agency operating the health system services. Separation of licensing from operation of the health service is essential in maintaining high professional standards.

The licensing authority is accountable to the state and the public. In some cases, this function is delegated to self-regulating professional bodies. In Canada, the licensing of the medical profession and specialty recognition are carried out by the medical profession with self-regulation. In the UK, medical licensing is by a state-appointed board and in the USA by state boards.

Medical schools, postgraduate training programs, and fellowships are all subject to periodic comprehensive assessments. Institutions that fail to meet the standard may have funding or licensure suspended until they have performed adequate remediation.

Health Facility Accreditation

Hospital accreditation in North America is by a voluntary grouping of professional associations, including the Canadian and American Colleges of Physicians and Surgeons, the hospital associations, and the Colleges of Nurses. The Joint Commission, originally operating in both Canada and the USA, carries out regular inspections of hospitals. In Canada, other organizations including the federal Department of Health, provincial ministries of health, the Canadian Diabetes Association, the Public Health Association, and the Standards Council of Canada participate in the Joint Commission as observers. Initially focusing on acute care hospitals, accreditation has been gradually extended to cover special hospitals, long-term facilities, home care programs, public health departments, and ambulatory care services.

Health facility accreditation is a systematic, multidisciplinary inspection of the physical and organizational structure of the facility or program and the functioning of its component parts. Factors measured include staff qualifications, facilities, organization, record keeping, and continuing education of staff.

The process of accreditation requires a request for accreditation from the board of governors of the hospital or health facility, implying acceptance of the standards of the commission. The accreditation process includes a self-assessment, an on-site survey, and follow-up action for correction of deficits and improvements. The commission is invited to conduct a survey, and resurvey as it sees fit. The hospital pays a fee and commits itself to provide all data requested and to cooperate with the site visit. The commission issues a confidential report, giving the accreditation rating and interim statement of deficiencies, and requests progress reports in correcting deficiencies. It is also empowered to carry out follow-up inspections and resurveys. Box 15.4 lists the areas of a large community or teaching hospital, regional health authorities, hospitals, and community-based programs and services, from both private and public sectors, not only in Canada but around the world.

The assessment survey examines the goals and objectives of the organization and its administration, the direction and staffing of the facility, policies, and procedures. Review includes medical staff organization, credentials and review procedures, clinical privileges, selection of department chairpersons and their responsibilities, standing committees, schedule of meetings, bylaws, and the role of the governing board of the hospital. The presence and nature of quality assurance organization, records review procedures, and continuing educations are assessed. The quality of clinical records is assessed by examination of charts for the completeness of histories and documentation of the course of the hospital stay including laboratory reports.

Each section of the program being accredited is assessed in the following categories:

- statement of purposes, goals, and objectives
- organization and administration
- human and physical resources
- orientation, staff development, and continuing education
- patient care
- quality assurance.

These categories are also used in the programs covered by the contracts between Accreditation Canada, formerly the Canadian Council on Health Services Accreditation (CCHSA), and other health and social service agencies.

Hospital accreditation was established in the UK and Australia in the 1980s and is attracting interest in other countries seeking ways to maintain and promote standards. The procedure for accreditation of hospitals is still voluntary in Canada, but in effect has become universal for hospitals of medium and large size (over 75 beds) and common for smaller hospitals. It is seen as advantageous for the governing board and the community and also for the medical staff in terms of medicolegal protection. In the USA, hospital accreditation has become virtually universal since payment for federally funded health insurance (Medicare and Medicaid) beneficiaries is not allowed for non-accredited hospitals, and many private insurers make this requirement as well. In some states, accreditation is mandatory for all hospitals.

Since the 1990s, CCHSA's accreditation program has expanded to cover a diversity of health care and service areas, through contract arrangements with independent non-hospital facilities such as highly specialized programs as well as community health and social service organizations. In 2006, CCHSA introduced standards for child welfare, hospice, palliative and end-of-life care facilities, prison facilities, biomedical laboratories, and supplementary criteria for telehealth. In

BOX 15.4 Accreditation Canada Standards

- System wide:
  - Governance
  - Infection prevention and control
  - Leadership
  - Leadership for aboriginal health services
  - Leadership for assisted reproductive technology
  - Leadership for primary care
  - Managing medications
- Population based:
  - Cancer populations
  - Child and youth populations
  - Maternal/child populations
  - Mental health populations
  - Populations with chronic conditions
  - Public health services
- Service excellence:
  - Acquired brain injury services
  - Ambulatory care services
  - Ambulatory systemic cancer therapy services
  - Assisted reproductive technology
  - Case management services
  - Child welfare services
  - Community health services
  - Community-based mental health services and support standards
  - Critical care services
  - Developmental disabilities services
  - Diagnostic imaging services
  - Emergency department services
  - Health care staffing services
  - Home care and support services
  - Hospice palliative and end-of-life services
  - Independent medical/surgical facilities
  - Laboratory and blood services
  - Long-term care services
  - Medical imaging centers
  - Medicine services
  - Mental health services
  - Obstetrics services
  - Operating rooms
  - Organ and tissue donation standards for deceased donors
  - Organ and tissue transplant
  - Organ donation standards for living donors
  - Point-of-care testing
  - Primary care services
  - Rehabilitation services
  - Reprocessing and sterilization of reusable medical devices
  - Spinal cord injury acute services
  - Spinal cord injury rehabilitation services
  - Substance abuse and problem gambling services
  - Surgical care services
  - Telehealth services
- Service distinction:
  - Acute stroke services
  - Audit tool for reprocessing and sterilization of reusable medical devices
  - Inpatient stroke rehabilitation services
  - Providing an integrated system of services to people with stroke

Source: *Accreditation Canada. Available at: http://www.accreditation.ca/en/content.aspx?pageid=54 [Accessed 14 December 2012].*

2008 CCHSA officially became Accreditation Canada, providing services to other countries. The ever-changing health and social environment now accommodates specialized needs in a diversity of service areas as an adjunct to the hospital accreditation process. Examples are shown in Box 15.5.

Licensing and regulation of health facilities are a government responsibility, but an independent accreditation authority has advantages. The national authority may fail to monitor its own facilities with the diligence or objectivity needed, and there may be a conflict of interest. Where there is a national system of organization, distinct departmentalization of the operating and certification functions may provide a greater measure of objectivity. Assistance from countries experienced in voluntary accreditation can help to establish accreditation mechanisms and provide technical and professional support to countries wishing to establish such programs.

In the current period of transition from central to decentralized management of health services in many countries, health facilities are being transferred from government operation to independent operation as not-for-profit or even for-profit facilities. Present methods of regulation by national or state levels of government will require review as decentralization and privatization take place. Regulation by governmental authorities and non-governmental professional bodies is mutually complementary in promoting accountability, standards, and quality of services.

Peer Review

A large part of the work of clinical and departmental managers in hospitals or other care settings relates to quality assurance. A major method of improving quality in a health program is through peer review by which the staff organizes systematic review of cases and records, using statistics on performance indicators. In hospitals, this includes review of deaths, maternal mortality and infant mortality cases, surgical rates, complications following surgery, and infection rates. Medical records and computer information systems permit users to review records

BOX 15.5 Accreditation Canada International Accreditation Program

The Canadian health services accreditation program began in 1917 in conjunction with the American College of Surgeons (ACS) with a hospital standardization program. The first Minimum Standard for Hospitals developed requirements of just one page. In 1918, on-site inspections of hospitals began, with 89 of 692 hospitals surveyed meeting the requirements of the Minimum Standard. In 1926, the first Standards Manual was issued.

In 1951, the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association joined with the ACS to create the Joint Commission on Accreditation of Hospitals (JCAH). It is an independent, not-for-profit organization whose purpose is to provide voluntary accreditation. In 1953, the Canadian Hospital Association (now the Canadian Healthcare Association), the Canadian Medical Association, the Royal College of Physicians and Surgeons, and l'Association des Médecins de Langue Française du Canada established the Canadian Commission on Hospital Accreditation. The Commission's purpose was to create a Canadian program for hospital accreditation, and in 1958 the Canadian Council on Hospital Accreditation (CCHSA) was incorporated.

In 2008 CCHSA became Accreditation Canada International. The accreditation program is used by all types of health facilities, from large and complex hospitals, to health systems, community health organizations, and residences providing long-term care. Its scope includes a wide range of programs, including standards on child welfare, hospice palliative and end-of-life care, biomedical laboratory services, blood banks, and supplementary criteria for Telehealth. The accreditation program covers a diversity of health care and service areas, service programs for brain injury, ambulatory care, assisted reproductive technology – clinical and laboratory services, Canadian Forces health services, cancer agencies, child welfare organizations, First Nations and Inuit addictions and community health services, the Federal Department of Veterans' Affairs, substance abuse and problem gambling treatment services.

The accreditation service is on a contract basis with specialized health programs, other federal government departments, for-profit health facilities, and community organizations across the provinces.

Accreditation Canada International works with other countries to develop national accreditation programs for their countries, and launched its first international program for acute care, primary care, ambulatory care, and clinical laboratories in 2010.

Source: *Accreditation Canada International. Available at: http://www.internationalaccreditation.ca/Accreditation/AccreditationProgram.aspx [Accessed 12 September 2012].*

by diagnosis. These records can be utilized to assess other events in hospitals, such as time from admission to surgery, lengths of stay by diagnosis, response to abnormal laboratory findings, and many other indicators of the process of care. Obstetric departments can review the frequency of and criteria for caesarean section deliveries. Surgical departments review their appendectomy rates to separate pathological findings from normal appendices. Organized peer review has also been called *medical audit* and essentially describes methods of self-policing and education to learn from mistakes and experience and to improve the quality of care.

In 1972, an amendment to the US Social Security Act required hospitals and long-term care facilities to monitor the quality of care given to Medicare and Medicaid patients through professional standards review organizations (PSROs). These were medical audit committees with specified tasks to conduct utilization review, medical care evaluation, and profile analysis of physician or institutional performance compared to accepted standards of the medical community. In 1982, peer review organizations (PROs) were created by federal statutes to replace PSROs. The PROs are non-profit corporations, staffed by physicians and nurses, to review medical necessity, quality, and appropriate level of care under the Medicare and Medicaid programs. The Centers for Medicaid and Medicare Services have an Office of Clinical Standards to conduct surveys, provide certification, and develop best practices guidelines, in a health care quality improvement program (HCQIP).

Hospitals have departmental clinical meetings, adverse incident or outcome committees, mortality rounds, and clinical pathology conferences to help staff to evaluate and learn from difficult cases. The presence of functioning peer review mechanisms indicates that quality is of concern to the professional and administrative network, raising the consumer's confidence in the system.

Maternal mortality committees have been widely used to assess preventable factors in deaths related to maternity and to point out areas of needed improvement in services. Identification of high-risk pregnancies emerged from this process and has become an important part of prenatal care. Infant mortality reviews by professional groups can similarly demonstrate areas of needed improvement in services. Death rounds are held to review cases of death following surgery or soon after admission, or "incidents", such as inappropriate medication given in error.

The successive waves of peer review initiatives in the USA represent attempts by the federal government to establish mandatory quality of care review by professional peers for facilities providing care to Medicare and Medicaid patients. The concept of requiring standards of care review has probably contributed to a greater awareness of the accountability of hospital-based practice. Frequent litigation may have contributed more to the sense that

the physician is accountable for services and outcomes of care. PROs are a form of quality regulation that represent a commitment by funding agencies to accountability in care systems and to identification of organizational and administrative weaknesses in health care generally and not only in hospitals. The generation of US physicians and health systems managers trained since the 1970s accepts peer review as an integral part of health services. Other countries use this kind of mechanism to maintain and promote quality of care.

Tracer Conditions

Tracer conditions are common medical conditions (or procedures) for which diagnostic criteria are well established and clear, there are effective preventions or treatments, and a lack of treatment can cause significant harm to the patient. Examples of tracer conditions include otitis media, appendectomy, caesarean section, and hysterectomy. These conditions, if evaluated in terms of incidence and actual chart review, can provide useful insights into departmental medical standards. Incident reports by nursing staff and nosocomial infections are examples of the functioning of the tracer condition concept.

Incident reports in hospitals are designed to determine the causes of errors, so that remedial action can be taken and similar events prevented. Tracer condition studies have become such an accepted part of modern health management that the absence of an organized review system could be considered a serious structural flaw in a health service, requiring remedial action.

Setting Standards

Standards recommended by independent professional organizations or by advisory committees appointed by ministries of health can play important roles in defining standards of care for specified conditions. In addition, organized professional bodies can issue practice guidelines or help governments or health care agencies to develop standards or algorithms for management of specific topics and conditions.

Specifying standards for preventive care, such as for infants and adults, assists local health authorities in planning and evaluating services. The American Academy of Pediatrics (AAP) has an extensive professional committee structure that publishes periodic guidelines for pediatricians on a wide variety of infant and child topics including nutrition, immunization, prevention of anemia and lead toxicity, child safety, and school health. Mandatory preventive care for newborns includes eye care and vitamin K injection in the USA (see Chapter 6). Mandatory immunization requirements for school entry and for health care personnel are discussed in Chapter 4.

The American Public Health Association (APHA) publishes the *Control of Communicable Diseases Manual*, now in its nineteenth edition (2008). It is the authoritative US manual on this topic. The AAP's Red Book on infectious diseases is used across North America by pediatricians in clinical practice. These organizations and their counterparts in obstetrics and many other clinical fields directly relevant to public health continually update practitioners and policy personnel in the "state of the art" or "gold standard", discussed previously. This constitutes a professional self-guidance system in standards. Managed care and other health provider systems also issue guidelines for member practitioners that serve to maintain standards of service.

The wide use of treatment protocols and scoring systems in hospital medicine helps to define standards of care in a measurable way. The Apgar score for rating newborn status has been a standard in hospitals worldwide for decades, helping to standardize infant assessment and care. The APACHE (Acute Physiology And Chronic Health Evaluation) scoring system is used widely to assess the chances of survival of patients admitted to intensive care units and to compare outcomes, for example, between teaching hospitals and community hospitals. It is also used in assessing patient outcomes with different modes of treatment. Scoring systems are also used in community health care, as in risk scoring for pregnancy care (see Chapter 6).

Algorithms and Clinical Guidelines

Algorithms are decision trees or a systematic series of decisions based on the outcomes of previous decisions, tests, or findings. Derived from operations research, this approach applied to medicine identifies all available choices (e.g., exposed versus non-exposed) and follow-up decisions based on findings from each previous option substantiated by observation. It is often presented graphically like the branches of a tree, showing the alternatives and subsequent decisions to be made.

A clinical algorithm is a systematic process defining a sequence of alternative, logical steps depending on outcomes of previous ones, incorporating clinical, laboratory, and epidemiological information, applied to maximize benefits and minimize risks for the patient. It gives the provider a review of the relevant literature and recommended standards of practice on a particular topic for preventive care or case management. These guidelines are usually arrived at by consensus of multidisciplinary working groups taking into account published studies on the topic. The guidelines may suggest that some procedures should not be carried out routinely.

Clinical guidelines are meant to establish accepted standards of care and may have important economic implications. *Medical Letter*, published by the Consumers' Union, is a long-standing and useful publication that reviews

TABLE 15.5 Adult Health Maintenance Checklist by Age Group

	Age (years)		
Procedure	**20–39**	**40–64**	**65+**
Checkup visit	Every 3 years	Every 2 years	Annually
Cholesterol	With checkups	With checkups	With checkups
Fecal occult blood	Age 40–49 if high risk	Annually	Annually
Clinical breast examination	Every 1–3 years	Annually[a]	Annually[a]
Mammography	Baseline age 35	Age 40–49, every 1–2 years	Over 70, every 2 years
Pelvic examination	Every 1–3 years	Every 1–3 years	Every 1–3 years
Pap smear	From age 21-29 every 3 years; from 30-65 every 5 years with HPV DNA test	From age 30–65 every 5 years with HPV DNA test	If previously negative, may stop 3 years
Colonoscopy	No	From age 40 for those with family history of colon cancer or polyps. After age 50, every 3–5 years	After age 50, every 3–5 years
Prostate and PSA Immunizations	No	Annually[a]	Annually[a]
Tetanus–diphtheria	Every 10 years	Every 10 years	Every 10 years
Pneumococcal pneumonia	For high risk	For high risk	Every 6 years
Influenza	For high risk	For high risk	Annually
Skin cancer	Annually[a]	Annually[a]	Annually[a]
Bladder cancer	Annual routine urinalysis	Annual routine urinalysis	Annual routine urinalysis
Lung cancer	Routine examination[b]	Routine examination[b]	Routine examination[b]
Testicular cancer	Routine examination[b]	Routine examination[b]	Routine examination[b]
Oral cancer	Routine examination[b]	Routine examination[b]	Routine examination[b]
Ovarian cancer	Routine examination[b]	Routine examination[b]	Routine examination[b]
Pancreatic cancer	Routine examination[b]	Routine examination[b]	Routine examination[b]
Routine vitamin supplements	Routine[b]	Routine[b]	Routine[b]

Note:
PSA = prostate-specific antigen.
Agency for Healthcare Research and Quality. Rockville, MD: AHRQ. http://www.ahrq.gov [Accessed 13 September 2012].
[a]*Inconclusive*
[b]*negative recommendation. The topics are under continuing review, and recommendations are in some cases left to the opinion of the provider as the current cumulative evidence is not affirmative, e.g., clinical breast examination annually or breast self-examination.*
Sources: US Preventive Services Task Force Ratings: Strength of recommendations and quality of evidence. guide to clinical preventive services. 3rd ed. Periodic updates, 2000–2003. Available at: http://www.uspreventiveservicestaskforce.org/3rduspstf/ratings.htm [Accessed 13 September 2012].

therapeutic issues of everyday medical practice and the relevant studies. It represents a balanced, updated view of medical practice and summaries of current literature, reviewed by respected, experienced, and competent medical authorities. Clinical practice guidelines are produced by hundreds of professional, medical, and governmental agencies in order to standardize and improve medical care.

Clinical and preventive care guidelines are helpful in clinical practice and in preventive medicine. They are increasingly used in managed care environments to assure standards, quality of care, and cost-effectiveness as well as legal protection. Guidelines for preventive medicine and public health practice are also part of the process of promoting the quality of individual and community health, as discussed in Chapter 11. Annual revision of the infant immunization program, discussed in Chapter 4, is a prime example, as is the set of guidelines for preventive care for adult health maintenance in Table 15.5.

The issue of application of current scientific knowledge for population health is a continuing struggle for recognition of the prime importance of health promotion and preventive care for health of a population. The selection of priorities in use of resources is vital especially in the many developing countries that are in various stages of economic development, or which have abundant income from natural resources such as oil and minerals. Implementation of programs designed to achieve the MDGs can help to serve this purpose.

Public health standards and clinical practice guidelines are an increasing part of quality improvement. It is important, however, that they are developed as best practices and

BOX 15.6 EISC: The Excellence in Science Committee of the Centers for Disease Control and Prevention

The Excellence in Science Committee (EISC) promotes the Centers for Disease Control and Prevention's (CDC's) scientific infrastructure and facilitates communication and collaboration that enhance scientific areas and activities needed for state-of-the-art conduct of science. EISC serves as a consulting body for science-related issues and makes recommendations to the CDC to foster, support, and protect an environment for the promotion of scientific integrity, quality assurance, and the rapid dissemination of scientific innovations, technology, and information, with the ultimate goal of improving public health.

EISC's specific functions include:

- promoting and protecting the scientific infrastructure
- providing a forum for information exchange among administration, directors for science, and liaison working members/groups
- communicating science-related issues to the CDC and related scientists
- promoting professional development and training
- recognizing and rewarding quality science
- acting as an advocate for scientific resources
- identifying and disseminating new information, e.g., new statistical/epidemiological techniques or new scientific technologies
- developing, revising, and promoting the implementation of cross-cutting scientific policies and procedures
- serving as a consulting body for science-related issues and making recommendations to the CDC
- fostering the development of methods for assessing and monitoring:
  - the environment for quality science and qualitative and quantitative scientific output within CDC and related organizations
  - the impact of CDC science on public health.

Source: *Adapted from Centers for Disease Control and Prevention. Science coordination and innovation [updated 3 November 2011]. Available at: http://www.cdc.gov/od/science/excellence/ [Accessed 13 September 2012].*

influenced as little as possible by commercial interests of drug or vaccine manufacturers. The proliferation of such guidelines by health authorities or professional associations of the USA, the UK, Canada, Australia, and other countries indicates a wide consensus on the importance of such written standards, guidelines, or "best practice" statements. The recommended childhood immunization program put forward annually by the CDC in conjunction with the AAP and other professional organizations is an example of such best practices and is accepted by health insurers and providers as the gold standard in this field. The concept of promotion of quality in health care and the adoption of current scientific standards are global issues and an integral part of the New Public Health (Box 15.6).

The Canadian Province of Saskatchewan Health Services Utilization and Research Commission publishes periodic reports presenting consensus positions of panels of medical faculty, clinical specialists in pathology and physical medicine, and public health specialists in nutrition, community health, and epidemiology. Its reports are circulated widely and serve to update medical practitioners, reduce unnecessary testing, promote appropriate use of laboratory and other diagnostic procedures, and provide standards of care for individual patients and community services, such as long-term care facilities and home health agencies.

The Canadian Medical Association issued its *Handbook on Clinical Practice Guidelines* in 2007, based on a systematic review of the literature, interviews of key professionals, consensus conferences, and continuing evaluation of both process and content of such guidelines. The Guideline International Network (GIN) Fourth International Conference, held in Toronto in 2007, involved experts in national and international practice guidelines from 31 countries to share experience and concepts in this ongoing field. The GIN library contains more than 6600 (by October 2012) guidelines, evidence reports and related documents, developed or endorsed by GIN member organizations (GIN, 2012).

An Institute for Clinical Evaluation (ICES) organization at the University of Toronto, established in 1992 with core funding provided by Ontario's Ministry of Health and Long Term Care, is mandated to conduct research that contributes to the effectiveness, quality, equity, and efficiency of health care and health services in Ontario. ICES uses an interdisciplinary research approach to health care, health services, and health policy.

The American College of Cardiology (ACC) provides a framework of evidence-based clinical statements and guidelines developed by leaders in the field of cardiovascular medicine with continuing adoption of new scientific information and experience in many aspects of this field (ACC, 2012). Many professional organizations such as the AAP, American Congress of Obstetricians and Gynecologists (ACOG), UK Faculty of Public Health, and European Society of Cardiology produce clinical guidelines which are updated regularly to provide physicians and health systems managers with current consensus on state-of-the-art standards, such as the European Society of Hypertension Guidelines released in 2013 (i.e., less than 140 mm. systolic for all).

The US Health Care Financing Administration (HCFA), Center for Medicare & Medicaid Services (CMS), and National Institutes of Health (NIH) have consensus programs to develop guidelines that are widely disseminated and set standards of practice. In 1977, the NIH issued its first consensus paper on breast screening for cancer, and this has been followed by many other topics each year since. The AHRQ also produces research related to efficacy of current and new practices and training material to promote their diffusion across the US health system. Cochrane

reviews and the Cochrane Library provide high standards of literature reviews and meta-analysis on many topics which serve to guide practitioners and policy makers in current standards. The US Healthy People 2020 project provides gold standards for preventive care which serve clinicians, public health practitioners, and health planner standards for their work. Evidence-based consensus guidelines were issued on the following topics: breast cancer screening for women aged 40–49, interventions to prevent HIV risk behavior, management of hepatitis C, genetic testing for cystic fibrosis, acupuncture, and effective medical treatment for heroin addiction.

Clinical guidelines are increasingly being promoted by professional, governmental, and managed care organizations with the purpose of promoting rational use of health care resources and at the same time promoting standards of care to incorporate good standards of clinical practice. Clinical practice guidelines are now common in the practice of primary care, mental health, and clinical specialties. The University of Southern California's list of clinical guidelines website (http://medicine.ucsf.edu/) provides access to hundreds of websites for such practice guidelines.

Clinical guidelines provide practicing doctors, peer review committees, health care managers, managed care companies, governmental bodies, and professional organizations with channels to set standards of practice and expectations of care standards. Legal aspects of health care also increasingly recognize the importance of clinical guidelines where committees of appropriate medical professionals convene and set out average or minimum standards of care for defined clinical entities. Thus, peer-reviewed guidelines set an appropriate standard (a silver if not a gold standard) for judging malpractice or adequate practice. Clinical guidelines should be under periodic review and subject to critical discussion and updating using the Cochrane review methods of literature review and analysis. Promotion by advocacy or special interest groups can be constructive, but the influence of drug companies can be insidious and reduce the professional objectivity of such reviews and their recommendations, a concern that must be carefully monitored and continuously kept in mind as a potential compromising bias.

The AAP produces policy statements, practice parameters, and model bills which have a wide distribution and influence; they are published in the academy's journal, *Pediatrics*. The AAP clinical practice guidelines issued include diagnosis and treatment of urinary tract infection in febrile infants and young children, long-term treatment of the child with simple febrile seizures, management of acute gastroenteritis in young children, management of otitis media with effusion in young children, and others. The policy statements of the AAP cover a wide range of topics including use of bicycle helmets, 55 mile per hour maximum speed limits, folic acid for the prevention of neural tube defects, and ethics in the care of critically ill infants and children. AAP guidelines are valid for 5 years only and are reissued or reconfirmed in order to keep up to date and to incorporate new or revised knowledge into practice standards.

Empirically derived, peer-reviewed, regularly updated guidelines have become an appropriate standard for practice and for judging malpractice, as well as balancing quality and cost-effectiveness. Clinical guidelines may become restrictive, but they help to reduce practice by whim and unsubstantiated belief to improve the quality of care overall. In large health care organizations they provide a basis for continuing education for staff and advancement of standards of the organization.

The *Community Guide* produced by the CDC provides an excellent source of evidence-based advice for community programs. It serves the needs of public health professionals, health care providers, legislators and policy makers, researchers, community-based organizations, employer–employee groups, and other purchasers of health services. The guide covers a wide range of health issues including alcohol, cancer, diabetes, mental health, motor vehicle safety, nutrition and obesity, oral health, physical activity, pregnancy, sexual behavior, social environment, substance abuse, tobacco, vaccines, violence, and workplace health issues.

In 1999, the UK National Health Service (NHS) established the National Institute for Clinical Excellence (NICE) as an independent organization to provide guidelines for public health, health technologies, and clinical practice guidelines for specific conditions. The Health Development Agency of the NHS was included in the NICE organization in 2005. Now called the National Institute for Health and Care Excellence, NICE publishes guidelines that provide a helpful basis for clinical practice and public health as well as other areas in the NHS to update the services provided. Topics for public health include smoking and tobacco control, diet and obesity, exercise and physical activity, sexual and mental health, and alcohol.

ORGANIZATION OF CARE

Administrative and financing systems are essential elements of quality assurance. They can be designed to promote standards of care and to reduce fiscal incentives that foster excess supply and overservicing. The organization of financing health care has important implications for quality, technology, and ethical issues in the New Public Health.

Diagnosis-Related Groups

DRGs, discussed extensively in Chapter 11, were developed in the 1960s as an alternative way of paying for hospital care in order to encourage shortened lengths of stay. Experience

with payment by days of care (per diem) showed that it promoted unnecessary, lengthy, and potentially dangerous use of hospital care, an important factor in the rapid escalation of costs in the health system. DRGs were adopted for payment for Medicare beneficiaries in the USA in 1983 and later became the standard method of payment for all insurance systems.

In the DRG system the insurer pays the provider hospital for a procedure or diagnosis rather than the number of days of stay in hospital. This has led to a large reduction in hospital days of care and a remarkable growth in the number of surgical procedures done on an outpatient basis. Since the introduction of DRGs, outpatient surgical procedures have grown from less than one-fifth to more than half of inpatient surgical cases. Outpatient surgery is safer for the patient and less costly to the insurer. DRGs have gradually been adopted as a case payment system for reimbursing hospitals in most developed countries.

The DRG system is widely considered to promote quality of care as an active process focusing on quickly addressing the diagnosis and management of the patient with rapid mobilization of treatment and return home. Critics of this system allege that DRGs encourage inappropriate early discharge of patients before optimal patient education and follow-up care have been provided, but long length of hospital stay has not been shown to improve patient outcomes. Critics also suggest that this may promote altering diagnoses to higher cost units of service. Others think that DRGs, by reducing length of stay, have turned hospitals into intensive care units with ultra-sick patients. Despite these issues, the trend towards short hospital stays and newer approaches to active treatment seems to be compatible with better care and improved outcomes, according to some measures. The rapid decline in mortality rates from coronary heart disease is thought to be due in large part to the activist treatment approach, with lengths of stay of 1 week or less for acute myocardial infarction compared to 6 weeks on average up to the 1970s.

Managed Care

Managed care systems developed in the USA in response to rapid cost escalation for health care and the successful experience of HMOs. Managed care is based on the concepts of resource management, and quality assurance with rationalized use of technology. The system developed over time with checks and balances to provide comprehensive care at lower cost than traditional fee-for-service systems by discouraging excessive utilization without compromising quality of service. Managed care systems include traditional HMOs and various other organizations which employ physicians or are made up of independent physicians working together who own or contract for hospital services (see Chapter 10).

HMOs, both for-profit and not-for-profit, and managed care itself, have been widely criticized as excessively limiting patient access to appropriate care in the interest of cost containment. The 2010 PPACA (Obamacare) is promoting development of newer innovations including patient-centered medical homes (PCMH), accountable care organizations (ACOs), and population health management systems (PHMSs), and early evidence shows that these models are quality management approaches for integrated primary and hospital patient care (see Chapter 11). Obamacare is a highly politicized and much debated topic in the USA; it seems likely to make a very big difference in coverage and fair practices of insurance with lower costs of private insurance.

District health systems in the UK, the Scandinavian countries, and the post-Soviet model of health care incorporate organizational and financial linkage between care systems and funding from tax sources. HMOs, sick benefit funds, and district health systems provide both prepayment and health services. Even in traditional private health insurance systems, the insurer is increasingly taking on the role of regulating reimbursement for medical services in order to contain costs and curb abuses by providers. In this context, emphasis is placed on maintaining health, preventive care, and financial incentives to efficiency in overall care. Clinical indications, utilization review, and organizational and professional standards are now becoming accepted parts of the health insurance milieu.

The competition between hospitals for referrals from managed care plans in the USA has created a market situation in which a high proportion of hospital beds are empty, and in which mergers or closures of hospitals are common. Closures or reductions in hospital bed supply are also occurring in the UK and in most industrialized countries of Europe.

PERFORMANCE INDICATORS

Performance indicators are measures such as morbidity, mortality, functional status, or immunization rates in a community, used to monitor the functioning of a health service. Routinely collected statistics are analyzed to compare performance against objectives, help monitor efficiency and effectiveness, point out problem areas within the service, and plan new health programs. This method is based on the use of the concept of management-by-objectives in health administration to promote achievement of national health targets.

The UK has a strong tradition of mapping diseases as a basis of epidemiological analysis and has applied this strategy to mapping of performance indicators to assess health care performance. The UK financing system is based on capitation adjusted by standardized mortality rates on the premise that mortality rates standardized and compared to

the national average serve as indicators of need. In this way, the approach helps to promote equitable funding among wealthy and poorer regions of the country, and thereby improve services in areas of greater need.

Performance indicators were introduced into the NHS during reforms of the late 1980s, providing a series of outcome or performance measures that are used to adjust payments allocated on a per capita basis to district health authorities. These authorities can be penalized for low rates of immunization, whereas general practitioners receive incentive payments for full immunization coverage. The result was a rapid improvement in immunization coverage of infants and children compared to rates in the previous decade. Incentive payments in many countries encourage women to go to hospitals for delivery or to attend prenatal care by making social maternity grants conditional on seeking care.

Use of performance indicators requires the development of health information systems with district health profiles to provide ongoing monitoring of health indicators in a district, compared to regional and national rates and targets. Health profiles help to establish and monitor the prevalence of chronic disease and measure the impact of health services. This enables the study of the performance of preventive and curative services, such as managing hypertension to reduce the incidence of strokes and related conditions. There are criticisms of performance indicators alleging a potential for manipulation and abuse of health intervention measures when the financial incentives are used for a specific activity. However, financial incentives are part of the DRG system and have been successfully used in the UK to improve vaccination coverage and implementation of other preventive health practices by family physicians. In Israel in 2007, payments to hospitals provided a bonus for surgical interventions for hip fracture within 48 hours of the event, resulting in a marked rise in early intervention and a reduction in mortality from hip fractures.

CONSUMERISM AND QUALITY

With decentralization and the growth of managed care, health systems must increase their attention to the attitudes of the consumer. Quality is, in part, how the client perceives the system, and how the system meets client needs in an acceptable manner, where privacy, dignity, the right to know, and the right to a defined set of services are protected. However, the rights of the client are not unlimited. A public or private health plan has the duty to manage the basket of services responsibly, which includes limitations such as in access to specialist services.

Patients' rights and consumer protection in health care often (but not always) include the right to select and change a health care provider, as well as the right to receive high-quality care for a designated range of services. The UK NHS issued a patient's Charter of Rights during the 1990s, which is perhaps idealistic and may not be actualized in practice, but still outlines an ideal of value both for practical application and for legal rights. The consumer's formal protection includes the right to complain and to seek redress of grievance and compensation for injury suffered from neglect or incompetent care (Box 15.7). In North America and Europe, there are at least four models of defining the rights of patients: the paternalistic model, the informative model, the interpretive model, and the deliberative model (WHO, 2012). Many new charters have been established such as data protection, end-of-life care, mental health, access to health services, quality of care and care giving environment, nationally approved treatments, drugs and programs, respect, consent and confidentiality specific to the UK and in Canada, New Zealand and other countries. The new US federal Affordable Care Act of 2010 (PPACA) includes a large element of patient's rights protection, as discussed in Chapter 10.

BOX 15.7 Patients' Rights, European Union, 2009

A review of patients' rights in countries of the European Union in 2009 focused on the following:

- Right to informed consent based on access to information for care or participation in research
- Right to information concerning own health, diagnosis
- Right to medical records
- Right to confidentiality of personal and health information and physical privacy during care
- Right to complain and compensation
- Right of free choice of provider and of treatment
- Respect of patient's time
- Right to observance of quality standards access to high-quality health services
- Right to safety and freedom from harm caused by the poor functioning of health services, medical malpractice and errors, and the right of access to health services and treatments that meet high safety standards
- Right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.

Source: *European Patients' Forum. Patients' rights in the European Union. Available at: http://www.eu-patient.eu/Documents/Projects/Valueplus/Patients_Rights.pdf [Accessed 25 October 2012].*

The patient or consumer of health care needs to be informed and conscious of health care costs if efforts to restrain cost increases are to be effective. Public attitudes are vital in terms of self-care, demands on the health service, and limitations to the potential of health care and resources for health care. The media and consumer organizations can play important roles in advocacy for health, in raising public consciousness of self-care, and as watchdogs on abuses.

Consumer acceptance is manifested through choice of health plan and practitioner, or by seeking alternative care

privately when service is unacceptable because of quality or style. Erosion of confidence in a public system of care can lead to a two-tier system with the public system serving the poor and a private parallel system serving the middle and wealthy classes. Such a division can seriously undermine a public system unless it is addressed by improving the quality and manner of the service and by establishing supervision and limitations on public and private practice.

The growing inequality caused by the rise of private practice outside a national health care system is a chronic problem in the UK's NHS, in Israel's health system, and in many countries developing their health systems through parallel public and private care. The issue is also surfacing in the USA in the transition to managed care with its inherent limitations of choice for people insured through their place of work or covered under the Medicare and Medicaid programs.

The PPACA requires insurance companies to accept anyone requesting cover without restrictions due to prior conditions or high expenses for serious conditions, and without other forms of discrimination common in the past. It also includes provisions for coverage of preventive care services and incentives for quality improvement. Extra billing, banned in Canada's national health insurance plan, is a recurring issue with the medical profession in some provinces.

Consumer knowledge, attitudes, beliefs, and practices are part of the health system, from health promotion to tertiary care. Informed and health-conscious consumers are stronger partners in the health system in achieving improved health than an ill-informed and apathetic public, so that health education and health promotion are fundamental to modern public health. The role of the consumer in health care is unique in that there is a significant information asymmetry between the consumer and provider. Health education programs and wide use of the Internet increase access to health and medical information, but this gap can never completely be eliminated. Patients may use their power as consumers to demand inappropriate care, such as unnecessary surgery or antibiotics when clearly not indicated, because of their preference for intervention and action over watchful waiting. However, there is an equal or perhaps greater danger of provider-induced demand for repeated and possibly unnecessary interventions that may be related to methods of paying the doctor or the hospital. The traditional doctor–patient relationship is still an important factor for the interests of patients and their health. A still effective method of having an individual quit smoking is a brief but stern lecture by the family physician.

THE PUBLIC INTEREST

Population-based interventions are often more effective and less costly ways to reduce morbidity and mortality than individual prevention or treatment services. A population-based preventive program may require behavior change by the individual, such as in mandatory seat belt and motorcycle helmet enforcement or banning smoking in public places. Fortification of flour, milk, and salt with essential micronutrients is a well-established public health measure. There is an element of compulsion in this, with the social gain usually considered to be sufficiently important to outweigh individual rights. Immunization is for the protection of individuals but also for the population, so that refusals to immunize children and adults can cause injury to others. Herd immunity is protective of people who are at high risk. Mandatory immunization for school entry in the USA has been effective in increasing coverage to levels akin to the most advanced health systems, over 95 percent coverage. Refusals and failure to harmonize immunization policies in Europe have resulted in mass epidemics of measles, rubella, and mumps in recent years.

There is often a delicate balance between community rights and individual rights which can lie at the heart of many controversies in modern public health and health care, ranging from chlorination or fluoridation of community water supplies to managed care systems for health services. Women's rights, gay rights and abortion are highly controversial and politicized in the USA, and in many other countries. The differences can become extreme and the source of international strife, such as in the movement to promote fundamentalist Sharia law in many countries that are severely restrictive of women's and minority rights.

In public health, issues should be examined on their merits, especially in terms of what is accepted as good public health practice, based on evidence from clinical trials, documented experience, and best practices in other countries. The evidence of successful public health measures in improving individual and collective health status is powerful, yet must always be balanced within the context of individual rights and the public interest. The ethical issues of individual and community rights of public health are discussed later in this chapter.

TOTAL QUALITY MANAGEMENT

Total quality management (TQM), as discussed in Chapter 12, was adapted from business management theory and practice to health care in the 1990s and provides a basis for promoting continuous improvement in health care systems. TQM involves everyone in the system, from all levels of management to production or service personnel and support staff, and thus helps to raise staff morale because of the shared involvement. Health is provided through multidisciplinary groups which need to approach problems with open and shared scientific inquiry and hypothesis formation, testing, and revision to find operational solutions to problems.

Electronic health records and information technology provide many new opportunities to improve patient care and data systems for monitoring the health status of population groups for process and outcome measures, or health targets, such as immunization coverage, or screening compliance for colon, cervical, or breast cancer, as measures of performance in primary care. Information technology adds a great deal of capacity for quality monitoring and improvement measures.

TQM incorporates statistical methods, comparing variations in patterns of service or use of resources. It employs epidemiological methods to draw conclusions for policy needs. It looks for continuous improvement, encouraging cooperation, and motivation to achieve common goals of service and client satisfaction. Psychological theory helps to foster higher levels of motivation, with early identification and resolution of conflict. Leadership is shared, and there is a basic need for cooperation. Cost and quality are interrelated, as poor quality leads to waste, inefficiency, and dissatisfaction of both clients and staff. High-quality, humane, and effective services are especially important in a competitive environment where clients have the right to choose and where costs and efficiency are factors in the well-being and indeed the survival of institutions.

Medical care is increasingly practiced in larger health care organizations. To provide technically competent medicine is not by itself sufficient. The patient's rights and sense of personal worth are also of great importance. Financial incentives can be effective in redirecting health care priorities, such as in reducing hospital length of stay and admissions, but may result in the patient or the family feeling that they are not receiving the best care. DRGs, HMOs, and other organizational and funding systems meant to increase efficiency of care may have the effect of alienating patients from a health care system. Staff attitudes towards patients are important for client satisfaction. The service must include ready access to a continuum of supportive services, such as home care and counseling, so that the patient and family do not feel abandoned by the system.

A byproduct of TQM is continuous quality improvement (CQI), by which institutions wishing to improve quality train and empower the staff to work in teams to assess their own performance and seek solutions to problems in their operational unit. People of different ranks and professions work in a network organization as well as in a traditional hierarchical organization in which rank and seniority provide authority. This community of practice is important for staff morale and a shared sense of responsibility for the patient and the institution.

CQI involves multidisciplinary approaches, not only to review problems but also to seek better ways of functioning and improving consumer satisfaction. The process includes all those involved in providing care, support services, and administration of a department, hospital, clinic, or community health program. This is not only professional self-policing but a method to find better ways of meeting needs and using resources. The involvement of all providers improves motivation and promotes a sense of common purpose in the organization.

Applying these principles in a health care setting can take many forms. Selection of topics by TQM/CQI committees in a hospital or another health facility may be based on surveys or interviews with staff, patients, or management. Satisfaction surveys among women following delivery in an obstetrics unit could point out remediable problems. An obstetrics department may be faced with issues related to high or low volume of deliveries, staff training, equipment and supplies, communication among staff, and among staff and patients and their families, cleanliness, sterile technique, staff satisfaction, client satisfaction, and many others. The team looking at such a problem should be multidisciplinary, and the emphasis should be on client attitudes and satisfaction.

Examination of the function of an emergency department in a hospital would similarly look at many functional and attitudinal aspects of the service including staff attitudes, training needs, waiting times, consultation services, and others. Addressing waiting times, for example, can lead to ways to reduce these substantially, improving both client satisfaction and the efficient management of the emergency department. Any service is there to serve patients and the community. A service is not primarily for the benefit of the staff, but staff satisfaction and morale are essential for successful service to clientele. CQI can also be applied to assessing and improving compliance with clinical guidelines or evidence. An example is assessing the proportion of diabetics whose hemoglobin A_{1c} (Hb_{A1c}) is measured at least twice annually, who have eye and feet examinations regularly, or whose blood pressure is managed with an angiotensin-converting enzyme (ACE) inhibitor.

The European Region of the WHO and the national medical associations in Europe agreed in 1995 that medical associations should take leading roles in programs of CQI to achieve better outcomes of health care in terms of functional ability, patient well-being, consumer satisfaction, and cost-effectiveness. This is in keeping with the European Region's *Health for All* targets: there should be structures and processes in all member states to ensure continuous improvement in the quality of care and appropriate development and use of health technologies.

The introduction in the 1990s of general practitioner fundholding for hospital care for patients on the general practitioners' roster in the UK encouraged the hospital to maximize patient satisfaction with the care system. This promotes application of CQI to improving the quality and acceptability of care. Similarly, performance indicators provide regional and district health authorities in the UK with tools for CQI approaches. The UK NHS established

BOX 15.8 The UK's National Institute for Health and Care Excellence (NICE)

The National Institute for Clinical Excellence (NICE), established in 1999, has a mandate to review health service treatments and effective therapies that should be commissioned and made available within the National Health Service (NHS) throughout England and Wales. The mission statement for NICE is that it "contributes to better health around the world through the more effective and equitable use of resources". In 2005 NICE was revised to include reviews of public health interventions, and its mandate was expanded to include quality standards for the English social care sector (English Health and Social Care Act of 2011). Now renamed the National Institute for Health and Care Excellence, NICE operates as a statutory independent special health authority in England and Wales. Commissioning bodies of the NHS are required to observe its recommendations. Guidance can be used by the NHS, local authorities, employers, voluntary groups, and anyone else involved in delivering care or promoting well-being.

NICE recommendations are respected elsewhere in the UK, but are not mandatory; in Scotland NICE recommendations are published after further review by NHS Quality Improvement Scotland (for health services issues) and by NHS Health Scotland (for public health recommendations). NICE recommendations are respected worldwide, including by the European Commission and by national governments; NICE International is a section of NICE established to meet non-UK needs (e.g., evaluating rural health programs in China).

An independent committee including lay representation advises on priorities for NICE consideration but final decisions on topics referred to NICE are made by the Department of Health. When making recommendations to the NHS on which services (e.g., treatments) should be provided routinely, it calculates the cost-effectiveness of treatment for each quality-adjusted life year (QALY) of health gain purchased.

NICE publications include guidance on 374 interventional procedures, 270 technology appraisals, 162 clinical guidelines, and 43 public health topics. From this latter group, some examples include:

- *Prevention of cardiovascular diseases (2010)* – provides evidence of effectiveness of population-based prevention programs as more effective than programs aimed at high-risk groups.
- *Alcohol dependence and harmful alcohol use (2011)* – summarizes all NICE guidance; designed to inform members of the public as well as health professionals.
- *Preventing type 2 diabetes through population and community interventions (2011)* – provides guidance to government departments, the commercial sector, health service organizations, and non-governmental organizations on integration of public policy to prevent obesity, and reduce diabetes prevalence and complications.
- *Preventing uptake of smoking by children and young people (2008)* – document to advise local health service commissioners; identifies target populations, reviews campaign messages, and provides recommendations for the mass media and retailers.
- *Promoting mental well-being at work (2009)* – guidance aimed at employers; reviews evidence in the field and recommends strategic approaches by firms, opportunities to promote well-being and assess risk, and systems of flexible working.
- *Preventing unintentional injuries among under-15s in the home (2010)* – reviews evidence and makes recommendations to local authorities and related agencies on training an appropriate workforce, advises government to fund curricula development, and indicates to the NHS appropriate surveillance and treatment services.

NICE is often criticized (especially by the pharmaceutical industry) for the time taken to carry out investigations of new treatments. It is also criticized by relatives of patients with "glamorous" conditions (e.g., cancer) for not approving drugs that might extend life by only 4–6 weeks, and perhaps approving instead new psychiatric therapies. The current government has recently sought to overrule some of these NICE recommendations in England. However, NICE methods and recommendations are held in high repute, within the UK and beyond.

Sources: *Christopher Birt FRCP FFPH, University of Liverpool, UK. Personal communication.*
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NICE as an independent body to promote "national guidance on promoting good health and preventing and treating ill-health". NICE produces guidance in three areas:

- *public health* – guidance for those working in the NHS, local authorities and the wider public and voluntary sector on promotion of good health and the prevention of disease
- *health technologies* – guidance on use of new and existing medicines, treatments and procedures within the NHS
- *clinical practice* – guidance on appropriate treatment and care within the NHS of people with specific diseases and conditions.

NICE guidelines are recommended practices with the objective of reducing ineffective practices. During 2007, guidelines were issued on topics including asthma, dermatitis, caesarean section, chronic obstructive lung disease, depression (in children and adults), eating disorders, fertility, contraception, multiple sclerosis, post-traumatic stress disorder, and diabetic foot care (Box 15.8).

BOX 15.9 Organizations to Promote Quality in Health, USA

- *National Committee for Quality Assurance (NCQA)* – This non-profit organization, founded in 1979 by the managed care industry, conducts surveys among managed care plans to evaluate clinical standards, members' rights, and health service performance. It accredits over 550 managed care plans in the USA, and in 2007 published rankings of the "best" health plans. Website: http://www.ncqa.org/
- *Agency for Healthcare Research and Quality (AHRQ)* – This is part of the US Public Health Service. Founded in 1995, it was mandated to develop an evidence-based practice program in 12 centers in the USA. It conducts systematic reviews of the literature and publishes analyses and findings of these reviews. Website: http://www.ahrq.gov/
- *Centers for Medicare & Medicaid Services (CMS) 2001* – The CMS, previously the Health Care Financing Administration (HCFA, 1977), is the federal agency of the Department of Health and Human Services, responsible for administering the Medicare and Medicaid and the State Children's Health Insurance Program (CHIP) health plans. Its roles include quality assurance, the requirements for managed care organizations, and quality improvement. Website: http://www.cms.gov/
- *Institute for Healthcare Improvement (IHI)* – Non profit organization founded in 1991 as a global resource for health care improvement knowledge to improve health care by fostering collaboration among health care organizations. IHI examines office practices of physicians, educational reform, and promotes interdisciplinary team work in quality improvement. Website: http://www.ihi.org/ihi/
- *National Patient Safety Foundation (NPSF)* – Sponsored by the American Medical Association as a response to findings of high rates of injury and death from iatrogenic disease in the USA, the NPSF promotes research into human error among health care providers, seeking ways to reduce the frequency and effects of medical error, such as misdiagnosis, medication errors, and mistakes during procedures. Website: http://www.npsf.org/au/
- *Joint Commission on Accreditation of Healthcare Organizations (JCAHO)* – Originating in 1917 by the American College of Surgeons, it began accrediting hospitals in 1918. It developed in 1953 as the JCAHO, becoming a national voluntary accreditation organization focusing mainly on hospitals. Its mandate was broadened in 1987 and, as of 2007, had accredited more than 15,000 health care organizations. Accreditation is mandatory for Medicare and Medicaid payment. The JCAHO is changing its approach from standards-based assessment every 3 years to one of reviewing performance data quarterly as a continuous surveillance activity for risk reduction. Website: http://www.jointcommission.org/

Source: *Websites accessed 12 September 2012.*

The USA has a number of government and independent organizations dedicated to improving quality in health care systems. The CDC and the Institute of Medicine of the US National Academies of Science play active roles in promoting research quality and methods of CQI in the US health care system. Canada is also very active in this regard, having national and provincial institutes for the evaluation of clinical effectiveness and clinical guidelines, and so too are European countries (Box 15.9).

PUBLIC HEALTH LAW

Public health workers need knowledge of government structure and public health legislation as basic to their professional work to understand their responsibilities, powers and liabilities. Law consists of a system of rules, regulations, and orders that govern the behavior of individuals and of society. Law represents the consensus of a society, as enacted by an elected legislature, put into effect by the executive branch of government, and interpreted by the courts as need be from time to time. The legislative and executive branches are separate under the US Constitution, but the two are united in the parliamentary system (Box 15.10). The authority, responsibility, and power to provide for and protect the public health are basic functions of a sovereign government, which may be delegated to another level of government (higher or lower) or even a non-governmental agency. The constitution of a sovereign government states explicitly or implicitly that responsibility, but accepted practice and court decisions (i.e., the common law) define the powers of the national, state, or local government to monitor and protect the health of its citizens.

In the USA, national legislation is enacted under the powers of the federal government, namely to regulate interstate commerce and the power to tax and spend for the general welfare. State legislation is enacted under the basic power of the state to protect the health, welfare, and safety of its citizens. Under these federal and state powers, a wide range of health legislation and regulations is enacted affecting public health, labor, and occupational health and safety, environmental controls, public welfare, and the financing of health services, agriculture, food, drugs, cosmetics, and medical devices. Public health law relies on a wide range of constitutional, statutory, administrative, and judicial decisions in both civil and criminal actions. Appropriation of funds is a legal act of legislative bodies to achieve objectives directly or indirectly by financial incentives.

Categorical programs may be directed to specific issues such as combating TB and promoting immunization or for work to combat NCDs such as diabetes, or in improving standards of facilities, and in providing health care services. The regulatory, enforcement, policing, and punitive functions of public health laws have evolved over many decades and in many countries lack clear definition. In the USA,

BOX 15.10 Legal Structure of Federal and Unitary Countries

In federal nations, political authority is divided between two autonomous sets of governments, one national and the other subnational. Both operate directly with the people in their jurisdiction based on a constitutional division of power between the national government, which exercises authority over the whole national territory, and state or provincial governments with independent authority within their own territories. The constitution is the supreme law of a country. It sets out the divisions of governmental powers including statutory authority, administrative, natural resources, and taxation between federal and state levels of government.

A federal legislature or congress makes the law of the land, but is subject to rulings of a Supreme Court as are state and local governments. State or provincial governments in a federal system have functions set out in the Constitution. They also have elected legislatures, and executive branches with taxing, regulatory, and punitive powers. Local governments for county, municipal, or city governments also have delegated taxing and regulatory powers including those of public health.

Canada, the USA, Brazil, Australia, India, and Argentina are organized on a federal basis. Federal countries also include Austria, Germany, Malaysia, Mexico, Nigeria, Switzerland, and Venezuela. Russia is called a federation. Usually there is some overlapping or shared powers between national and state constitutions, legislatures, and court systems, and public agencies, taxing powers and regulatory functions, such as in interstate commerce and emergency response to natural or other disasters.

In a unitary government system, most or all of the governing power resides in a centralized government. This contrasts with a federal system. In unitary systems the central government commonly delegates authority to subnational units and channels policy decisions down to them for implementation. A majority of nation-states are unitary systems. They vary greatly. The UK includes England, Scotland, Wales, and Northern Ireland, each with legislatures, but the Westminster Parliament in London maintains national powers. In health, each of the four member entities of the UK conducts a National Health Service with autonomy but common features. The national government may delegate certain powers to self-governing regions/local authorities, and there is a growing tendency to devolve various governmental functions such as health to regional authorities. More than 150 countries are unitary states, including France, Italy, Spain, China, and Japan.

In both forms of government, local authorities are established under state law with governance by councils elected by the people, with taxing and regulatory powers within the state or provincial laws, with a high degree of autonomy but within state regulation, standards, and financial support. Local authorities have major responsibilities in public health such as in sanitation, licensing, and regulation of businesses and zoning, as well as many other areas, including social welfare.

Note: See also Chapter 10.

Source: *Differences between federal and unitary forms of government. Available at: http://www.preservearticles.com/201107139054/difference-between-unitary-and-federal-forms-of-government.html [Accessed 15 December 2012].*

Encyclopedia Britannica. Unitary government. Available at: http://www.britannica.com/EBchecked/topic/615371/unitary-system [Accessed 15 December 2012].

Encyclopedia Britannica. Political systems. Available at: http://www.britannica.com/EBchecked/topic/467746/political-system/36704/Federal-systems [Accessed 15 December 2102].

efforts are being made to update and reform laws in the public health sector. In 1988, the Institute of Medicine (IOM) in the USA (the Future of Public Health) called for codification of public health law as essential for the public good, while questioning the soundness of certain US public health laws. More recently, the Model State Emergency Health Powers Act in the USA, the Quarantine Act in Canada, and the revised International Health Regulations (2007) have sought to update century-old legislation. The revised international regulations provide for a global approach to control the spread of epidemics and public health emergencies while minimizing disruption to international activities such as travel, trade, and economics.

A combination of the regulatory, persuasive, and funding approaches is widely used in public health in control of communicable and non-communicable diseases, in improving standards of facilities, and in providing health services. The regulatory, enforcement, policing, and punitive functions of public health are important in health promotion and assurance of health care. The taxing power of government is essential for public health to ensure that adequate facilities and access to care are available to all members of the community, especially those in financial need and thus at greater risk for disease.

Medical officers of health and their staff have legal authority to issue formal orders for health protection of the public. Situations which require court proceedings are referred to the justice system. Situations that may require enforcement by court proceedings are referred to the justice system. Laws may be enacted to fund public health activities, whether provided by public health authorities or by acting through official or non-official agencies or providers. Public health authorities, namely medical officers of health, have the legislative power to issue orders to individuals or businesses where there is a threat to the health of the public such as food establishments. Administrative resources are needed to enforce laws, such as through the FDA and the Environmental Protection Agency, which come under the aegis of the Department of Health and Human Services. Other departments such as Agriculture, Education, or interdepartmental agencies (e.g., Homeland Security), also are key to public health activities, such as in disaster situations.

Other intergovernmental activities may require special legislation to empower, finance, and promote their cooperation, such as in the case of establishing an authority to manage long-term efforts to clean up a contaminated river or basin, which involves the cooperation and coordination of many local authorities.

Health protection of individuals and communities may require legal action to detain a person in order to prevent the spread of a reportable communicable disease, to protect a mentally ill patient, or to restrain a violent person. Such powers should be used as a last resort if voluntary compliance and education fail, and where the danger to the community or the individual is sufficient to convince a court of the public need to override the personal liberty of an individual. An example is a 2007 case of a person with MDR-TB who was taken into custody on arrival for compulsory treatment after traveling across the Atlantic Ocean on a commercial airline, against the specific instructions of his physician, thus endangering fellow passengers. Outbreaks of measles in the UK (2006–2007) and in Israel via imported cases among ultraorthodox Jews or conservative protestant groups in the Netherlands, with transmission among religious people who tend not to immunize their children, led to pressure by health authorities to immunize those placed at risk by such contacts at weddings or other large public events.

However, these measures are currently used less than voluntary isolation or quarantine and placarding homes for reportable infectious diseases such as measles. Powers are essential in extreme cases where refusal to comply with public health measures endangers others. Such powers should have been used more vigorously in the early years of the AIDS epidemic at a time when individual rights took precedence over protection of the population, including vulnerable high-risk groups. The severe acute respiratory syndrome (SARS) epidemic of 2003 led to sequestering hospital staff in Toronto, Canada, for lengthy periods to prevent spread of the disease, and subsequent influenza pandemic threats have raised questions as to whether hospital personnel should be required to be immunized to protect patients and their families from onward transmission of dangerous infections.

Recent cases in the USA, the UK, and Norway demonstrate the responsibility of governments to protect the public from incidents of violence by dangerous, mentally disturbed individuals who carry out mass killings. In Norway, 69 people, mostly teenagers, were killed by a radical ideologue while many others sustained serious injuries; and in the USA, Islamic terrorists at the Boston Marathon killed three and seriously injured more than 200 others; a 20-year old fatally shot his mother then killed 20 children and six adult staff members at Sandy Hook elementary school in Newtown, Connecticut, before killing himself; and an army psychiatrist who had become an increasingly devout and radicalized Muslim psychiatrist shot and killed 13 people and injured more than 30 others in a Texan army base. Background checks and other restrictions on gun sales are an important public health and political issue, especially in the USA. The wide availability of guns, including military-style assault weapons, presents a serious danger for impulsive or planned mass killings.

Public health has generally evolved with greater reliance on health promotion through voluntary cooperation of a patient or community than on compulsion. Enabling legislation may permit a local authority to fluoridate its water supply, but the enactment of local legislation and funding to implement it may also require a public referendum. In some states in the USA and in Israel, fluoridation of community water supplies is mandatory, which is also part of the health promotion approach to public health.

Appropriation of public funds to promote public health is through approval by the legislature for a specified program. Provision of public funds may take the form of categorical grants for specified services, such as immunization, prenatal care, school health, or specific disease management such as TB control, cancer control, or AIDS education. Programs may be designed to promote certain types and quality of services, such as the Hill–Burton Act, which provided federal grants for hospital construction in the 1950s to 1970s, conditioning these grants on certain requirements concerning hospital licensure and hospital planning. Such legislation has a "carrot and stick" effect of attracting lower levels of government to seek such funding but also requiring them to accept the conditions and regulations that accompany the grants. The Canadian federal government's cost sharing of provincial health (hospital and medical) insurance programs is based on federal criteria requiring public administration, portability between provinces, accessibility without payment, comprehensiveness, and banning extra billing by physicians (see Chapter 13).

Public funds are also appropriated in the context of legislated programs in which people are entitled to the services defined in the appropriation legislation, such as in the amendments to the Social Security Act providing Medicare and Medicaid programs, or national health insurance legislation in many countries. These and their regulations spell out categories and specified entitlement benefits.

Legislation and court decisions to protect the rights of the individual are part of public health. Public health law is meant to protect individuals and communities from potential abuse, of both individual and community human rights, as in the US Bill of Rights. Enforcement of public health law may infringe on individual rights by enforcing sanitation, food and drug safety, and supervision of restaurants and catering firms. Laws may allow restriction of civil rights, such as rarely used mandatory treatment of a person with a dangerous contagious disease or mental illness. Freedom of religion may come into conflict with other

laws in public health where restrictive practices may deny the use of publicly supported health facilities, as when a religiously affiliated hospital may refuse an abortion procedure in a case of rape. Religious practices or other personal beliefs may endanger others in the community, such as in the refusal to immunize children so that an imported infectious disease may spread among non-immunized people and even affect those who are immunized, as occurs with imported measles cases even when domestic transmission of the disease has previously been eradicated. General legislative provisions applied to public health forbid misleading or unethical advertising. Legislative provisions may also ban advertising for products, such as tobacco, which are legal but may be harmful to health. These laws affect public health but are provisions in other statutes such as the regulation of business enterprises. Legislation may also make smoking in public places illegal, with fines for offenders and operators of places such as public bars.

Since the 1973 US Supreme Court decision of *Roe v. Wade*, the law has allowed women to seek safe and legal abortion. This remains a highly controversial political issue in the USA and several other countries. The potential conflict between community and individual interests and rights is part of the dynamics of public health law and public health practice. The issues involved are complex and highly politicized, and often involve ethical distinctions where "the greatest good for the greatest number" may limit the legitimate rights of individuals and vice versa. The PPACA in 2010 is a fundamental legislative initiative, upheld by the US Supreme Court to become the law of the land. It will bring millions of Americans into regulated health insurance with many protective elements to prevent abuse by private insurance company through arbitrary exclusions or limitations.

The legal aspects of public health are vital to its operation and are increasingly complicated by ethical issues, and by public and political debate. Health protective legislation and regulation for sanitation of food, water, and air are fundamental to public health, as is the control of drugs, cosmetics, vaccines, and biologicals, the manufacture of devices, and the licensing of health personnel and facilities. Limitations of legal suits (torts) against manufacturers of vaccines proved to be a successful measure in the USA with the introduction of the National Vaccine Injury Compensation Program (NVICP) in 1988. This is funded by a modest surcharge tax collected from vaccine manufacturers. It protects both public and private interests while providing a fair compensation system to ensure patients' rights but without jeopardizing immunization to prevent widespread disease, and also protects manufacturers from litigation with high legal costs and excessive compensation awards by the jury system. Promoting healthy behavior through the prudent use of the legal system of regulation and taxation is increasingly utilized to protect the health of the population. This is widely applied in promoting road safety, in tobacco control measures regarding banning of advertising, high taxes on alcohol, and banning smoking in public places including restaurants and bars.

Environmental Health

There is growing concern by the public and by governments over climate change, global warming, air and water pollution, and other noxious and harmful industrial and commercial processes. Environmental laws affecting the public health include legislation on clean air, clean water, toxic substances, solid waste control, and other noxious substances. Non-compliance with the legislative provisions can result in prosecution in the civil or criminal courts or both.

Infringement of public health laws and regulations may lead to criminal action as an increasingly common method of sanction. While such violations may not be seen as "truly" criminal and may be treated in the courts as misdemeanors, they can lead to fines or even jail. Such cases are increasingly being addressed seriously in the judicial system.

The CDC, in 1999, defined 10 great achievements of public health of the twentieth century. These achievements are identified as control of infectious disease, motor vehicle safety, fluoridation of drinking water, recognition of tobacco use as a health hazard, immunization, decline in deaths from coronary heart disease and stroke, safer and healthier foods, healthier mothers and babies, family planning, and safer workplaces (Goodman et al., 2006). Of the 10 great achievements in the twenty-first century (2001–2010) identified by CDC, seven of the 15 leading causes of death (largely NCDs) resulted in a decline in the age-adjusted death rate in the USA from 881.9 per 100,000 population in 1999 to 741.0 in 2009. This decline was a result of a combination of supportive laws and legal tools at the local, state, and federal levels. In other industrialized countries similar legislation has led to equal or greater achievements in public health over the past century.

Public Health Law Reform

Public health law is scattered through many legislative statutes and administrative documents which developed historically. Efforts to codify public health law may contribute to greater understanding and enforceability of the many separate pieces of legislation (Box 15.10). Such reform will enhance understanding in the legislative, judicial, and administrative branches of government as well as in business, non-governmental organizations, and the community. Box 15.11 suggests topics for model public health consolidation or compendia for states. The principles of this formulation may also apply to other countries at the national and state or provincial levels.

BOX 15.11 Public Health Law Program of the Centers for Disease Control and Prevention

The Public Health Law Program (PHLP) is administered by CDC's Office for State, Tribal, Local and Territorial Support (OSTLTS). PHLP develops law-related tools and provides legal technical assistance to public health practitioners and policy makers in state, tribal, local, and territorial (STLT) jurisdictions.

The PHLP works with state/territorial health departments and other partners to:

- identify public health law priorities
- research laws that impact the public's health
- analyze public health legal preparedness
- conduct comparative analyses across jurisdictions; prepare guidance, articles, reports, and toolkits; and develop and disseminate public health law curricula.

Source: *Centers for Disease Control and Prevention. Public health law. Available at: http://www.cdc.gov/phlp/about.htm [Accessed 27 October 2012].*

BOX 15.12 Topics for a Model State Public Health Act

- Mission and functions
- Public health infrastructure
- Collaboration and relationships
- Public health authorities and powers
- Public health emergencies
- Public health information privacy
- Criminal/civil
- Enforcement
- Legislative response to the need to reform core public health powers such as surveillance, reporting, epidemiological investigations, partner notification, testing, screening, quarantine, isolation, vaccination, and nuisance abatement
- Medicaid
- Affordable Care Act insurance agency

Source: *Centers for Law and the Public's Health. A Collaborative at Johns Hopkins and Georgetown Universities (CDC Collaborating Center). Available at: http://www.publichealthlaw.net/ [Accessed 23 September 2012], and Chapter 10 references.*

ETHICAL ISSUES IN PUBLIC HEALTH

The field of public health includes a wide range of activities and professional disciplines, ranging from health promotion to disease protection, epidemiology to environmental health, and financing to supervision or provision of clinical care. Each of these disciplines works within systems that face ethical dilemmas, and public health workers' understanding and motivation within the ethical guidelines of their professions and roles are important in their training and practice conduct. Ethical frameworks have evolved in part as the result of bitter experience with ethical failures which were later recognized and affect public health standards of practice for future generations (Box 15.12).

Ethics in health are based on the fundamental religious and humanistic values and concepts of a society. If the principle of saving a life is valued above all other considerations (i.e., Sanctity of Life or *Pikuah Nefesh*) (see Chapter 1), then all measures available are to be used, irrespective of the condition of the patient or the cost. If sickness and death are seen as acts of God, possibly as punishment for sin, then prevention and treatment may be considered to be interfering with the divine will, and the ethical obligation may be limited to relief of suffering. Humanism balances these two ethical imperatives: saving of life and relief of suffering. Materialistic political philosophies may view health care as primarily a function to preserve health for economic prosperity and social well-being. Secular humanism adopted many of the religious precepts of the worth and rights of the individual and these have become part of the standards of law and ethics in modern secular societies.

The role of society in protecting the health of the population grew during the nineteenth century with the sanitation movement, while medical care became an effective part of public health during the twentieth century. The astonishing successes of public health during the past century increased life expectancy in the high-income countries by some 30 years, mostly through improved living conditions and health protection, as well as societal and medical advances to make care available to all. In the 1970s the Lalonde concept that individual behavior was one of the key determinants of health (see Chapter 2) placed much of the onus of illness and its prevention on the individual, but fostered health promotion as an essential component of public health theory and practice. All these points of view are involved in the ethical issues of the New Public Health (Box 15.13).

Resources for health care are limited even in industrialized countries, so that priority setting and judicious allocation of scarce resources are always issues. Money spent on new technology with only marginal medical advantages is often at the expense of well-tried and proven lower cost techniques to prevent or treat disease. The potential benefits gained by the patient from more and more interventions are sometimes very limited in terms of length or quality of life. These are difficult issues when the physician's commitment to do all to preserve the life of the patient conflicts with the patient's concept of quality of life and his or her right to decline or terminate heroic measures of intervention. Many health systems use clinical guidelines that are mandatory for a health facility or a doctor in the clinic. Preparation for surgery requires a signature from the patient to consent to the procedure being carried out, careful preoperative procedures to ensure that the correct organ is addressed, antiseptic preparation of the site, and checking that all instruments are accounted

BOX 15.13 Study and Practice of Public Health Ethics

Ethics is a branch of philosophy that deals with distinctions between right and wrong, with the moral consequences of human actions. The ethical principles that arise in epidemiological practice and research include:

- informed consent
- confidentiality
- respect for human rights
- scientific integrity.

"As a field of study, public health ethics seeks to understand and clarify principles and values which guide public health actions. Principles and values provide a framework for decision making and a means of justifying decisions. Because public health actions are often undertaken by governments and are directed at the population level, the principles and values which guide public health can differ from those which guide actions in biology and clinical medicine (bioethics and medical ethics) which are more patient or individual-centered.

As a field of practice, public health ethics is the application of relevant principles and values to public health decision making. Public health ethics inquiry carries out three core functions:

(1) *identifying and clarifying the ethical dilemma posed,*
(2) *analyzing it in terms of alternative courses of action and their consequences, and*
(3) *resolving the dilemma by deciding which course of action best incorporates and balances the guiding principles and values." (CDC, 2001)*

Sources: *Last JM, editor. A dictionary of epidemiology. 4th ed. New York: Oxford University Press; 2001.*
Centers for Disease Control and Prevention. Science coordination and innovation. Public health ethics; 2001. Available at: http://www.cdc.gov/od/science/phec/ [Accessed 23 September 2012].

for. The checklist approach is well established for care in many settings and protects the patient from neglect or faulty follow-up, such as in the management of hypertension and diabetes.

The suffering that a terminally ill patient may endure during radical treatment, which may prolong life by only hours or days, clashes with the physician's ethical obligation to do no harm to the patient. The ethical value of sustaining the life of a terminally ill patient suffering extensively is an increasing medical dilemma. The issue is even more complex when economic values are included in the equation. There are potential conflicts among the economic issues, the role of the physician in preserving life, the physician's obligation to do no harm, the felt needs of the patient and his or her family, and the needs of the community as a whole. The complex issues involved in the "right to die" and end-of-life care raise many ethical and legal questions for the patient, the family, society, and caregivers.

The state represents organized society and has, among its responsibilities, a duty to promote healthful conditions and to provide access to health care and public health services. The conflict between individual rights and community needs is a continuous issue in public health. Application of accepted public health measures for the benefit of some people in society may require applying an intervention to everyone in a community or a nation. The majority thus are subject to a public health activity to protect a minority, without designating which individual's life may be saved. Furthermore, a society may in special cases need to restrict individual liberties to achieve the goal of reducing disease or injury in the population. Raising taxes on alcohol and tobacco products, mandatory speed limits, driving regulations, and seat belt usage laws are examples of public health interventions that interfere with individual liberty but protect individuals, and thereby the community at large, from potential harm.

Many public health measures originally criticized as interventions in private rights are generally accepted as essential for health protection and promotion to reduce the risk of disease in the population. Chlorination of community water supplies is a well-established, effective, and safe intervention to protect the public health. Fluoridation of drinking water to prevent tooth decay in children means that other people are also drinking the same fluoridated water, which is of less direct benefit to them. Fortification of foods with vitamins and minerals is also a cost-effective community health measure with advocates and opponents. The addition of folic acid to food as the most effective way to prevent neural tube defects in newborns is an intervention mandated by the US FDA since 1998.

Confidentiality to assure the right of the individual to privacy involves ethical issues in the use of health information systems. Birth, death, reportable conditions (not all reportable diseases are infectious), and hospitalization data are basic tools of epidemiology and health management. The use of detailed individual data is needed for case-finding and follow-up activities which are vital to good epidemiological management of diseases, including STIs. However, caution is needed in data use to avoid individual identification that could be used punitively, for example, in denial of access to health insurance for smokers, alcoholics, or AIDS patients because health damage may be attributable to a self-inflicted risk factor. Increasingly, however, reporting is also mandatory for physical or sexual abuse and criminally linked injuries as essential for the protection of individuals at risk or the general public from serious harm.

Individual and Community Rights

The protection of the individual's rights to privacy, and freedom from arbitrary and harmful medical treatments, procedures, or experiments, may come up against the rights of the community to protect itself against harmful health issues. This conflict comes into much of what is done in public

health practice, which has both an enforcement basis in law and practice and a humanitarian and protective aspect based on education, persuasion, and incentives. Society permits its governments to act for the common good, but sets limits that are protected by the courts and administrative appeal mechanisms.

Society has the right to legislate the side of the road on which one is permitted to drive, the speed permitted, the wearing of seat belts, and the non-use of alcohol or drugs before driving or cell phones while driving. Offenders may be punished by significant fines or jail and are subject to strong educational efforts to persuade them to comply. Similarly, the community must ensure sanitary conditions and prevent hazards or nuisances from bothering neighbors or the public. Society must act to protect the environment against unlawful contamination or poisoning of food, drugs, the atmosphere, the water supply, or the ground.

Enforcement is thus a legitimate and necessary activity of the public health network to protect the community from harm and danger to health. Table 15.6 shows topics where individual rights and responsibilities predominate, and a second set of rights that are the prerogative of the community to protect its citizens against public health hazards. Sometimes the issues overlap and sometimes come to political, advocacy, or legal action, so that court decisions are needed to adjudicate precedents for the future.

The AIDS epidemic in the 1980s and 1990s raised a host of public health, ethical, and issues. Management of the AIDS epidemic is in some respects in conflict with the long-established role of society in contacting and quarantining people suffering from transmissible diseases. It is not acceptable or feasible in modern society to isolate HIV carriers. But failure or delay of public health authorities even in the late 1980s to close public bathhouses in New York and other cities in the USA, where exposure to multiple same-sex partners promoted transmission of the infection, could be interpreted as negligence. During the 1980s, the gay community in the USA centered its concern that HIV testing would be used in a discriminatory manner. AIDS was initially addressed as a civil liberties issue and not as a public health problem. Screening, reporting, and case contact follow-up were seen as an invasion of privacy and proved counterproductive by increasing resistance to and avoidance of testing. Protection of privacy and an educational approach were adopted as most feasible and acceptable. International opinion and national court decisions have emphasized the right to privacy with decriminalization of non disclosure of HIV status to sex partners (UNAIDS 2013).

The AIDS epidemic and public anxiety about contracting AIDS through casual contact reinforced the need for public education on safe sex. This has been raised as an ethical issue because such education may be construed as condoning teenage and extramarital relations. The issue of HIV screening of pregnant women in general or in high-risk groups took on a new significance with the findings that treatment of the pregnant woman reduces the risk of HIV infection of the newborn, and that breastfeeding may be contraindicated. This issue is arising anew in the context of using the HPV vaccine for preteen girls to prevent the sexually transmitted infection, which is also controversial, and in the USA this vaccination will be mandatory for school entry.

A pre-eminent ethical issue in public health is that of assuring universal access to services, and/or the provision of services according to need. An important ethical, political, and social issue in the USA in the twenty-first century is how to achieve universal access to health care. The solidarity principle of socially shared responsibility for funding universal access to health care is based on equitable prepayment for health care for all by nationally regulated mechanisms through place of work or general revenues of government. A society may see universal access to health care as a positive value, and at the same time utilize incentives to promote the use of services of benefit to the individual, such as hospital care, immunization, and screening programs. Some services may be arbitrarily excluded from health insurance, such as dental care, although this is to the detriment of children and a financial hardship for many. Strategies for program inclusion are often based on historical precedent rather than cost-effectiveness or evidence. While efforts are being made to include more children in the program, the Medicaid system in the USA defines eligibility at income levels of 185 percent of the poverty line, thus excluding a high percentage of the working poor. Health is also a political issue in countries with universal health systems where funding may be inadequate or patient dissatisfaction common.

Choices in health policy are often between one "good" and another. Limitations in resources may make this issue even more difficult in the future, with aging populations, increasing population prevalence of physical disabilities, and rapid increases in technology and its associated costs. For example, the UK's NHS at one point refused to provide dialysis to people over the age of 65. When computed tomography was first introduced, Medicare in the USA refused to insure this service as an untested medical technique. Owing to a lack of facility resources such as incubators and poor prospects for the survivors, the Soviet health system considered newborns as living only if they weighed over 1000 g and survived for more than 7 days. Those under 1000 g, who would be considered living by other international definitions, would be placed in a freezer to die. At the opposite extreme, many western medical centers use extreme and costly measures to prolong life in terminally ill patients, preserving life temporarily but often with much suffering for the person and at great expense to the public system of financing health care.

In many countries, such as those in the former Soviet system of health care, spending for hospital services, in

TABLE 15.6 Individual and Community Rights and Responsibility in Health: Ethical/Legal Issues

Ethical/Legal Issues	Individual Rights and Responsibilities	Community Rights and Responsibilities
Sanctity of human life	Right to health care; responsibility for self-care and risk reduction	Responsible for providing feasible basket of services, equitable access for all
Individual vs community rights	Immunization for individual protection	Immunization for herd immunity and community protection; education; community may mandate immunization
Right to health care	All are entitled to needed emergency, preventive, and curative care	Community right to care regardless of location, age, gender, ethnicity, medical condition, and economic status
Personal responsibility	Individual responsible for health behavior, diet, exercise, and non-smoking	Community education to health-promoting lifestyles; avoid "blame the victim"
Corporate responsibility	Management accountability to criminal and civil action	Producer, purveyor of health hazard accountable for individual and community damage
Provider responsibility	Professional, ethical care and communication with patient	Access to well-organized health care, accredited to accepted standards
Personal safety	Protection from individual, family, and community violence	Public safety, law enforcement, protection of women, children, and elderly; safety from terrorism
Freedom of choice	Choice of health provider; limitations of gatekeeper functions; control costs while function; right to second opinion; right of appeal	Confidentiality; informed consent; birth control ensuring individual rights; limitations of self-referrals to specialist
Euthanasia	Individual's right to die; limitations by societal, ethical, and legal standards	Assure individual and community interests; prevention of abuse by family or others with conflict of interests
Confidentiality	Individual's right to privacy, limitation of information	Mandatory reporting of specified diseases; data for epidemiological analysis
Informed consent	Right to know, risks vs benefits; agree or disagree to treatment or participation i n experiment	Helsinki Committee approval of research; regulate fair practice in right to know; Patient's Bill of Rights
Birth control	Right to information and access to birth control and fertility treatment; woman's rights over her body	Political, religious promotion of fertility; alternatives to abortion; protection of women's rights to choose
Access to health care	Universal access, prepayment; individual contribution through workplace or taxes	Solidarity principle and adequate funding; right to cost containment, limitations on service benefits
Regulation and incentives to promote preventive care	Social security for hospital delivery, attendance for prenatal care; primary care, ambulatory care; home care	Incentive grants to assist communities for programs of national interest; limit institutional facilities
Global health	Human rights and aspirations; economic development, health, education, and jobs	Transfer of health risks; occupational hazards and environmental damage
Rights of minorities	Equality in universal access	Special support for high-needs groups
Prisoners' health	Human rights	Security and human rights; reduce inequalities in sentencing convicts, harsh dangerous conditions in prisons; prohibition of torture and execution
Allocation of resources	Lobbying, advocacy for equity and innovation	Equitable distribution of resources; targeting high-risk groups; cost containment

some cases grossly in excess of need, is accompanied by a lack of adequate funds for primary care or adding new vaccines to the immunization program for children. The majority of Americans have health insurance which increasingly includes preventive care services, but a substantial percentage lack such coverage which limits their access to routine preventive care. The Affordable Care Act brings an improvement in coverage and inclusion of preventive care with incentives (see Chapters 10 and 13). In many countries, including in Europe, delay in updating immunization

programs may be due to a lack of funding or to delays in professional or governmental acceptance of "new" vaccines.

The closure or amalgamation of hospitals involves difficult decisions and is a source of friction between central health authorities, the medical professions, and local communities. Health reforms in many industrialized countries, such as reducing hospital bed supplies and managed care systems promoting cost containment and reallocation of resources, raise ethical and political issues often based on vested interests such as private insurance systems, hospitals, and private medical practitioners.

Where there is a high level of cumulative evidence from the professional literature and from public health practice in "leading countries" with a strong scientific base and case for action on a public health issue, when does it become bad practice or even unethical public health practice to ignore and fail to implement such an intervention? Such ethical failures occur frequently and widely. For example, is it "unethical" not to fortify grain products with folic acid, and salt with iodine? Should there be a recommended European immunization program; should milk be fortified with vitamin D; should vitamin and mineral supplements be given to women and children; should all newborns be given intramuscular vitamin K routinely? Other examples include the issues of fluoridation of water supplies and opposition to genetically modified crops or generic drugs in African countries. These issues are continuously debated and the responsibility of the trained public health professional is to review the international literature on a topic and formulate a position based on the cumulative weight of evidence. It is not possible to wait for indisputable evidence because in epidemiology and public health this rarely occurs. This is another reason for guidelines established by respected agencies and professional bodies, which are free from financial obligations to vested interest groups, being essential for review of the evidence which continues to accumulate on many issues thought to have been resolved or which reappear repeatedly despite strong evidence of effectiveness and public health benefit.

Tragic Deviations in Public Health Ethics

In the nineteenth century the germ and miasma theories both produced enormous gains in public health. The biomedical paradigm addressed alleviation of disease risk or manifest disease; the health paradigm addressed the improvement of social and environmental conditions for reducing disease. During the early part of the twentieth century, a segment of the social hygiene movement promoted ideas of Social Darwinism or racial improvement by sterilization of mentally ill, retarded, and other "undesirable" people.

The dominant biomedical model of public health and medical professionals adopted policies of eugenics in Sweden, the USA, and Canada, leading to policies and programs to force the sterilization of mentally handicapped or mentally ill patients. This distorted a socially oriented concept of public health. This euthenasia policy was adapted to a racially oriented policy with horrendous policies of mass murder in the name of racial purity as a public health policy in Nazi Germany with the near-total support and participation of a highly Nazified medical profession, and used in murder, by gassing or planned starvation, of half a million "undesirables" under the eugenics "T-4" program administered from Hitler's headquarters. Although this program was stopped after parental and Church protests in Germany, the methods used were adopted in newly occupied countries and for concentration camps organized for the mass extermination of Jews, Gypsies, and others in the Holocaust.

The eminent historian Sir Richard Evans (Regius Professor of History at Cambridge University), in his classic *The Third Reich at War*, wrote:

"At the heart of German history in the war years lies the mass murder of millions of Jews in what the Nazis called 'the final solution to the Jewish question in Europe'. This book provides a full narrative of the development and implementation of this policy of genocide, while also setting it in the broader context of Nazi racial policies toward the Slavs, and toward Gypsies, homosexuals, petty criminals and 'asocials'. … For many years, and not merely since 1933, the medical profession, particularly in the field of psychiatry, had been convinced that it was legitimate to identify a minority of handicapped as 'a life unworthy of life', and that it was necessary to remove them from the chain of heredity if all the many measures to improve the German race under the Third Reich were not to be frustrated. Virtually the entire medical profession has been actively involved in the sterilization programme, and from here it was but a short step in the minds of man to involuntary euthanasia."

The twentieth century was replete with mass murders, executions, and genocide, with nationalistic, ideological, and racist motives perpetrated by fascist, Stalinist, and radical xenophobic political or religious movements when gaining governmental power by election or by revolution, in some cases applying common public health terminology and concepts to uses of genocide and ethnic cleansing (Box 15.14).

An outline of genocides of the past 100 years is seen in Box 15.15. These include the Turkish genocide of the Armenians in 1917 followed by horrific genocides in which many millions of people were killed, carried out under the communist regime of the Soviet USSR in the 1920s and subsequently, in the People's Republic of China under Chairman Mao in the 1950s, and by the Khmer Rouge in Cambodia in the 1980s, and in the wars resulting from the breakup of the Yugoslav Republic in the 1990s.

The human and national cost of genocide lasts for generations. The hatred and fear may wane but the trauma goes deep. It lasts with the victims and their descendants, but

BOX 15.14 Values and Ethical Principles of Public Health

- *Sanctity of human life.*
- *Individual human rights* – liberty, privacy, protection from harm.
- *Solidarity* – sharing the burden of promoting and maintaining health.
- *Beneficence* – reduce harm and burdens of disease and suffering.
- *Non-malfeasance* – do no harm.
- *Proportionality* – restriction on civil liberties must be legal, legitimate, necessary, and use the least restrictive means available.
- *Reciprocity principle* – public responsibility to those who face disproportionate health and social burden.
- *Transparency principle* – honest and truthfulness in the manner and context in which decisions are made must be clear and accountable.
- *Precautionary principle* – decision makers have a general duty to take preventive action to avoid harm even before scientific certainty has been established.
- *Failure to act* – public health officials and policy makers have a duty to act and implement preventive health measures demonstrated to be effective, safe, and beneficial to population health. Failure to enforce public health regulations with resulting disease or deaths may constitute negligence on the part of responsible officials with civil or criminal penalties.
- *Equity* – reduce inequities.
- *Cost and benefits*
- *Stewardship* – responsibility of governance in a trustworthy and ethical manner.
- *Trust* between the many stakeholders in health.
- *Reasonableness* – decisions should be evidence based and revised based on new evidence.
- *Responsive to needs* and challenges as they may be anticipated and appear with close monitoring of health status.

Source: *Modified from Lee LM. Guest editorial: Public health ethics theory: review and path to convergence. Public Health Rev 2012;34(1). Available at www.publichealthreviews.eu [Accessed 17 December 2012].*

also with the perpetrating country and its culture. The Nazi Holocaust has had downstream effects in public health in the German-speaking countries which last to the present time, seven decades since the events took place. The long-term damage done to public health in Germany and Austria is described in Box 15.16.

The Nuremberg Doctors' Trial in 1946–47 convicted many leading Nazi physicians of crimes against humanity and resulted in severe punishments including hanging or long prison terms. This trial was a seminal event in establishing the ethical standards required for medical research and human rights. However, many in the medical profession aligned with these horrors remained leading figures in the German medical community, one even being elected to head the World Medical Association, then discussing the Helsinki Declaration of Ethics in Biomedical Research, before being forced to resign. The Nuremberg Trials and the subsequent Helsinki Declaration laid the fundamentals of biomedical ethics for the following generations, regulated by requirements of ethical procedures and institutional research board approvals for funding, conducting, and publishing research involving human subjects (Table 15.7).

The United Nations Convention on Prevention and Punishment of the Crime of Genocide (UNGC) of 1948 defines acts committed with intent to destroy, in whole or in part, members of a national, ethnical, racial, or religious group as crimes against humanity. This convention specifies that incitement to genocide is itself a crime against humanity. Legal action should focus on state-sanctioned incitement as a recognized early warning sign. The UNGC defines genocidal acts to include the following as punishable under international law:

- genocide
- conspiracy to commit genocide
- direct and public incitement to commit genocide
- attempt to commit genocide
- complicity in genocide.

The reappearance of genocide in the late twentieth century in the Balkans and Rwanda, and in the twenty-first century by Sudanese in Darfur, highlights genocide as a public health concern and its prevention as a public health and international political responsibility. Incitement to genocide is a crime against humanity and was the basis for the trials and convictions of leaders of the Rwandan Tutsi tribe, as well as inciters to ethnic violence and the political leaders and perpetrators of mass murders in the former Yugoslav Republic. The threat and practice of genocide are still present, whether in the murderous raids of Sudanese Janjaweed militias in Darfur and South Sudan, the threats of genocide by Iran and associated terrorist organizations against Israel and Jews in general, or the killing of Christians in northern Nigeria and Egypt, of Muslims in Burma/Myanmar, and others. Incitement to genocide is now common as part of international discourse.

Genocide represents the most extreme assault on the right to life and respect for life. In the twentieth century, an estimated 200 million people perished through genocide. Totalitarian dictatorships, past wars, and ideologies of exclusiveness, ethnic purity, and religious fundamentalism increase the risks for genocide. Perpetrators use dehumanizing, demonizing, and delegitimizing hate language to desensitize or intimidate bystanders and to mobilize, order, and instruct followers.

Genocide prevention requires international surveillance networks for monitoring and reporting incitement and hate language in the media, textbooks, places of worship, and the Internet, which should monitor and identify their sources

BOX 15.15 Eugenics and Genocide: The Slippery Slope

Eugenics was a movement within the "social hygiene" concept of the early part of the twentieth century. It was widely promoted to reduce births among mentally ill and handicapped people in some states in the USA and was upheld in decisions of the Supreme Court. It was also practiced in Canada and Sweden. This idea was promoted by Hitler in *Mein Kampf* and adopted by the Nazi Party, which was legally elected to office in 1933 and began to implement it. Organized massacres of mentally ill and handicapped children and adults led to practices of organizing various modes of killing, including gas chambers, which were applied in concentration camps and in the Holocaust murder of 6 million Jews and millions of others.

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1915–1917 Armenian genocide by Ottoman Turkish Empire – 1.2 million killed
1920s–1940s Eugenics movement in USA and Sweden
1920s Mass executions, deportations, and starvation as policy in Soviet Union Stalinist regimes
1930s–1940s Mass sterilization of "defectives" in the USA and Sweden
1930–1940s Mass murder of "defectives" in Nazi Germany – 750,000 killed
1940s Quarantining as pretext for ghettos by Nazis
1940s Concentration camps, human experimentation
1940s Holocaust of 6 million Jews and genocide in Nazi occupation of Poland and in Soviet Union
1947 Nuremberg Trials – convictions and capital punishment for war crimes and genocide by Nazi leaders and doctors
1950s Mass starvation in Maoist China – estimated deaths of 21 million people
1948 Convention on the Prevention and Punishment of the Crime of Genocide
1975–1979 Cambodian genocide – 1.7 million killed
1988 Iraqi genocide of Kurds in town of Halabja by poison gas
1988 Brazil genocide conviction of Tikuna people
1995 Serbian massacres in Srebrenica in Bosnia and Herzegovina
2004 Rwandan genocides
2003–2012 Sudanese genocide in Darfur – over 400,000 killed
2011 Sudanese genocide of Nuba people
2012 Iran incitement to genocide of Israel
2012 Syria: civil war and genocide
2012 Democratic Republic of Congo massacres of Kivu reported

Sources: *Richter ED, Genocide Prevention Center, Braun School Public Health, Hebrew University –Hadassah, Jerusalem, Israel. Personal communication.*
United Nations. Convention on the prevention and punishment of the crime of genocide. Available at: http://www.hrweb.org/legal/genocide.html and www.un.org/millennium/law/iv-1.htm [Accessed 16 December 2012].
Richter ED. Commentary. Genocide: can we predict, prevent, and protect? J Public Health Policy 2008;29:265–74.
Stanton G. The eight stages of genocide; 1998. Available at: www.genocidewatch.org/aboutgenocide/8stagesofgenocide.html
Genocide Watch. http://www.genocidewatch.org/ [Accessed 25 December 2012].

and map their distribution and spread. Dehumanization, demonization, delegitimization, disinformation, and denial are the danger signs of potential genocidal actions. Genocide results from human choice and bystander indifference. One lesson of the Holocaust is that silence in response to incitement to genocide makes one a complicit bystander. Public health professionals and institutions have a responsibility to speak out publicly on such dangerous early warning signs (Richter E, personal communication, 2012).

Human Experimentation

Human experimentation has been a subject of great concern since the Nazi and Imperial Japanese armed forces' experiments on prisoners and concentration camp victims during World War II. The Nuremberg Trials set forth standards of professional responsibility to comply with internationally accepted medical behavior (Table 15.7).

The Helsinki Declaration was first adopted by the World Medical Assembly in 1964, and amended in 1975, 1983, 1989, and 1996. It delineates standards of medical experimentation and requires informed consent from subjects of medical research. These standards have become an international norm for experiments, with national, state, and hospital Helsinki committees regulating research proposals within their jurisdiction. Funding agencies require standard approval by the appropriate Helsinki committee before considering any proposal, with informed consent on any research project.

The Tuskegee experiment (Box 15.17) was a grave and tragic violation of medical ethics, but in the context of the 1930s was consistent with widespread and institutionalized racism. It provides an important case study which has repercussions until the present time in suspicion of public health endeavors, particularly among the African American community in the USA.

BOX 15.16 The Rise, Fall, and Slow Recovery of German Public Health

In the German context the social–ecological health paradigm can be traced back to the late eighteenth and early nineteenth centuries when the country was a loose alliance of kingdoms or princedoms lagging behind the economic, cultural, and political developments in England and France. Ensuring population health was seen as the obligation of the state, while the family was responsible for caring for the health and well-being of its members. Organized health care and health maintenance was seen in the framework of *Medizinische Polizey*, as a model of the health systems. Leading scholars in law and medicine shared a normative perspective of promoting a healthy lifestyle (known as *dietetics*), and provision of shelter, food, and spiritual aid in asylums for the sick and disabled, or in private homes the for wealthy.

In the second half of the nineteenth century evidence from medical statistics and overwhelming practical experience indicated that widespread poverty was the critical factor explaining high rates of typhus or cholera epidemics in lower social classes among children and industrial workers. A social health movement fought for healthier living and working conditions, education, and democracy. The movement's prominent leaders were Salomon Neumann, a physician pioneer in medical statistics, and Rudolf Virchow, the renowned pathologist and outspoken political activist.

Between 1890 and 1930 the conceptual framework of public health was defined as "social hygiene" or "health science", an interdisciplinary field to conduct scientific research, academic teaching, and community-based activities aiming at the promotion of individual and collective health and the prevention of disease. In the 1920s the field was highly developed and pioneering the modern academic public health.

Social hygiene was a general framework open to different definitions. A group of academic teachers and publishing scientists sharing the social–ecological paradigm, among them a high proportion of German Jews, wanted to continue the social reform strategy and to strengthen local communities to take an active role in the formulation and implementation of health policies.

Public health activists sharing the biotechnological disease paradigm favored a more focused approach aiming at the control of disease through medical care. Although there was no supportive evidence, in the late nineteenth century a racial eugenic movement emerged widely in Europe and the USA. A conceptual model derived from the disease paradigm postulated racial factors to explain disease. A healthy population was assumed to be "free" of "racially contaminated" individuals and inferior groups. Health-related public policy was supposed to eliminate racially "unclean" members, e.g., by forced sterilization or murder. This was a central theme in Hitler's *Mein Kampf* and was enacted as basic policy by the Nazi Party in Germany as a fundamental ideological basis of racial theory and public health.

When the Nazis were legally elected in Germany in 1933, and later seized power in Austria, this policy provided fertile ground to open the door to euthanasia, leading to mass murder. This was implemented in the well-organized, medically directed execution of mentally and physically handicapped Germans and others in psychiatric facilities. This provided a working model for the industrialized murder of 6 million Jews in the Holocaust and millions of gypsies, homosexuals, communists, and others.

It took only 10 years to eradicate a 200-year tradition of German socially oriented public health grounded largely in the political philosophy of human rights and social justice. Most of those advocates were exiled or murdered. Many of the academic medical leaders after World War II remained in key positions in the German public sector for decades.

In contrast to many other countries, the two wealthy German-speaking countries, with over 90 million people, have few academic public health resources. In there is only one German School of Public Health, and a small number of institutes, far fewer in Austria than in Germany. More than half a century has passed since the Nazi period and the populations of these two countries are slow to build a new socially oriented public health system.

Sources: *Horst Noack MD, PhD, Professor Emeritus, Medical University of Graz, Austria. Personal communication; 24 December 2012.*
Flügel A. Public Health und Geschichte. Weinheim: Beltz Juventa; 2012.
Heinzelmann W. Sozialhygiene als Gesundheitswissenschaft. Bielefeld: Transcript Verlag; 2009.
Noack H. Governance and capacity building in German and Austrian public health since the 1950s. Public Health Rev 2011;33:264–76.

Ethics in Public Health Research

The border between practice and research is not always easy to define in public health, which has as one of its major tasks the surveillance of population health. This surveillance is mostly anonymous but relies on individually identifiable data needed for reportable and infectious disease control as well as for causes of death, birth defects, mass screening programs, and other special disease registries. It may also be necessary to monitor the effects of chronic disease, for example, to ascertain repeat hospitalizations of patients with congestive heart failure to assess the long-term effects of treatment, and the effects of strengthening ambulatory and outreach services to sustain chronic patients at a safe and functional level in their own homes.

Hospitalizations, immunizations, and preventive care practices (e.g., Pap smears, mammography, and colonoscopies) are all part of the New Public Health. Impact assessment of preventive programs may require special surveys and are important to assess smoking and nutritional status and other measures of health status and risk factors. Every effort must be made to preserve the anonymity and privacy of the individual but in some cases, where the disease is contagious, case contact is crucial. This can entail identifying people who attended an

TABLE 15.7 Ethical Issues of Medical Research Derived from the Nuremberg Trials, the Universal Declaration of Human Rights, and the Declaration of Helsinki

Nuremberg Doctors Trial, 1946–47	The voluntary consent of a human subject is absolutely essential, with the exercise of free power of choice without force, fraud, deceit, duress, or coercion
	Experiments should be such as to bear fruitful results, based on prior experimentation and the natural history of the problem under study. They should avoid unnecessary physical and mental suffering
	The degree of risk should not exceed the humanitarian importance of the experiment
	Persons conducting experiments are responsible for adequate preparations and resources for even the remote possibility of death or injury resulting from the experiment
	The human subject should be able to end his participation at any time
	The scientist in charge is responsible to terminate the experiment if continuation is likely to result in injury, disability, or death
Universal Declaration of Human Rights, 1948	Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services
United Nations covenants for protection of human rights	Covenant on Civil and Political Rights
	Optional Protocol to the Covenant on Civil and Political Rights
	Covenant on Economic, Social, and Cultural Rights
	Convention Against Torture
	Convention Against Genocide
	The Geneva Conventions
	Convention on the Rights of the Child
	Convention on Elimination of Discrimination Against Women
	Charter of the United Nations
Declaration of Helsinki, 1964	Research must be in keeping with accepted scientific principles, and should be approved by specially appointed independent committees
	Biomedical research should be carried out by scientifically qualified persons, only on topics where potential benefits outweigh the risks, with careful assessment of risks, where the privacy and integrity of the individual is protected, and where the hazards are predictable. Publication must preserve the accuracy of research findings
	Each human subject in an experiment should be adequately informed of the aims, methods, anticipated benefits, and hazards of the study. Informed consent should be obtained, and a statement of compliance with this code
	Clinical research should allow the doctor to use new diagnostic or therapeutic measures if they offer benefit as compared to current methods
	In any study, the patient and the control group should be assured of the best available methods. Refusal to participate should never interfere with the doctor–patient relationship. The well-being of the subject takes precedence over the interests of science or society

Source: Summarized from the Nuremberg Trials (1948) and World Medical Association, Declaration of Helsinki.
Website sources include: World Medical Association. Available at: http://www.wma.net/
Australian Government Department of Health and Ageing. Available at: http://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs/human-research-ethics-committees-hrecs/national
United Nations. A Summary of United Nations Agreements on Human Rights. Available at: http://www.hrweb.org/legal/undocs.html (accessed 10.1.14).
United Nations. Available at: http://www.un.org/en/events/humanrightsday/2007/hrphotos/declaration%20_eng.pdf (accessed 10.1.14).
US Food and Drug Administration. World Medical Association Declaration of Helsinki. Available at: http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC20-Attach-1.pdf (accessed 10.1.14).

event or traveled on an airplane where an infected person may have been, so as to take appropriate preventive measures.

The general distinction between research and practice has to do with the intent of the activity. Clinical research uses experimental methods to establish the efficacy and safety of new interventions or unproved interventions; many drugs and procedures in common use have never been subjected to randomized controlled trials. In practice, many methods are devised that are held to be effective and safe by expert opinion and documented as such. Researchers comparing HIV or hepatitis B transmission rates among intravenous drug users not using needle-exchange programs would be conducting unethical research, according to accepted current standards, by giving needles to the experimental group

BOX 15.17 The Tuskegee Experiment

The Tuskegee experiment was carried out by the US Public Health Service between 1932 and 1972. It was meant to follow the natural course of syphilis in 399 already infected African American men in Alabama and 201 uninfected men. The men were not told that they were being used as research subjects. The experiment had been intended to show the need for additional services for those infected with syphilis. However, when penicillin became available, the researchers did not inform or offer the men treatment, even those who were eligible when drafted into the army in 1942. The experiment was stopped in 1972 as "ethically unjustified" when the media exposed it to public scrutiny.

The case is considered unethical research practice because, even at the time it was conducted, it did not provide the patients with available care and their well-being was put aside in the interest of the descriptive study. A similar experiment was conducted by the US Public Health Service in cooperation with the Guatamala Ministry of Health during the 1960s, in which syphilis was actually given to soldiers, prisoners, and others by sexual contact with prostitutes known to have the disease, but the study was terminated when it was discovered by a public health historian and reached public attention in the USA.

In 1997, President Bill Clinton apologized to the survivors and families of the men involved in the experiment on behalf of the US government. The Tuskegee experiment is the source of lingering widespread suspicion in the African American community to the present time.

Sources: *Lombardo PA, Dorr GM. Eugenics, medical education and public health: another perspective on the Tuskegee syphilis experiment. Bull Hist Med 2006;80:291–316.*
Centers for Disease Control and Prevention. US Public Health Service Syphilis Study at Tuskegee. Available at: http://www.cdc.gov/tuskegee/timeline.htm [Accessed 13 December 2012].

and withholding them from the control group. The scientific justification of an experiment must be made explicit and justifiable. Clinical equivalence is a necessary condition of all clinical and public health research and provision of standard of care treatment to control groups is a minimal requirement for most research ethics boards. Determination of the standard, and whether it should be place, time, and community specific, is an area of ongoing controversy.

In 1996 a US Public Health Service study, supported by the NIH and WHO, compared a short course of zidovudine (AZT) to a placebo given late in pregnancy to HIV-positive women in Thailand, measuring the rate of HIV infection among the newborns. The experiment was terminated when a protest editorial appeared in a prominent medical journal. This study confirmed previous findings that AZT given during late pregnancy and labor reduced maternal–fetal HIV transmission by half. When a study shows clearly positive results, it should be discontinued and reported so that the findings can be applied generally. The findings indicated that AZT should be used in developing countries, and the manufacturers agreed to make it available at reduced costs. The result has been a major success in helping with more recent medications to reduce maternal–fetal transmission in many places in Africa with help from GAVI, and a slowing of the spread of HIV/AIDS-related deaths.

Public health may face the challenge of pandemic influenza, such as avian flu, with decisions regarding the allocation of vaccines, treatment of massive numbers of patients arriving at hospitals in acute respiratory distress with very limited resources available, coping with sick or absent staff, and many other issues requiring not only individual life and death situations, but mortality en masse. The ethical questions will be replaced by struggles to cope with such situations. Preparation for such potential catastrophic events will be a challenge to public health organizations and the health system in general.

An outstanding case of a breach of ethics in public health research occurred with the "Wakefield effect", as described in Chapter 4 and Box 15.18.

Ethics in Patient Care

Ethical issues between the individual patient and health care provider are important in the New Public Health. A doctor is expected to use diligence, care, knowledge, skill, discretion, and caution in keeping with practice standards accepted at the time by responsible medical opinion and to maintain the basic medical imperative to do no harm to the patient. Patients have the right to know their condition, available alternatives for treatment, and the risks and benefits involved. They also have a right to seek alternative medical opinions, but this right is not unlimited, as any insurance plan or health service may place restrictions on payment for further opinions and consultation without the agreement of a primary care provider.

Health care has a responsibility beyond that of the payment of health service bills and individual care by a physician, in institutions, or through services in the community or the home. The contract for service is becoming less between an individual physician and his or her patient, and more among a health system, its staff, and the client. This places a new onus on the physician to ensure that patients receive the care they require. Conversely, the US provider often faces the dilemma of knowing that a patient may not access needed services because of a lack of adequate health insurance.

Sanctity of Life Versus Euthanasia

The imperative to save a life is an important ethical and practical issue in health care. Advocates of physician-assisted suicide (euthanasia) argue for the right of the patient to die with dignity when the illness is terminal and the individual is suffering excessively. This is not a medical decision alone, and is an agonizing issue for society to address. The Nazi euthanasia program and its human experiments provided

BOX 15.18 The Wakefield Effect

In 1998, *The Lancet*, published an article by a number of well-known researchers headed by Dr Andrew Wakefield. The article reported on 12 cases of autistic children and alleged to show a connection to immunization with the MMR (measles–mumps–rubella) vaccine.

The immediate effect of this "revelation" was widespread alarm over the MMR vaccine and a fall off in immunization coverage by measles-containing vaccines in the UK and elsewhere with many mothers refusing to have their child vaccinated due to a "risk of autism". As a result, measles epidemics occurred in the UK and in many other countries, with measles again becoming endemic in many parts of Europe, especially England and France.

After a long series of investigative journalism in the British press, the article came under scientific scrutiny and withdrawal of many of the coauthors but a consistent insistence by the lead author of its authenticity.

Investigation by British medical authorities later found Dr Wakefield guilty of medical negligence and the UK General Medical Council withdrew his license to practice medicine. The coauthors were found to have been credulous and insufficiently vigilant in agreeing to coauthorship of the paper. In 2000, 12 years after the original publication, *The Lancet* formally withdrew the article.

The effect of this fraudulent scientific publication was a serious loss of credibility of immunization in general and especially regarding the MMR vaccine, one of the greatest life savers in public health technology.

The return of measles in Europe to large scale epidemics with frequent international transmission furthered the loss of confidence of mothers in immunizations and public health. Measles-containing vaccines were particularly strongly affected owing to the publicity given to the Wakefield case. The journal editors could be seen as irresponsible for failing to ensure the scientific integrity of lead authors and coauthors, and the journal for failing to retract a fraudulent article sooner than 12 years after the first publication.

In other public health issues, single publications of findings of small sample and poorly assessed studies published in haste without adequate inquisitive review occur with great frequency. The electronic media often include unscientific opinion blogs which appear larger than life which provoke great anxiety over accepted and successful public health interventions such as fluoridation or folic acid fortification of flour, with unsubstantiated claims that they cause cancer, asthma, and other ill-effects.

The interface between ethics, law, and science in public health requires continuous sensitivity to the downstream effects of "shouting fire in the theater".

Sources: *Wakefield AJ, Murch SH, Anthony A, Linnell, Casson DM, Malik M, et al. Ileal lymphoid nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children [retracted]. Lancet 1998;351:637–41.*

Office of Research Integrity. Definition of research misconduct. Available at: http://ori.hhs.gov/misconduct/definition_misconduct.shtml

General Medical Council. Andrew Wakefield: determination of serious professional misconduct 24 May 2010. Available at: www.gmc-uk.org/Wakefield_SPM_and_SANCTION.pdf_32595267.pdf

Murch SH, Anthony A, Casson DH, Malik M, Berelowitz M, Dhillon AP, et al. Retraction of an interpretation. Lancet 2004;363:750.

Godlee F, Jane Smith J, Harvey Marcovitch H. Editorial. Wakefield's article linking MMR vaccine and autism was fraudulent. BMJ 2011;342:c7452.

the direst of warnings to societies of what may follow when the principle of the sanctity of the individual human life is breached. The issue, however, returned to the public agenda in the 1980s and 1990s as advances in medical science have allowed the prolongation of human life beyond all hope of recovery. Legislation in the Netherlands, the USA ("assisted suicide" in the states of Washington, Oregon, and Montana), and northern Australia has legally sanctioned euthanasia with various safeguards in a variety of circumstances, such as long-term comas or terminal illnesses.

Doctors, patients, relatives, and health care organizations need clear guidelines, orientation, procedures, legal protection, and limitations where failure to take utmost steps to "save" the patient by intubation, resuscitation, or transplantation may cause legal jeopardy. Even though a distinction can be drawn theoretically between permitting and facilitating death, in practice, doctors in intensive care units face such decisions regularly where the line is often blurred. Hospital doctors routinely go to extreme measures to prolong the life of hopeless cases. Such decisions should not be considered for economic reasons alone, but in practice the costs of care of the terminally ill will be a driving force in debate of the issue. Living wills allow a patient to refuse heroic measures such as resuscitation, with "do not resuscitate" standing orders and assignment of power of attorney to family members to make such decisions. Family attitudes are important, but the social issue of redefining the right of a patient to opt for legal termination of life by medical means will be an increasingly important issue in the twenty-first century.

The Imperative to Act or Not Act in Public Health

As in other spheres of medicine and health, in public health the decision whether to intervene on an issue is based on identification and interpretation of the problem, the potential of the intervention to improve the situation, to do no harm, and to convince the public and political levels of the need for such intervention along with the resources to carry it out. This process requires patience and a longer timeframe than many other fields in health.

Some interpretations of ethics in health consider that the only purpose for which power can be rightfully exercised over any member of a democratic community, against his will, is to prevent harm to others. But this is not a dictum that is applied to public health, which is obliged to act to protect the public health in so many spheres such as food and drug safety and environmental health, on a spectrum that extends to banning smoking in public places, mandating food fortification, and many other areas of civil society.

Failure to act is an action, and when there is convincing evidence of a problem that can be alleviated or prevented entirely by an accepted and demonstrably successful intervention, then the onus is on the public health worker to advocate such action and to implement it as best as possible under the existing conditions. Failure to do so is a breach of "good standards of practice" and could be unethical. Inertia of the public health system in the face of evidence of a demonstrably effective modality such as adoption of state-of-the-art vaccines or fortification of flour with folic acid to prevent birth defects would come under this categorization and may even constitute neglect and unethical practice. This is not an easy categorization, because there is often disagreement and even opposition to public health interventions, as was the case with opposition to vaccination long after Jenner's crucial discovery of this procedure in the late eighteenth century. It is also true today with opposition to many proven measures such as fluoridation or fortification of basic foods. Box 15.19 shows the ethical standards of the APHA in 2006.

The use of ethical and high standards of practice in public health (Box 15.20) requires an ideological commitment to the advancement of health standards and use of best practices of international standards to the maximum extent possible under the local conditions in which the professional is working. This is not an easy commitment as there is often dispute and outright hostility to public health activities, in part because of ethical distortions of great magnitude in the past. But this is an optimistic field of activity because of the great achievements it has brought to humankind. Preparation for disasters and unanticipated health emergencies in addition to addressing current issues is a vital part of the New Public Health and our ethical and professional commitments.

BOX 15.19 Principles of Ethical Public Health Practice: American Public Health Association, 2006

- Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.
- Public health should achieve community health in a way that respects the rights of individuals in the community.
- Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.
- Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.
- Public health should seek the information needed to implement effective policies and programs that protect and promote health.
- Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.
- Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.
- Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.
- Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.
- Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the likelihood of significant harm to the individual or others.
- Public health institutions should ensure the professional competence of their employees.
- Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.

Source: *American Public Health Association. Public Health Leadership Society. Principles of the ethical practice of public health. APHA; 2002. Available at: http://www.apha.org/NR/rdonlyres/1CED3CEA-287E-4185-9CBD-BD405FC60856/0/ethicsbrochure.pdf [Accessed 13 December 2012].*

SUMMARY

In order to maintain and improve standards of care, health systems need quality assurance and technological assessment as part of their ongoing operation. Poor-quality care is costly in terms of iatrogenic diseases and prolonged or repeated hospitalization. If innovations such as endoscopic surgery are not introduced, then longer hospital stays are needed for the same operation, wasting the patient's time and productivity, while utilizing expensive health care resources, and incurring the risks associated with more invasive surgery.

Health care is provided by people, as well as by institutions with a range of devices and equipment. The people providing care, more than the technological facilities, set the quality of care. Nevertheless, progress on the technological side of medical care is vital to the continuing development of the field. Modern medications, monitoring equipment, laboratory services, and imaging devices have made enormous contributions to advances in medical care. Appropriate

BOX 15.20 The Ethics of Publication in Public Health

Publication in peer-reviewed journals is a key part of the advancement in science and a vital part of the development of the scientific basis for public health practice. The process of publication should promote rigorous standards of high quality ethical research and the wide dissemination of their findings. Codes of practice for editors and publishers of peer-reviewed journals have been developed by both the Committee on Publication Ethics (COPE) (Rees, 2011) and the World Association of World Editors (WAME).

Editors are subject to competitive pressures, and the overarching metric of success is seen to be the impact factor, a measure of the frequency with which the "average article" in a journal has been cited in a particular year or period. Relevant, rigorous research of better quality will tend to be cited more frequently, and thus editorial strategies that look for quality and relevance in the given field will increase the impact factor. However, there can also be potential distorting factors. Publishing a highly controversial paper can result in high citation levels. Publishing studies which demonstrate negative findings may be less likely to attract large numbers of citations.

Key issues relate to conflicts of interest, and the potential for advertising and sponsorship to distort editorial decision making (Gray, 2012). A particular concern has been the pernicious influence of the tobacco industry in sponsoring, frequently covertly, research which has aimed to confuse or obfuscate key findings linking second hand exposure to tobacco to adverse impacts on health. Similar tactics are used in other areas where health and commercial interests collide. Clear statements of potential conflicts of interest are essential. Journal owners must not interfere in the evaluation, selection, or editing of individual articles, either directly or by creating an environment in which editorial decisions are strongly influenced.

Other challenging areas are plagiarism and research misconduct. The latter is extremely difficult both to detect and to deal with, and requires close working between institutions and editors who may suspect professional misconduct. In cases of fraud, the publishing journal should withdraw the article in a timely fashion (see Box 15.18: The Wakefield Effect).

There has been a rapid rise in open access publishing, in part underpinned by an ethical belief that research is a public good, and an increasing number of influential research funders now require that there should be unrestricted access to the published output of research. In addition, several publishers make their journals free to those in selected low-income countries, promoting dissemination to those who might not otherwise afford them.

In summary, publication in peer-reviewed journals remains a key method for establishing and progressing the evidence base for public health practice. The consequences of poor or frankly fraudulent science can have a substantial adverse impact both on health and on the use of resources. Editors must adhere to high ethical and professional standards and remain vigilant to avoid allowing external drivers to distort their decision-making processes. They must strive to maintain integrity and high scientific standards to advance the field of public health practice (Smith, 2007).

Sources: *Selena Gray, BSc, MBCHB, MD, FFPH, FRCP, Professor, University of West of England, Bristol, and Deputy Postgraduate Dean, Severn Deanery, Bristol, UK. Personal communication.*

Rees M. Code of conduct and best practice guidelines for journal editors. Committee on Publication Ethics; 2011. Available at: http://publicationethics.org/ [Accessed 21 August 2012].

Gray S. The ethics of publication in public health. Public Health Rev 2012;34. Epub ahead of print. Available at: www.publichealthreviews.eu [Accessed 20 December 2012].

Smith R. The trouble with medical journals. London: Royal Society of Medicine Press; 2007.

technology is a critical issue for international health, since the most advanced technology may be completely inappropriate in a setting that cannot afford to maintain it or lacks the trained personnel to operate it, or where it comes in place of more vital basic primary care services. Technology assessment needs to be seen in the context of the country and its resources for health care.

Ethical issues in public health are no less demanding than those related to **individual** clinical care. The rights of the individual and those of the community are sometimes in conflict. Technology, quality, the law, and ethics are closely interrelated in public health. Well-informed and sensitive analysis of all aspects of their development is a part of the New Public Health. The balance between individual and community rights is very sensitive and must be kept under continuous surveillance.

The New Public Health is replete with technological and ethical questions, especially in a time of cost restraint, increasing technological potential, the public expectation of universal access to health care, and the assumption that everyone will live a healthy and long life. Health status has always been linked with socioeconomic status and, despite enormous gains, this remains true even in the most egalitarian countries. Expansion of market mechanisms, such as controlling the supply of hospital beds, doctors, and access to referrals, competition and incentives/disincentives in payment systems for hospital and managed care systems, contribute to a need for dynamic health policy management capacity. The New Public Health assumes a social responsibility for health for all, using community and personal care modalities as effectively as possible to achieve that overall goal.

NOTE

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

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