



1.2 The Health System

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1.2.1 DETERMINANTS OF INDIVIDUAL AND POPULATION HEALTH

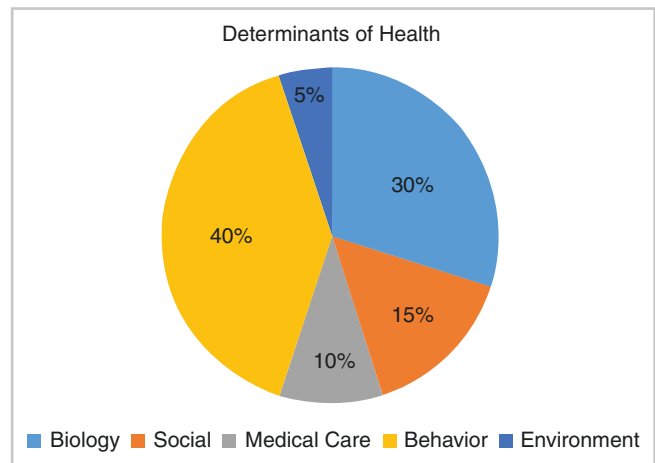
There are several factors (or **determinants**) that contribute to the health of a person or a population. According to McGinnis, these factors are divided into five categories¹: Biology, Behavior, Social, Environment and Medical care. Of these, biology and behavior have the largest contribution to the health of an individual, followed by social, medical care and environment. Figure 2-1 shows the relationship among these determinants.

1. **Biology**: the age and sex of the person; the genetic makeup including heritable diseases. At the current time, biological factors are the hardest to change, although many are hopeful that genetic engineering may change this at some point. For this reason, most public-sector investment in public health aims to affect the behavioral, social, environmental and medical access determinants.
2. **Behaviors**: alcohol, tobacco, substance abuse; risk-prone lifestyles, such as working as a miner or prostitute.
3. **Social**: discrimination, income disparities, socioeconomic status, education, occupation, class, social support. Poorer people often lack time and opportunity to exercise. Food for a healthier diet tends to be more expensive and takes longer to prepare. A strong and consistent finding of epidemiological research is that there are health differences among socioeconomic groups. Lower mortality, morbidity, and disability rates among socioeconomically advantaged people have been observed for hundreds of years.
4. **Environment** (or total ecology): where a person lives, sanitary and crowding conditions, air and water quality, lead exposure, and the design of neighborhoods. Some of the most dramatic improvements in population health during the twentieth century include: improved water, food, and

¹ McGinnis JM, Foege WH. Actual causes of death in the United States. *JAMA* 1993; 270:2207–2212.

FIGURE 2-1

Determinants of health. Biology and Behavior are the most important determinants of health, followed by social, medical care and environment. Based on data from McGinnis JM, Foege WH. Actual causes of death in the United States. JAMA 1993; 270:2207–2212



milk sanitation, reduced physical crowding, improved nutrition, and central heating with cleaner fuels. Most Americans live in urban areas, which are often associated with harmful health behaviors, such as lack of exercise, poor diet, sexual behavior, alcohol and substance abuse.² Cities also have higher levels of air pollution, which may cause cardiovascular and respiratory disease. Crowded buildings may increase the risk of lead exposure as well as asthma. Those that live in rural areas have other risks, such as exposure to pesticides.

5. **Medical care:** access to quality health care; having insurance. For example, the availability of Medicaid (health insurance for the poor) was expanded greatly with the passage of the Affordable Care Act. This resulted in greater access to medical care for a previously underserved population. Similarly, the nationwide shift to high-deductible insurance plans has actually reduced accessibility to affordable healthcare for many.

None of these determinants functions in a vacuum. They are intertwined and often interdependent. Ameliorating issues in one of the determinants may exacerbate issues in another. For example, a Health Impact Assessment by the World Health Organization studied the effects of transportation on public health. As with any intervention, there are both risks and benefits.³

1. More vehicles on the road increases the risk of motor vehicle accidents (especially at extremes of age).
2. Air pollution results in climate change and increased incidence of respiratory disease.
3. Noise pollution may cause disrupted sleep cycles.
4. Building highways or train tracks may separate communities or decrease the amount of arable land.
5. Increased transportation allows for better access to employment and economic development, possibly resulting in better infrastructure and better access to medical care.
6. Cycling or walking may improve physical activity. Driving or taking a train may reduce physical activity.
7. Better transportation allows for wider dispersal of vector borne diseases (e.g. SARS, Ebola).

² Some cities, especially New York City, are healthier than their rural neighbors. Prohibitively expensive private transportation coupled with a thriving culture encourage denizens of New York to get out and walk more. See New York Magazine article at <http://nymag.com/news/features/35815>. This is supported by research by Jawbone, showing that New Yorkers walk more than most Americans. See <https://jawbone.com/blog/jawbone-up-data-by-city/>

³ The determinants of health. WHO. <http://www.who.int/hia/evidence/doh/en/index2.html> (accessed February 6, 2017).

Place-Based Approaches

Some argue that the natural and built environment in which a person lives may be more predictive of future health than his genetic make up.⁴ Therefore, solutions which target specific social or community problems are more likely to succeed. For example, the Colorado Health Foundation sought to fight obesity by building parks and playgrounds with walking trails. In Camden, NJ, public health officials noted an extraordinarily high rate of patients going to the Emergency Department (ED) for issues that could be handled by primary care doctors. In response, they set up a referral program which set up high-utilizing patients with clinics, thereby reducing unnecessary ED visits.

Most individual health efforts involve clinical interventions with high-risk groups (such as treating patients with hypertension). However, these measures do very little to prevent a population from getting sick in the first place. Recognizing the spectrum of risk and applying interventions more broadly may be more efficacious.⁵

1. All risk exists on a spectrum. Risk factors for certain diseases have traditionally been recorded as either present or not present (i.e. either the patient has a history of diabetes or he doesn't). However, a more accurate way of recording risk is through continuous instead of dichotomous variables. For example, there is no convenient level of zero risk for conditions such as blood pressure, cholesterol, alcohol consumption, tobacco consumption, physical activity, weight or lead exposure.
2. Only a small percentage of the population is at the extremes of risk. Exposure of a large number of people to a small risk results in more burden of illness than exposure of a small number of people to high risk. Therefore, the most effective interventions will be aimed at the moderate risk categories, even though they are not themselves sick.
3. An individual's risk can only be interpreted in the context of his population. For example, the risk of a person in the United States of dying from an acute myocardial infarction is higher than a person in Japan, possibly because the incidence of hyperlipidemia is higher in the US than Japan. People planning population based health interventions should first ask why the population in Japan has lower cholesterol and only then try to figure out ways to lower cholesterol in the US.

1.2.2 PRIMARY DOMAINS, ORGANIZATIONAL STRUCTURES, CULTURES, AND PROCESSES

There are many domains, structures, cultures and processes which define the health care system.

1.2.2.1 Health Care Delivery

The American health system is a complex web of healthcare providers, insurers, regulators, pharmaceutical and equipment manufacturers, and, of course, patients. These interact in myriad patterns, often productive, sometimes ethical, occasionally wonderful. One thing is constant: a huge amount of information is generated and recorded during these interactions. See Figure 2-2.

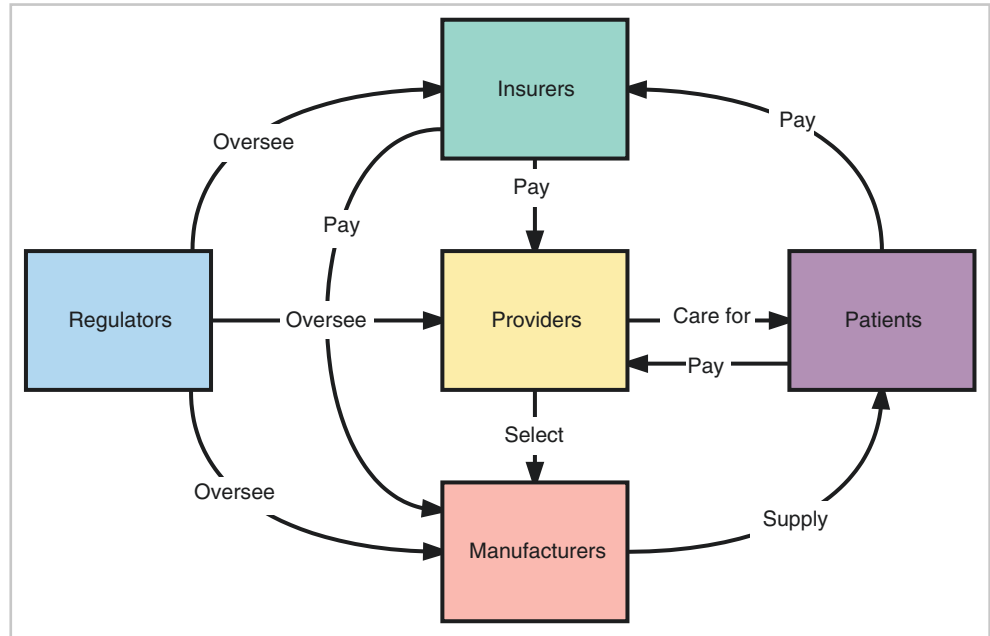
Healthcare **providers** include those persons and institutions who provide direct or indirect care for patients, such as doctors, hospitals, nurses, respiratory therapists, nutritionists, and many others. There are many ways that these individuals are paid—sometimes directly, but usually by means of a third-party payor, such as an **insurer**. The insurer may be a traditional health insurer, or may be a workmen's compensation insurer in the case of a workplace injury, or may be an auto insurer in the case of a motor vehicle accident.

⁴ It is sometimes said that a person's zip code is a better predictor of longevity than his genetic code.

⁵ Understanding Population Health and Its Determinants. Institute of Medicine. 2003. The Future of the Public's Health in the 21st Century. Washington, DC: The National Academies Press.

FIGURE 2-2

The relationships among regulators, insurers, providers, manufacturers and patients. It's complicated



In the course of care, the patient may require medication or durable medical equipment, such as a wheelchair. These items are made by **manufacturers** and are generally paid for by insurance, although there is significant variation in coverage, especially for medications. Manufacturers tend to spend a great deal of energy marketing their products to providers and directly to consumers as well.

In order to protect all stakeholders, **regulators** oversee the activities of manufacturers, providers and insurers. Oversight may be federal (such as the Food and Drug Administration) or on a state by state basis (such as state licensing boards).

For example, a patient complains of symptoms of gastroesophageal reflux disease. On television, he sees an ad for over-the-counter (OTC) omeprazole (manufactured by Procter and Gamble) as well as an ad for prescription-only pantoprazole (Pfizer). The FDA was responsible for approving both of these medications for sale in the US. The FDA also regulates ads for prescription medications, while the Federal Trade Commission regulates non-prescription ads. The patient is unsure which medication is better for him, so he makes an appointment with his provider. The provider (who holds a state license to practice medicine) reviews several published studies on proton pump inhibitors and suggests omeprazole as it is noninferior to and less expensive than pantoprazole. When the patient goes to the local pharmacy (which is licensed by the state as well as the federal Drug Enforcement Agency), he compares prices for the available drugs. His insurance plan does not cover OTC drugs, but it will cover part of the cost of prescription drugs with a co-payment. The state Department of Banking and Insurance has mandated that there must be more than one drug in each therapeutic class placed in the lowest tier of co-pays, which means that the co-pay for pantoprazole is actually lower than the retail cost of omeprazole.

1.2.2.2 Public Health

While most of medicine focuses on individual patients, the field of public health is dedicated to improve the health of populations by treating and preventing disease. This may include many activities, such as surveillance of different symptoms, tracking of infectious diseases and promotion of healthy behaviors.

Syndromic surveillance involves tracking the presentation of certain symptoms as a potential early warning sign of an epidemic. For example, an unexpected rise in Emergency Department visits for gastroenteritis in a small geographical area could signify

contamination of a water supply or spoiled produce, or even a terrorist attack. Early detection may prevent others from becoming sick.

Keeping track of infectious disease and controlling its spread is an important public health function. At the end of 2014, there was an outbreak of ebola virus in West Africa. Through a coordinated effort, public health officials were able to restrict travellers and prevent the disease from spreading within the US. In addition, they ensured that hospitals had adequate education and supplies to care for patients if they did arrive.

Promoting healthy behaviors includes funding public education on health risks such as smoking or obesity. It may involve prevention programs directed at certain high-risk groups, such as distributing condoms and needle exchange programs.

1.2.2.3 Clinical Research

Clinical research entails creating a study question, formulating an experiment to test that question, and ultimately publishing the results (be they positive or negative). Drug and device manufacturers spend approximately \$70 Billion per year on research, with an additional \$50 Billion from public sources, most notably the National Institutes of Health.

Industry funded research may be carried out within the company's own laboratories, but also may exist as a partnership with an academic institution. In order to preserve the autonomy of the academic researchers, institutions are given unrestricted grants (monies dedicated to furthering the goals of the institution, rather than a particular project). In practice, however, unrestricted grants are usually given to those institutions that further the goals of the industry. For this reason, studies funded by industry sources are generally less reliable than those funded by public sources.

Research findings are promulgated through publication in journals dedicated to the particular area of study. Peer-review is a process which enables other scientists to validate the methods and/or findings prior to publication. One unfortunate weakness of this process is that journals only tend to publish articles which have positive findings that impact readers. This leads to a relative difficulty in publishing negative studies known as publication bias. (See Sects. 2.2.1 and 2.2.2).

1.2.2.4 Education of Health Professionals

Nurses

Most hospitals require nurses to have 4-year Bachelor in Science of Nursing (BSN) degrees, although 2-year associates (ASN) degrees are still relatively common in doctors' offices, schools and home care. A Licensed Practical Nurse (LPN) is a 1-year degree and often assists other nurses, but the scope of practice is limited compared to other nurses.

Physicians

In the US, physicians and surgeons typically receive 4 years of medical school training after completing an undergraduate bachelor's degree. After medical school, they typically have 3–7 years of postgraduate education (internship/residency) in their particular field of study. Those pursuing subspecialization will do a fellowship for 1–3 additional years. National, standardized exams punctuate each of the transitions between phases of training.

Getting into medical school is competitive, and only 44% of US college seniors who apply will ultimately get in. Approximately 80% will matriculate in an allopathic medical school and earn a Medical Doctor (MD) degree, while 20% will obtain a Doctor of Osteopathy (DO) degree. Osteopathic schools are slightly less competitive than allopathic schools. Due to the high cost of premedical education, applicants from lower socioeconomic status tend to have a disadvantage compared to their wealthier rivals. Applicants whose parents are among the top 40% earners in the US make up about 75% of acceptances.

Medical education itself is quite expensive. The average medical student attending a private medical school will pay nearly \$300,000 in tuition over the course of 4 years. Most of

this money will be borrowed against the hope of future earnings, and is repaid over the ensuing 10–20 years.

Traditionally, the first 2 years of medical school are dedicated to the study of basic sciences (anatomy, physiology, histology, genetics, biochemistry, microbiology, pharmacology, etc), while the third and fourth years are composed of clinical clerkships. Many modern medical schools have modified this curriculum to introduce students to clinical medicine earlier in their studies. Others have reduced the basic sciences requirement so as to emphasize other aspects of medicine or to offer students the opportunity to earn another degree, such as a Masters of Public Health, or a Masters of Business Administration. Yet others have required students to perform original research to produce a dissertation.

After medical school, students enter a competitive match for residency programs. Residencies in popular cities and in specialties that pay well tend to be more competitive. Most primary specialties and subspecialties have board exams which are taken during the first year or two after finishing residency. Clinical informatics is unusual in that candidates may take the board exam without having formal training, although they must demonstrate real-world experience. Starting in 2022, doctors who wish to take the Clinical Informatics board exam will have to complete a 2-year fellowship. Many board exams require recertification every 10 years, although this has become a contentious topic amongst practicing physicians.

After graduation from residency or fellowship, physicians are required to complete courses as part of Continuing Medical Education (CME) every year that they maintain their license. CME courses are generally accredited by universities or state medical societies and must meet certain criteria for content and relevance. In addition, certain states require specific CME content. New Jersey, for example, requires two credits on End-of-Life care per 2-year licensing cycle.

Dental schools and podiatry schools have similar educational programs, although there is less reliance on residency programs.

Associate Practitioners⁶

Not all providers are physicians.

Nurse Practitioners are nurses who have obtained an advanced degree, usually a Masters of Science in Nursing, sometimes a Doctor of Nursing Practice. Nurse Practitioners are allowed “full practice” in 21 states, which means that they are allowed to practice medicine without supervision of a doctor. They are allowed to perform simple invasive procedures, but are not allowed to perform complex operations alone. Some advanced practice nurses have very specific training, such as nurse midwives and nurse anesthetists.

Physician Assistants usually obtain a Masters of Science degree, but occasionally a Bachelors of Science. Physician Assistants are licensed to practice medicine under the supervision of a physician, but their scope of practice is limited to that of their supervisor. The degree of physician oversight varies from state to state, and from practice to practice. For example, California requires *one* of the following levels of supervision⁷ (1) The physician sees the patients the same day that they are treated by the PA; (2) The physician reviews, signs and dates the medical record of every patient treated by the PA within 30 days of treatment; (3) The physician adopts written protocols which specifically guide the actions of the PA. The physician must review 5% of the medical records within 30 days. There is some debate as to whether PAs should complete a residency similar to physicians. Currently they do not.

Other Certifications

There are many other medical certifications with widely varying educational requirements. Certified Nurse Assistants have a 6- to 12-week training program after high school. Emergency Medical Technicians who staff ambulances have a 125-h training course. Paramedics, who are allowed to administer medications, have about 1000 h of education.

⁶ There is great debate about the appropriate terminology for nurse practitioners and physician assistants. The term *midlevel provider* has been cited as demeaning, while the term *non physician provider* has been cited as nonspecific.

⁷ Section 1399.545 of Title 16 of the California Code of Regulations.

Dieticians require a bachelor's degree in order to practice, while audiologists require a doctorate (Aud. D.). Physical therapists and Occupational therapists may hold a 2-year master's or 3-year doctoral degrees.

1.2.2.5 Personal Health

The World Health Organization defines health as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. There are many dimensions to health and wellness which must interact to make a person feel "healthy".

1. Emotional wellness involves being in touch with one's feelings, developing love, trust and self-confidence.
2. Intellectual wellness refers to developing the mind to perform critical thinking, curiosity and creativity.
3. Social wellness helps people find their station in life and develop meaningful relationships with their peers
4. Spiritual wellness revolves around developing a personal belief system and adherence to that system, while finding meaning and validation in actions.
5. Physical wellness includes paying attention to medical problems and treating them appropriately. It also involves developing safe habits regarding activity, sleep, nutrition and exercise.

1.2.3 THE FLOW OF DATA, INFORMATION, AND KNOWLEDGE WITHIN THE HEALTH SYSTEM

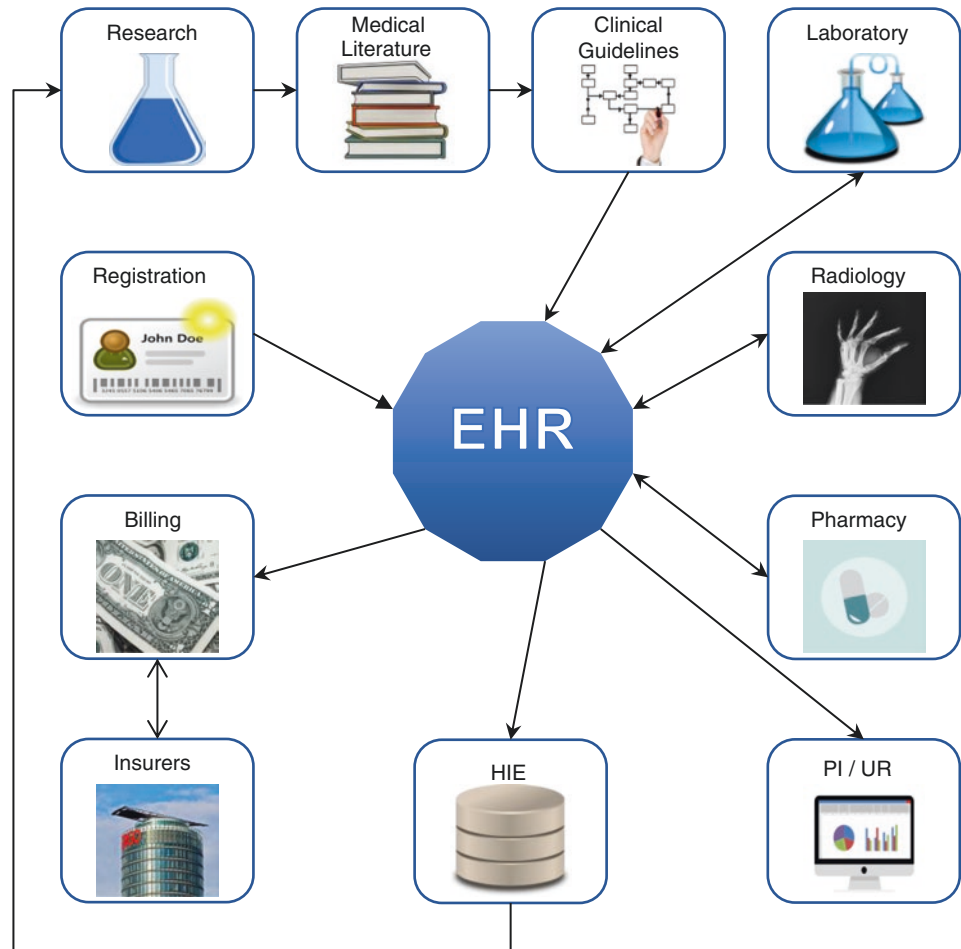
In healthcare, data flows in many directions, often at the same time. As an example, medical research produces medical literature which informs clinical guidelines which are incorporated into an Electronic Health Record (EHR) which is used for patient care. Patient information and demographics are collected by registrars who also enter this information into the EHR. Physicians use a clinical decision support system to place orders for laboratory, radiology and pharmacy. Each of these departments performs tests or therapies. When the tests have been resulted, the information is returned to the EHR to further guide patient care. When care is complete, the data is sent to billing and collections. This often requires two-way communication with insurers and other payors to provide justification and explanation of services. The EHR is also used for chart reviews within the institution for quality assurance, performance improvement and utilization review. Patient data is also sent to the regional health information exchange, where it will be used to guide care if this patient is seen at another institution. In addition, the data may be used for secondary analysis for epidemiological studies by researchers who then contribute to the medical literature and so on (Figure 2-3).

Some dataflows are unidirectional while others involve two-way communication. When a department director conducts a performance improvement (PI) project, she reviews data from the EHR regarding care given to particular patients. Since the data only flows from the EHR to the PI activity, it is unidirectional. However, when a doctor orders a laboratory test, the laboratory receives the order from the EHR, completes the order and then sends results back to the EHR, resulting in bidirectional dataflow.

As we have mentioned before, there is a distinction between data, information and knowledge flow. Data are raw and without context, such as the result of a blood test. Information is data in a clinical context, such as a creatinine which is trending upwards. Knowledge is the application of information, such as using a clinical decision rule. Bidirectional communication is relatively straightforward with data, but becomes increasingly difficult with information and knowledge.

FIGURE 2-3

Information flows. *EHR* Electronic Health Record, *HIE* Health information exchange, *PI/UR* Process improvement/utilization review. Arrows indicate direction of flow



1.2.4 POLICY AND REGULATORY FRAMEWORK

The rules under which medicine is practiced in the United States originate from multiple intersecting and occasionally conflicting sources, including federal, state and local governments as well as quasi-governmental agencies such as the Joint Commission. Superimposed on this dense thicket of regulatory controls are institutional policies and procedures.

The broadest source of rulemaking is the federal government, which is composed of three branches: Legislative (writes laws), Executive (enforces laws) and Judicial (interprets laws).

The legislative branch (Congress) includes the Senate and the House of Representatives. Laws are created when a bill is presented, discussed and approved by both houses and then sent to the president for signature. Examples of federal laws impacting medicine include the Emergency Medical Treatment and Active Labor Act (EMTALA, 1985); Health Information Technology for Economic and Clinical Health Act (HITECH, 2009) and countless others.⁸

In the executive branch, the Department of Health and Human Services (HHS) is the agency responsible for monitoring and administering healthcare in the US. HHS has many well-known divisions.⁹

1. **Agency for Healthcare Research and Quality (AHRQ).** AHRQ supports research designed to improve the outcomes and quality of health care, reduce its costs, address patient safety and medical errors, and broaden access to effective services.

⁸ It seems that having an easy-to-pronounce law increases its perceived importance. The same may be true in medical research. See Stanbrook MB, Austin PC, Redelmeier DA. Acronym-Named Randomized Trials in Medicine—The ART in Medicine Study. *N Engl J Med* 2006; 355:101–102.

⁹ You can see the complete organizational chart for the department of health and human services at <https://www.hhs.gov/about/agencies/orgchart/>

2. **Agency for Toxic Substances and Disease Registry (ATSDR).** ATSDR’s mission is to prevent exposure and adverse effects from hazardous substances in the environment.
3. **Centers for Disease Control and Prevention (CDC).** CDC’s mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. The CDC is often at the forefront of detecting and controlling infectious disease outbreaks (such as Ebola)
4. **Food and Drug Administration (FDA).** The FDA ensures the safety of foods, cosmetics, pharmaceuticals, biological products, and medical devices.
5. **Health Resources and Services Administration (HRSA).** HRSA directs national health programs by assuring equitable access to comprehensive, quality health care for all.
6. **Centers for Medicare and Medicaid Services (CMS).** CMS administers Medicare, Medicaid, and the State Children’s Health Insurance Program (CHIP). CMS also provides administrative support for the Health Insurance Portability and Accountability Act (HIPAA).
7. **Indian Health Service (IHS).** IHS is the principal Federal health care provider for American Indians and Alaska Natives.
8. **National Institutes of Health (NIH).** NIH is the research arm of HHS. It provides grants and leadership to researchers. The National Library of Medicine supports MEDLINE/Pubmed, the most comprehensive database of research articles.
9. **Substance Abuse and Mental Health Services Administration (SAMHSA)** SAMHSA works to improve the quality and availability of prevention, treatment, and rehabilitative services to people with substance abuse and mental illnesses.
10. **Office of the Assistant Secretary for Preparedness and Response (ASPR).** ASPR provides advisory staff on bioterrorism and other public health emergencies.
11. **Office of the Secretary (OS).** Two divisions of the OS are noteworthy for informatics.
 - (a) **Office of the National Coordinator for Health Information Technology (ONC).** ONC is responsible for achieving the mission of the Health Information Technology for Economic and Clinical Health Act (HITECH), which is to establish a national Health IT infrastructure. ONC certifies technology to be eligible for Meaningful Use payments, in coordination with CMS.
 - (b) **Office for Civil Rights (OCR).** OCR administers HIPAA in coordination with CMS.

In addition to federal law, states and municipalities often create statutes that impact medical practice. These laws may differ from state to state or from region to region. See Sect. 1.1.6 for more information.

1.2.5 HEALTH ECONOMICS AND FINANCING

The United States has, by far, the most expensive healthcare system in the world. In 2016, the United States spent \$3.3 trillion on healthcare, representing about 18% of the gross domestic product (GDP), and amounting to \$10,345 per person. Most of that money (54%) went to doctors and hospitals, with the remainder spent on drugs, medical equipment, long term care and administration.¹⁰ For a comparison with other countries, see Figure 2-4.

Healthcare hasn’t always been so expensive. Historically, doctors were tradespeople who would provide services in exchange for professional fees. Since these fees were paid directly by the patient to the provider, doctors used trade secrets such as patent medicines or specialized

¹⁰ Keehan SP et al. National Health Expenditure Projections 2015–25: Economy, prices and aging expected to shape spending and enrollment. *Health Affairs* 2016 35(8): 1–10.

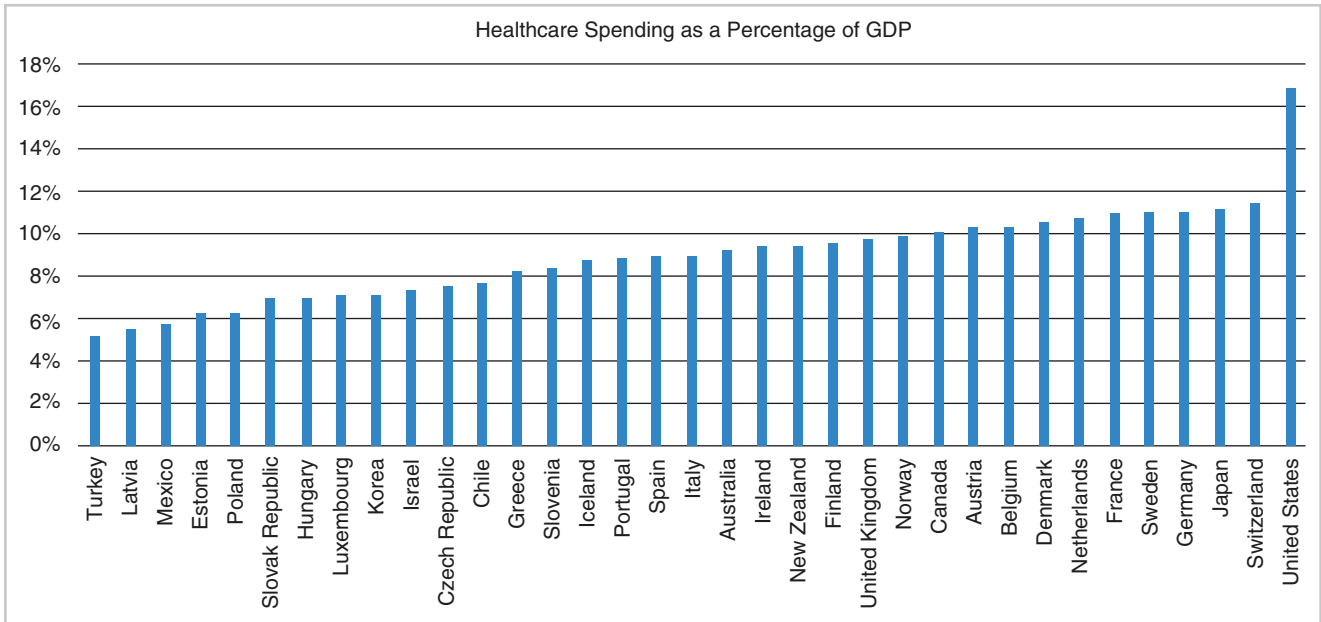


FIGURE 2-4

Healthcare spending as a percentage of GDP in 2015. Data courtesy Organization for Economic Co-operation and Development, accessed May 10, 2017

surgical implements to distinguish themselves from one another. Without a backing of science, it was charisma more than any other trait that helped patients choose their physician.

In the 21st century, the advent of formalized medical education and widely published research reduced some of the most egregious variations in practice and helped eliminate some of the quackery that had plagued the field. The commoditization of medication and surgical supplies helped define standards of care to which the majority of physicians would adhere. Charisma, reputation and cost still played a role in a patient's decision to choose a physician.

By the 1970s, health insurance, rather than individuals, paid for the majority of care. More than three-quarters of the population had health insurance through their employer. Public health insurance, in the form of Medicare (for persons aged 65 and older or those with disabilities) and Medicaid (for the poor) accounted for most of the remainder. A small minority purchased their own insurance, and some had no insurance at all.

Insurance companies function by collecting regular premiums from their customers (or taxpayers in the case of public insurance). Using actuarial tables, the insurer calculates how likely an insured person is to need medical services over the course of a year. In practice, a large number of people will require a small amount of service, and a small number of people will require a large amount of service, even though everyone's premiums are essentially the same. The process of distributing the cost of care over a large number of people is called **risk spreading**.

Since Medicare and Medicaid paid less than commercial insurance, they were less desirable to physicians. Patients with this type of coverage found themselves in a position where they had insurance but did not have **access** to health care because doctors wouldn't accept their insurance. Hospital-run clinics, which were staffed by physicians in training, were obligated to accept public insurance.

Among commercial insurers, however, **indemnity** policies were common. Patients chose their doctors at will and submitted their bills to the insurer for reimbursement. In most cases, the fees were completely paid, based on the services provided (**fee-for-service**). When the fees seemed outrageous, the insurer would pay what they felt was **usual, reasonable and customary**. This was calculated by determining the average cost for similar services in the

region where the service was provided. In many cases the reimbursement for particular services was negotiated beforehand. Depending on the supply and demand for services, either the insurer or provider has an upper hand in constructing the pay scale. When a person pays for healthcare directly, there is frequently much more room for negotiation.

This arrangement encouraged patients to seek care more frequently and encouraged physicians to increase the intensity and diversity of services provided. This was the heyday of the fee-for-service system. Doctors and hospitals continued to provide increasingly expensive treatments which were paid in full by insurers. Hospitals were paid a daily rate for inpatients, and therefore tended to keep their patients as long as possible.¹¹ As the cost of being sick skyrocketed, it became financially impossible for persons without insurance to pay for their care. As a result, profitable hospitals would routinely refuse to accept uninsured patients.

In an effort to decrease utilization, insurers began requiring **co-payments** at the time of service. Co-pays are typically a small fraction of the total cost of care and are paid directly from the patient to provider. When each visit requires a co-pay, patients may think twice before seeing their doctor. More recently, **co-insurance** has become a standard part of most policies. Co-insurance requires the patient to pay a fixed fraction (usually 10–40%) of the cost of care. Since hospital admissions can easily run into \$100,000 or more, this becomes a significant financial burden for the majority of healthcare consumers. Needless to say, it functions as strong disincentive for seeking medical care. The mechanism of requiring patients to pay some fraction of the cost of care is called **cost sharing**.

Managed Care Organizations were created to control healthcare spending. In 1973, Congress passed the **Health Maintenance Organization (HMO) Act** which required employers to offer HMO insurance if they offered traditional insurance. The essence of managed care was that patients were limited to providers who had agreed to follow the HMO's guidelines and restrictions. One of the common managed care strategies involved shifting the financial risk from the insurer to the providers. One example is **capitation**, where a primary care doctor was given a certain amount of money per patient per year. If the patient required hospitalization or an expensive procedure, it came out of the doctor's share. Similarly, if the patient remained healthy, the doctor profited. In theory, doctors were now incentivized to provide preventive care to their patients, in order to avoid expensive hospitalizations.

HMO's also expanded the process of **pre-authorization**, which required the patient to obtain permission before acquiring certain costly services. Some drugs, radiology procedures (especially MRI) and even hospital admission required the approval of the insurer. Patients were warned that they would be fully responsible for the costs of care if they did not obtain the appropriate pre-authorizations. Practically speaking, the responsibility for obtaining pre-authorizations has fallen upon physicians.

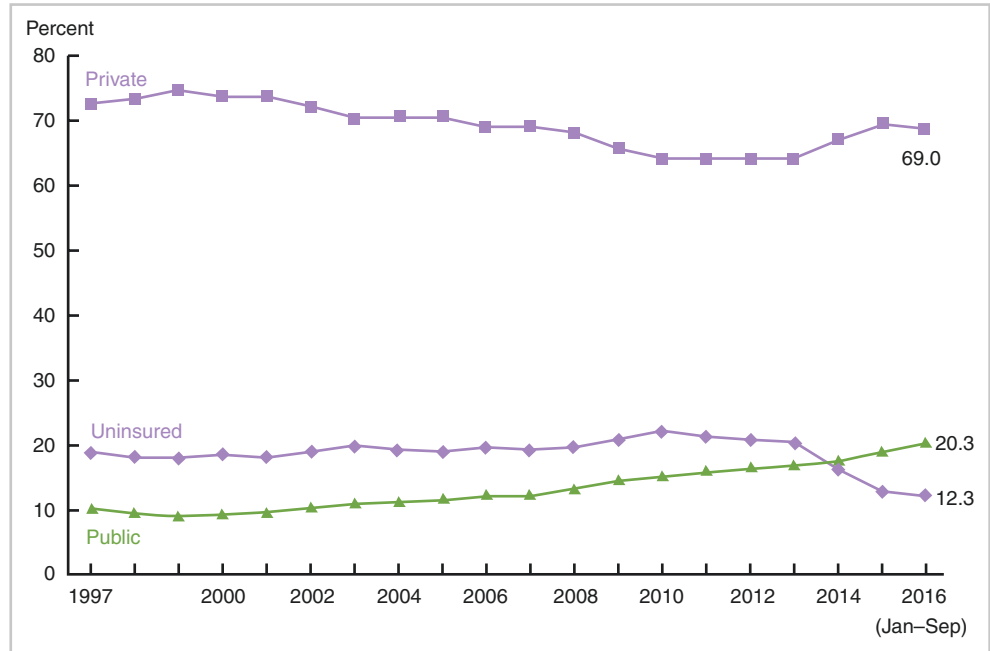
In 1983, Medicare began the **inpatient prospective payment system** based on **diagnosis related groups (DRGs)**. Instead of paying a daily rate for hospitalized patients, Medicare now paid the hospital a fixed rate based on the primary discharge diagnosis. Additional payments are made to hospitals which are training residents (indirect medical education) and to hospitals which treat a large number of indigent patients (disproportionate share hospital adjustment). Very quickly, hospitals began looking for ways to minimize the amount of time patients spent in the hospital (Length of Stay (LOS)). Unfortunately, this created a conflict between the hospitals and the physicians, who were not paid via IPPS but instead were paid on a fee for service basis.

In 1985, the Emergency Medical Treatment and Active Labor Act (EMTALA) mandated that hospitals provide a medical screening exam to anyone who comes to the hospital and on whose behalf a request for treatment is made. This had profound implications for care. Since hospitals were no longer able to discriminate on the basis of ability to pay, they had provide identical care to patients regardless of the reimbursement that they would ultimately receive. In order to pay for indigent care, the hospital had to use money collected from insured patients to pay for uninsured patients. This process is called **cost-shifting**.

¹¹ In the mid-1960s, for example, it was not uncommon for a woman to remain in the hospital for 10 days after a vaginal delivery. Today, most patients are discharged in 48 h.

FIGURE 2-5

Percentage of Americans with private and public insurance, 1997–2016. The decrease in uninsured population is associated with the passage of the Affordable Care Act in 2010. Image public domain by U.S. Department of Health and Human Services • Centers for Disease Control and Prevention • National Center for Health Statistics • Released 2/2017



Several initiatives have been designed to link quality of care to reimbursement, usually under the rubric of **pay for performance (P4P)**. In general, a basket of quality measures is defined and incorporated into a scorecard. Doctors and hospitals can then earn a bonus based on their performance on the scorecard. For Medicare, the IPPS payment is modified on the basis of certain quality metrics (called value-based purchasing) and the number of times a patient is readmitted to a hospital within 30 days of their last discharge (via the hospital readmission reduction program).

The modern iteration of the HMO is an **Accountable Care Organization (ACO)**, which is a group of providers who voluntarily band together to coordinate services. Although the initials have changed, the key motivating factor in the ACO remains capitation. The organization will be paid a certain fee for the number of lives covered. The fewer services provided to the patients, the more money is made by the ACO.

There are many instances where health care services are given without direct reimbursement. Communities often establish free clinics which are supported by grants and contributions. Many states have a payment tier between medicaid and traditional insurance. In New Jersey, for example, patients who earn too much to qualify for medicaid, may be eligible for a program known as Charity Care. Physicians frequently donate their time and expertise for charitable causes, although the regulatory burden and the medical liability climate in the United States makes it unattractive to do so. Charitable organizations (e.g. Doctors Without Borders) often provide free medical services to indigent populations.

Perhaps the most important change in financing in recent memory is the passage of the Affordable Care Act (ACA), designed to improve access to health insurance by providing state-run insurance exchanges, requiring people to sign up for health insurance or face a tax penalty and expanding public insurance (mostly medicaid). Figure 2-5 shows that the ACA decreased the number of uninsured Americans by encouraging enrollment in private insurance as well as dramatically increasing public insurance. At the same time, however, the cost of private insurance is still increasing at a rate that easily outstrips increases in family income, as seen in Figure 2-6.

As the cost of insurance increases and the percentage of costs that are borne by the patient increases and the cost of healthcare itself increases, there is a renewed public debate in the US about universal health care, similar to the single-payer model that exists in most other developed nations.

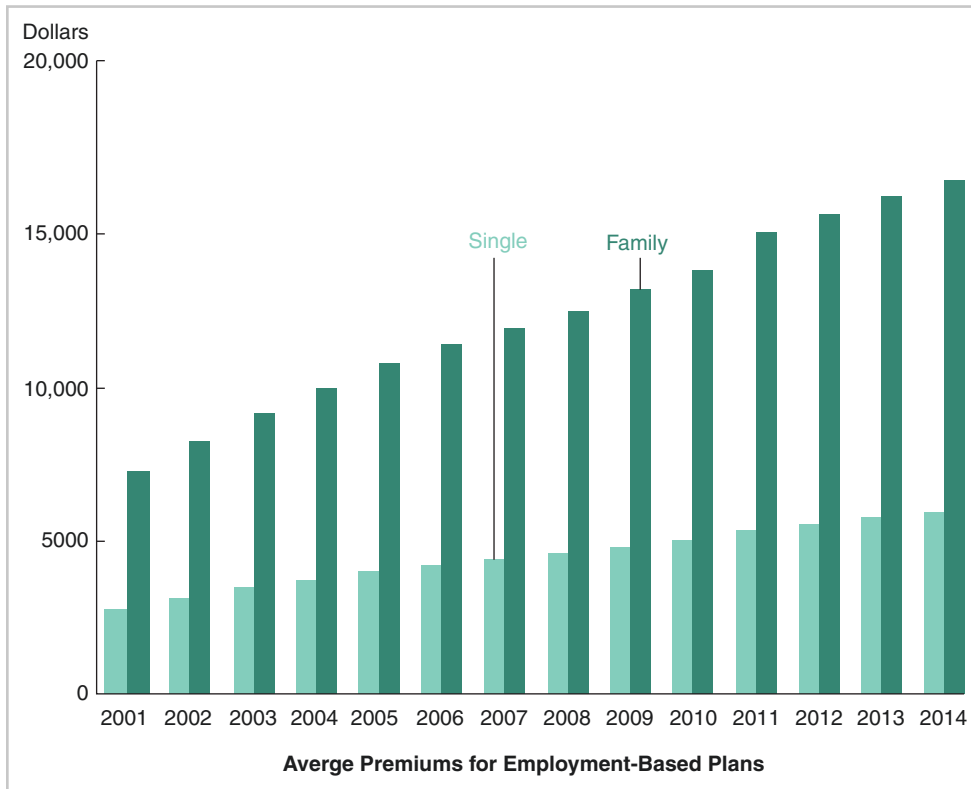


FIGURE 2-6

Average premiums for employer-based insurance plans, 2001–2014. Image public domain by Congressional Budget Office, Feb 2016

1.2.6 FORCES SHAPING HEALTHCARE DELIVERY

Reimbursement

Many forces shape healthcare delivery, the most important of which is reimbursement. See Sect. 1.2.5 for some examples about how reimbursement has changed during the past century and how it has impacted on the physician-patient relationship.

Defensive Medicine

Nearly every doctor will be sued for malpractice at some point in their careers, and some will be sued more than once. Even when unfortunate cases do not result in litigation, doctors often feel that they are under a microscope. State boards of medicine, hospital quality committees and patients themselves often question, probe and otherwise critique medical care.

In order to avoid lost time, embarrassment and financial losses, many physicians practice in such a way as to minimize the possibility of later inquiry. This may include ordering tests in situations of low clinical suspicion or prescribing drugs which are unlikely to alter disease progression and to recommend consultations with other physicians when very little clinical uncertainty exists.

For example, a patient presents to the Emergency Department with a nonproductive cough of two days duration. He has no travel or sick contacts. There is no fever, hypoxia, tachycardia or respiratory distress. Examination reveals clear breath sounds.

The physician has two choices: one option is to discharge the patient home with reassurance; the other option is to order a chest x-ray, consult with a pulmonologist and prescribe antibiotics. The physician is afraid that if the patient ultimately has a bad outcome, no matter how unlikely, he will be held liable for “not doing enough”. Moreover, it costs the physician literally nothing to provide those interventions. In fact, there are several real benefits: providing his pulmonologist-colleague with business; increasing customer satisfaction; granting some measure of liability protection; providing the patient with a degree of validation that his

disease was real. Some may argue that ordering a needless chest x-ray increases the risk of malignancy and therefore violates the ethical principle of *primum non nocere*, or first do no harm. However, practically speaking, the harm caused by the increased radiation exposure is very remote, while an unhappy patient can create a problem right now.¹²

Efforts such as *Choosing Wisely*,¹³ have attempted to remind physicians about their fiduciary responsibilities to populations, but have been only minimally effective in reducing the impact of defensive medicine.

Pharmaceutical Companies

Pharmacology remains the basis of therapeutics for the majority of disease conditions. However, the Food and Drug Administration requires significant evidence of safety and efficacy before it will allow a drug to be sold. Bringing a new drug from the research bench to the pharmacy shelves often takes hundreds of millions of dollars. To provide financial incentive to support research into new drugs, the US offers 20 years of patent protection for new drugs. Typically, a company applies for a patent on a new drug and then does about 10 years of research to demonstrate safety and efficacy on voluntary subjects. If successful, the drug goes to market, and the drug company enjoys a 10-year monopoly, charging whatever price the market may bear. When the patent expires, generic drug manufacturers are free to produce the drug at whatever cost they choose. For example, during the time that ondansetron (Zofran[®]) was under patent, the average retail cost was about \$30 per 4 mg pill. When it became generic, the price dropped to \$0.30 per pill.

Pharmaceutical companies have used aggressive sales techniques with providers for many years. Since convincing a single doctor to switch from one blood pressure medication to another may result in hundreds of thousands of dollars in annual profit, drug manufacturers are willing to spend lavishly to “educate” physicians.

Generic drug manufacturers are also responsible for some of the changing costs in retail pharmaceuticals. Often, the margin on a generic drug is so small that only one manufacturer will endeavor to make it. In those cases, even though the drug is generic, the manufacturer can quickly raise the price as high as the market will bear until a competitor is willing to undercut them.

Quality Organizations

Various quality organizations, most famously the Joint Commission, establish criteria for quality management of patients. In some cases, the recommendations are merely mirrors of common practice, such as administration of aspirin for stroke or acute myocardial infarction. In other cases, the recommendations have been well intended but not based on clinical evidence, such as the admonition to prescribe antibiotics for pneumonia within 4 h of hospital arrival. Under pay-for-performance systems, adherence to these guidelines directly influences reimbursement, which can have dramatic effects on physician behavior.

Specialization

Physicians who pursue specialization generally earn more than their primary care counterparts. As the number of specialists increases and primary care doctors become more familiar with their practice, the number of consultations increases. As time goes on, primary care providers become less familiar with problems that have been delegated to specialists, which causes a shift in standard of care. After a time, caring for patients with these kinds of problems falls outside the usual scope of practice for primary doctors.

¹² Consider, for example, a child with a traumatic neck injury. Ordering a CT scan is more likely to cause thyroid cancer than it is to discover a fracture. However, the cancer will not likely be detected for another 20 years and will be very difficult to tie to this individual encounter. Therefore, the provider chooses to order the study. See Muchow RD. Theoretical increase of thyroid cancer induction from cervical spine multidetector computed tomography in pediatric trauma patients. *J Trauma Acute Care Surg*. 2012 Feb;72(2):403–9.

¹³ See <http://www.choosingwisely.org/> for more information and recommendations.

1.2.7 INSTITUTE OF MEDICINE QUALITY COMPONENTS

In *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Institute of Medicine claims “The American health care delivery system is in need of fundamental change.”¹⁴ In addition to the safety concerns raised in *To Err is Human*,¹⁵ the authors cite systematic inefficiencies in the way medicine is practiced. Tests are often duplicated because various providers are unable to access each other’s records; patients are harmed by adverse drug events which could have been prevented by a robust drug interaction checking system; despite rapidly advancing medical knowledge, bedside care lags far behind the state of the art. The committee gave four recommendations: (1) create an infrastructure to support evidence-based practice, (2) expand the use of information technology, (3) align payment incentives, and (4) prepare the workforce to better serve patients in a world of expanding knowledge and rapid change.

They further specified that care should be dictated by patient needs and desires: care should be always available with the patient in control. Patients should be provided with unfettered access to their medical information as well as resources needed to interpret their medical conditions and make rational care choices based on best-available evidence. Safety and transparency should be built into the system, which would anticipate patient needs instead of react to them. Continuous and easy cooperation among clinicians would result in a decrease in wasted time and costs.

The six pillars of quality are Safety, Effectiveness, Efficiency, Patient-centeredness, Timeliness and Equity.

1.2.7.1 Safety

Safety implies that patients will not be harmed by the care that they receive. As a corollary, the members of the healthcare team should not be harmed when providing care to patients. Medical errors which have the potential to cause patient harm are generally classified as either failure to complete a planned action or selecting an inappropriate action for a given problem.

The committee emphasizes that safety should be pervasive for all patients at all times. Institutions should not have a lower standard for safety on nights, weekends or during times of change. Further, patient information should be wholly available to all people involved in care in an easily accessible manner. When errors do occur, the patient should be notified and institutions should strive to investigate ways to prevent future occurrences.

1.2.7.2 Effectiveness

Effectiveness is the use of evidence to guide interventions that produce better outcomes than alternatives, including the alternative of doing nothing at all. Evidence must be robust, reliable, well-collected, properly tabulated and analyzed, and must take into account patient’s personal needs and values. In order to be effective, evidence garnered from the medical literature must be combined with clinical acumen, skill and experience to produce effective interventions.

1.2.7.3 Efficiency

In an efficient system, limited resources are maximized to get the best bang for the buck. There are two ways to accomplish this goal: (1) modify inefficient and costly processes; and (2) reduce or eliminate administrative overhead.

¹⁴ Institute of Medicine. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: The National Academies Press.

¹⁵ Institute of Medicine. 2000. *To Err Is Human: Building a Safer Health System*. Washington, DC: The National Academies Press.

Most successful quality improvement projects reduce waste, either by decreasing the amount of unnecessary work, or by protecting against future injuries. Administrative overhead can often be addressed with improvements in technology. For example, replacing a paper-based filing system with an electronic one can improve accessibility of documents while simultaneously decreasing the human labor costs associated with such a system.

Another example: in most hospitals, the operating room schedule is far busier on Monday than Saturday because surgeons tend to schedule procedures earlier in the week to avoid weekend stays in the hospital. Smoothing out the operating schedule can make better use of resources and reduce waiting times.

1.2.7.4 Patient-Centeredness

The patient's experience of health and disease is a reflection on the care he receives. A system is considered patient-centered when it embodies compassion, empathy, responsiveness, and respect for individual values and preferences.

There has been some research demonstrating the extent to which patients are excluded from decision-making. In one study from 1984, it was shown that physicians interrupt patients an average of 18 s into giving a history.¹⁶ Research has also shown that patients rarely understand when they give written informed consent.¹⁷

However, there are examples where patient-centeredness is improving. Today, it is commonplace for patients to independently review medical diagnoses online and bring their concerns to their physician.

Gerteis¹⁸ listed six dimensions of patient-centeredness

1. Respect for values, needs and preferences. Historically, doctors have treated patients in a patrician way by making all decisions based on their own value system, which may not be concordant with the patient's value system. This privilege was predicated on the assumption that patients did not possess enough information or understanding to make their own medical decisions. In a patient-centered environment, the provider assumes the role of teacher and advisor, rather than decider.
2. Coordination of care. Patients who travel from one institution to another may find themselves subjected to repeated failed therapies simply because the current providers are unfamiliar with the workup which has been done before. In a patient-centered environment, a patient gives a history once and it follows the patient wherever he goes
3. Education and communication. Inherent in coordination of care is education of the patient and communication of all relevant information at all times.
4. Comfort. Providing relief of pain and suffering is one of the cornerstones of medical practice. Some providers feel that treating disease is more important than treating pain (which may obscure important symptoms). However, research has shown that patients who are comfortable are better empowered to make reasonable and rational decisions about their own care.
5. Emotional support. Alleviating emotional pain, such as fear and anxiety, can be as important to empowering patient decision making as is relief of physical pain. Providing a supportive environment with easily reachable providers and complete transparency can help a patient understand their disease and begin the coping process.
6. Involvement of friends and family. Recruitment of other caregivers into the patient's illness provides the Social and familial support that is required to overcome illness.

16 Beckman HB, Frankel RM. The effect of physician behavior on the collection of data. *Ann Intern Med* 1984;101(5):692–6.

17 Gerteis M, Edgman-Levitan S, Daley J. *Through the Patient's Eyes. Understanding and Promoting Patient-centered Care.* San Francisco, CA: Jossey-Bass, 1993.

18 Grady C. Enduring and Emerging Challenges of Informed Consent. *N Engl J Med* 2015;372:855–62.

1.2.7.5 Timeliness

Timeliness refers to respecting a patient's time and convenience as much as possible. Lack of timeliness indicates a systematic disregard for flow and a degree of disrespect that would not be tolerated in other consumer-centered environments.

Queueing theory and other flow-directed technologies exist in other industries and may be applied to healthcare. In some cases, a balance must be struck between timeliness and efficiency. Consider, for example, the example of the operating room schedule smoothing example (above, in Sect. 1.2.7.3).

Most healthcare encounters currently require face-to-face interaction in order to qualify for reimbursement from insurers. Replacing some of these visits with telephone or virtual interactions has the potential to dramatically improve timeliness. However, in order for this to happen, insurers must be willing to align the goals of cost containment with timeliness.

1.2.7.6 Equity

The aim of equity is to ensure that all people are equally able to avail themselves of health care services when needed. At the population level, equity requires that any systematic improvements in health care be provided in a way that reduces disparities among various subgroups. In essence, equity demands universal access to healthcare. Specifically, the quality and availability of care should not depend on characteristics as gender, race, age, ethnicity, income, education, disability, sexual orientation, or location of residence.