After reading this chapter, you should know the answers to these questions:

- Why are standards important in medical informatics?
- What organizations are active in standards development?
- What aspects of medical information management are supported today by standards?
- What is the process for creating consensus standards?
- What factors and organizations influence the creation of standards?

6.1 The Idea of Standards

Ever since Eli Whitney developed interchangeable parts for rifle assembly, standards have been created and used to make things or processes work more easily and economically—or, sometimes, to work at all. A standard can be defined in many physical forms, but essentially it comprises a set of rules and definitions that specify how to carry out a process or produce a product. Sometimes, a standard is useful because it provides a way to solve a problem that other people can use without having to start from scratch. Generally, though, a standard is useful because it permits two or more disassociated people to work in some cooperative way. Every time you screw in a light bulb or play a music cassette, you are taking advantage of a standard. Some standards evolve over time\(^1\); others are developed deliberately.

The first computers were built without standards, but hardware and software standards quickly became a necessity. Although computers work with values such as 1 or 0, and with "words" such as 10101100, humans need a more readable language (see Chapter 4). Thus, standard character sets, such as ASCII and

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\(^1\)The current standard for railroad-track gauge originated with Roman chariot builders, who set the axle length based on the width of two horses. This axle length became a standard as road ruts developed, requiring that the wheels of chariots—and all subsequent carriages—be the right distance apart to drive in the ruts. When carriage makers were called on to develop railway rolling stock, they continued to use the same axle standard.
EBCDIC, were developed. The first standard computer language, COBOL, was written originally to simplify program development but was soon adopted as a way to allow sharing of code and development of software components that could be integrated. As a result, COBOL was given official standard status by the American National Standards Institute (ANSI).² In like manner, hardware components depend on standards for exchanging information to make them as interchangeable as were Whitney's gun barrels.

A 1987 technical report from the International Standards Organization (ISO) states that "Any meaningful exchange of utterances depends upon the prior existence of an agreed upon set of semantic and syntactic rules" (International Standards Organization, 1987). In medical informatics, where the emphasis is on collection, manipulation, and transmission of information, standards are greatly needed but have only recently begun to be available. At present, the standards scene is evolving so rapidly that any description is inevitably outdated within a few months. In this chapter we therefore emphasize the need for standards in general, standards-development processes, current active areas of standards development, and key participating organizations that are making progress in the development of usable standards.

### 6.2 The Need for Health-Informatics Standards

Standards are generally required when excessive diversity creates inefficiencies or impedes effectiveness. The healthcare environment has traditionally consisted of a set of loosely connected, organizationally independent units. Patients receive care across primary, secondary, and tertiary care settings, with little bidirectional communication and coordination among the services. Patients are cared for by one or more primary physicians, as well as by specialists. There is little coordination and sharing of data between inpatient care and outpatient care. Both the system and patients, by choice, create this diversity in care. Within the inpatient setting, the clinical environment is divided into clinical specialties that frequently treat the patient without regard to what other specialties have done. Ancillary departments function as detached units, performing their tasks as separate service units, reporting results without follow-up about how those results are used or whether they are even seen by the ordering physician. Reimbursement requires patient information that is often derived through a totally separate process, based on the fragmented data collected in the patient’s medical record and abstracted specifically for billing purposes. The resulting set of diagnosis and procedure codes often correlates poorly with the patient’s original information (Jollis et al., 1993).

Early hospital information systems (HISs) for billing and accounting purposes were developed on large, monolithic mainframe computers (see Chapter 10); they

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²Interestingly, medical informaticians were responsible for the second ANSI standard language: MUMPS (now known as M).