Chapter 7.14
Standardization in Health and Medical Informatics

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ABSTRACT

Standard is a thing or quality or specification by which something may be tested or measured. The development of standards is organized on a global, international level, existing also on a national level, well harmonized with an international one. International developers are organizations working on this matter, like the International Organization for Standardization (ISO) or the European Committee for Standardisation (Comité Européen de Normalisation—CEN). Standards in health and medical informatics enable access to patient health records to read or to add some new data relevant to other healthcare providers taking care of a patient. Bad medical informatics can lead to patient deaths, and standardization in the field can prevent this from happening.

INTRODUCTION

When things go well, often it is because they conform to standards (International Organization for Standardization [ISO], 2005). In the Oxford Dictionary of Modern English, there is a lot of explanation of what the word standard means, but, in the context of the first sentence, the best meaning is the following: "standard is a thing or quality or specification by which something may be tested or measured." A personal computer is a standardized computer. This means that all of its components are made according to strictly defined specification. Consequently, it does not matter who produces the components or where they are produced.

Industry put in the first demand for standards. Standardization is especially important for electronics, and for ICT and its application in different

areas. Nowadays, the developing of standards is organized on a global, international level, but it exists also on the national level, which is well harmonized with the international one.

Developers of standards are organizations and groups working on this matter. The leading standard developer in the world is the International Organization for Standardization. ISO is a nongovernmental organization that was established February 23, 1947. Its mission is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological, and economic activity (International Organization for Standardizaton, 2005). ISO collaborates with its partner in international standardization, the International Electrotechnical Commission (IEC), a nongovernmental body whose scope of activities complements ISO's. The ISO and the IEC cooperate on a joint basis with the International Telecommunication Union (ITU), part of the United Nations organization whose members are governments. The ISO standard can be recognized by the ISO logo, ISO prefix, and the designation "International Standard."

The European developer of standards is the European Committee for Standardisation (Comité Européen de Normalisation, CEN). It was founded in 1961 by the national standards bodies in the European Economic Community and EFTA countries. CEN promotes voluntary technical harmonization in Europe in conjunction with worldwide bodies and its partners in Europe, and the conformity assessment of products and their certification (Comité Européen de Normalisation, 2005). CEN cooperates with the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). A product of this cooperation is the European standard, which can be recognized by the prefix EN. Any added prefix to the existing one, for both the ISO and CEN standards, means that this standard is the result of cooperation with another standardization group or organization. The prefix ENV in European standardization means that this standard is not yet a full standard (it is under development by CEN).

ISO and CEN have technical committees working in specific areas. ISO/TC215, established in 1998, and CEN/TC251, established in 1991, are corresponding technical committees working on standardization in health and medical informatics. Both standardization bodies cooperate and mutually exchange their standards.

There are also a variety of other organizations and groups developing standards, either cooperating with ISO and CEN or acting as administrators and coordinators in standardization. For example, there are Health Level 7 (HL7); Digital Imaging and Communications in Medicine (DICOM); the American National Standards Institute (ANSI), a nonprofit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system, and so forth.

BACKGROUND

Definition

A standard is a set of rules and definitions that specify how to carry out a process or produce a product, or more precisely, a standard is a document established by consensus and approved by a recognized body that provides, for common and repeated use, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

The main role of a standard is raising the levels of quality, safety, reliability, efficiency, and interchangeability, and consequently lowering costs (International Organization for Standardization, 2005).