IT–Standards and Standardization Approaches in Healthcare

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INTRODUCTION

E-health basically comprises health services and information delivered or enhanced through the Internet and related technologies (Eysenbach, 2001). The future healthcare system and its services, enabling e-health, are based on the communication between all information systems of all participants of an integrated treatment. Connecting the elements of each healthcare system (general practitioners, hospitals, health insurance companies, pharmacies, and so on)—even across national borders—is an important issue for information systems research in healthcare. Current developments, such as upcoming or already-deployed electronic healthcare chip cards (that are to be used across Europe), show the need for Europe-wide standards and norms (Schweiger, Sunyaev, Leimeister, & Krcmar, 2007). In this article, we first outline the advantages of the standards, and then describe their main characteristics. After the introduction of communication standards, we present their comparison with the aim to support the different functions in the healthcare information systems. Subsequently, we describe the documentation standards, and discuss the goals of existing standardization approaches. Implications conclude the article.

BACKGROUND

The advantages of generally accepted standards for the processes in healthcare and the medical market can be summarized as follows (CEN/TC 251 European Standardization of Health Informatics, http://www.centc251.org/; Wirsz, 2000):

- Standards increase competition and reduce costs;
- Standardized products could easily be replaced or updated;
- Standardized products of various suppliers could easily exchange medical information;
- Healthcare institutions are able to iteratively extend their offers/capabilities;
- Standardized products could reduce errors and make healthcare services safer.

Several national and international committees, German as well as European or American (CEN/TC 251 European Standardization of Health Informatics; DIN, http://www.din.de; Integrating the Healthcare Enterprise (IHE), http://www.ihe.net; Integrating the Healthcare Enterprise-Europe (IHE-E), http://www.ihe-europe.org; World Health Organization (WHO), http://www.who.int), have been founded to ensure unified standardization of national and international healthcare systems. Accordingly, there are numerous standardization attempts, which partly correspond to, but also disagree with, each other (Märkle & Lemke, 2002). Two main objectives of these committees can be distinguished: the development of standards for communication, and standards for documentation in healthcare. The former focuses on enabling an efficient and effective combination of medical information systems, in order to enable the exchange of data between
different medical information systems (refer to IHE). The latter are supposed to ensure the right interpretation of the content of electronically exchanged information (Haas, 2005).

**IT-STANDARDS IN HEALTHCARE**

The transmission of data between heterogeneous and isolated medical information systems requires interoperability of systems and data (Hasselbring, 1997). The interoperability on its side is composed of norms, interfaces, and standards—the basis for data exchange and communication between participating applications (refer to World Health Organization (WHO), http://www.who.int). For an overview of common interoperability standards in the healthcare sector, and the graphical classification of its relations, see Figure 1.

**Communication Standards**

Communication standards, also called syntactical standards, ensure a correct transmission of medical and administrative data between different information systems. In the clinical area, one can distinguish them worldwide, mainly between the established standards of Health Level 7/Clinical Document Architecture, (HL7/CDA), Digital Imaging and Communications in Medicine (DICOM), and Electronic Data Interchange for Administration, Commerce and Transport (EDI-FACT) (Pedersen & Hasselbring, 2004). The reason for their acceptance is mainly the openness of these standards.

Health Level 7 is an international, vendor-independent, and main communication standard in healthcare for the exchange of information between systems and institutions. The Version 2 family of this standard is based on events that trigger the exchange of data. Beginning from Version 3 XML\(^1\), data structure is supported, alleviating the integration of data into information systems, since adequate libraries for XML handling are available. HL7 operates at the application layer of the ISO/OSI reference model (ISO7498-1, International Organization of Standardization (ISO), 2006). The Clinical Document Architecture (Health Level Seven Inc., http://www.hl7.org/) amplifies the HL7-standard with the description of the structure and the contents of clinical documents (e.g., discharge summaries and progress notes), based on an XML-format. HL7/CDA also offers a model for the exchange or the common use of information, and the option to individually reuse this information (Dolin, Alschuler, Boyer, Beebe, Behlen, & Biron, 2006).

Digital Imaging and Communications in Medicine (National Electrical Manufacturers Association (NEMA), http://medical.nema.org) is an open standard

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**Figure 1. Medical communication and documentation standards**

[Diagram of medical communication and documentation standards]

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1. XML: Extensible Markup Language