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Health informatics — Framework for healthcare and related data reporting

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This first edition of ISO 29585 cancels and replaces ISO/TR 22221:2006 and ISO/TS 29585:2010, which have been technically revised.

The main changes are as follows:

— consideration of the impact of developments such as the availability of big-data and federation of services;

— each requirement has an identified actor responsible for its delivery and each requirement is intended to be clear and unambiguous.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 Background

A considerable amount of data is collected during the provision of care and treatment, some of it specific to the patient being treated, and some of it not. The primary purpose of this information is to support and improve individual patient care and much of it is held under professional and legal obligations of confidentiality. However, this information, often in conjunction with other records, is of value for many other purposes to support healthcare for groups of patients or for populations.

Healthcare data reporting provides many benefits. The health and well-being of the population are improved by activities such as disease surveillance, screening, needs assessment and preventative activities such as identifying the relationship between infected water and cholera resulting in better sewers. Research has led to major benefits in health practice such as the cure of duodenal ulcers, prevention of spina bifida, effective treatment of breast cancer and the carrying out of hip replacements. Research has also reduced risks through a greater understanding of HIV prevention, the relationship between smoking and lung cancer and the ill effects of the use of aspirin for children. The regulation of new medicines and other treatments relies on evidence of safety and efficacy from clinical trials.

Providing appropriate conditions are met, these data can legitimately be used to support these other purposes. In practice, such healthcare data reporting covers a wide spectrum including:

— Protecting the health of the public through surveillance and immediate response to infectious disease and other environmental threats to health, monitoring adverse effects of therapeutic interventions and informing and evaluating screening.

— Providing better information to the general public about healthy lifestyles.

— Improving the quality and safety of care or reducing the impact of new risks to population.

— Improving the management of the health system, for example by supporting the more efficient commissioning of services and value-based care.

— Improving the quality of clinical care within an institution, for example through the audit of clinical practice.

— Identifying patients who interact with multiple parts of the health system in order to monitor equity of access and provision:

  — ensuring consistent care for people who interact with multiple parts of the system,

  — monitoring equity of access and provision.

— Ensuring that health policy is evidence-based through carrying out empirical research.

0.2 Healthcare data reporting

Where the term "clinical data warehouse" implied a specific, bounded, repository of data, with specific functions, recent developments have greatly increased the ways of addressing potential applications. For instance:

— The era of "big data" offering new sources and modes of data, with a massive increase in data capture and use, including structured, unstructured, text, images, near real-time, combination of data sources, e.g. personal device data, also social determinant of health data to inform population health and a wide range of presentation and visualization tools.

— The establishment of federated services that can link data sources which previously could not be combined and, hence, supporting distributed queries. These federated approaches can support moving from hierarchical views of data to multi-layered and multi-dimensional approaches, the separation of data sources and data consumers, distributed queries and moving from data warehouses / data marts to data lakes and data labs.

— The potential for analysing data on a much wider scale, particularly for areas such as rare diseases where federated big data enables studies requiring this population size.

— The push for transparency of data has further reinforced the opportunities and responsibilities of sharing the value of such analysis with a wider public.

In view of these developments, this document provides a framework for healthcare and data reporting, addressing both the opportunities and the responsibilities of the handling of the data. Figure 1 summarizes the stages, products and actors through the lifecycle.

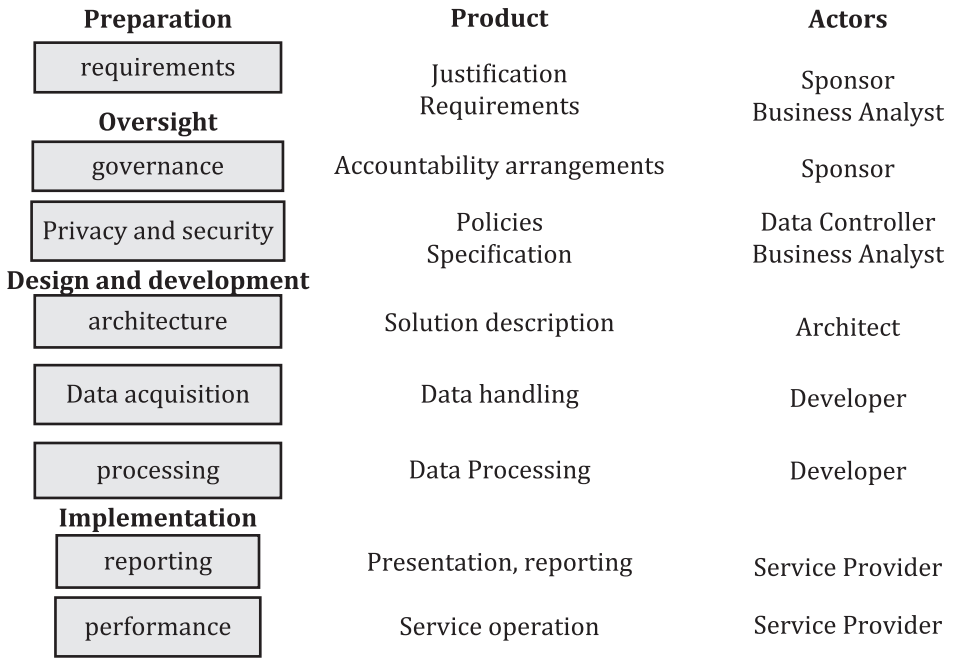

Figure 1 — Lifecycle for a healthcare data reporting service

Clauses 5 to 12 specify requirements, each of which is allocated to one actor. Requirements are individually referenced by actor (e.g. SPnnn for sponsor, DCnnn for data controller, ANnnn for business analyst, ARnnn for architect, DVnnn for developer and PRnnn for service provider).

Health informatics — Framework for healthcare and related data reporting

1 Scope

This document deals with the reporting of data to support improved public health, more effective health care and better health outcomes.

This document provides guidance and requirements for those developing or deploying a healthcare data reporting service, addressing data capture, processing, aggregation and data modelling and architecture and technology approaches.

The role of a healthcare data reporting service is to enable data analyses in support of effective policies and decision making, to improve quality of care, to improve health services organizations and to influence learning and research. This document has relevance to both developing and more established health systems. It enables meaningful comparison of programs and outcomes.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 62304, *Medical device software — Software life cycle processes*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
analyst
member of the technical community who is skilled and trained to define problems and to analyze, develop, and express algorithms

EXAMPLE Systems engineer, business analyst.

3.2
architect
person, team, or organization responsible for the process of defining a collection of hardware and software components and their interfaces to establish the framework for the development of a computer system

[SOURCE: ISO/IEC/IEEE 24765:2017, modified — Combined definitions of "architect" (3.209) and "architectural design" (3.211).]

3.3
business analyst
person who bridges the gap of understanding between business and technology to accurately define software requirements and carefully control scope