TECHNICAL REPORT

ISO/TR 23358

First edition
2022-11

Health informatics — A case study on establishing standardized measurement data in cardiac examination reports

Informatique de santé — Étude de cas sur l'établissement de données de mesure normalisées dans les rapports d'examens cardiaques

Reference number
ISO/TR 23358:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

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

Various clinical examinations, such as ultrasonic echocardiography (UCG), electrocardiogram (ECG) and coronary angiogram (CAG) are used for diagnosis and treatment of cardiovascular diseases. Cardiologists not only use imaging during those examinations but also numerical measurement data obtained from clinician observation and the various medical device systems used in daily clinical examination routines. They also consider information such as the patient's symptoms and the examination procedure(s) performed. These data are stored with images and waveforms in standard formats such as DICOM®[1)][1] and MFER[2], or are stored as non-interoperable, manufacturer-specific data formats.

In cardiac examinations, multiple devices are used simultaneously for diagnostic and therapeutic purposes, and corresponding reports are produced by each device and system. This includes “cath labs” (Cardiac Catheterization Lab) where multiple device modalities (e.g. haemodynamic monitoring and imaging) are utilized and reports generated; however, as pointed out above there is little consistency in the resulting reports, especially with respect to parametric data.

The contents of data required for these cardiac examination reports is generally different for each medical facility, as well as clinicians performing the procedures. In addition to these general interoperability challenges, medical researchers want to utilize such data for secondary purposes utilizing a clinical database or registry to support, for example, nation-wide” big data” analytics research programs. In order to support this secondary use, one must both collect the data generated from devices and reporting systems and then register that data used in the cardiovascular division in a clinical information database. However, since the contents and formats of the examination data are not standardized and consistent, special conversion is required. The cost of machine conversion is typically high, and there are increased risks of human error when an operator re-enters data manually.

The reporting of cardiac examination export measurement data (CE-EMD) to clinical databases has not been standardized for numerous reasons, including the following:

— Requested CE-EMD content varies depending on the medical facility and care providers/clinicians;

— Produced CE-EMD is different for each manufacturer;

— Name and contents (data elements) of CE-EMD are not uniform;

— Format of CE-EMD is often not represented or “coded” according to any standard.

Figure A.1 provides an overview of the use context for this document. Although guidance for the creation of radiology reports has been developed (e.g. in IHE and DICOM), this is not the case for cardiology examination reporting.

This document provides an overview of the rules on how to establish and maintain standardized CE-EMD report content based on the SEAMAT program in Japan as applied to cardiac examination reports, which has been organized to present the approach that successfully employed in both establishing and maintaining CE-EMD specifications. This approach could be as a reference for applying in other national or regional contexts.

Annex A provides a more detailed history of the SEAMAT program.

1) DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Health informatics — A case study on establishing standardized measurement data in cardiac examination reports

1 Scope

This document reposts a case study on how to establish and maintain standardized cardiac examination export measurement data (CE-EMD), especially for enabling its secondary use for medical research. The document includes information for CE-EMD on:

— Building a representative coalition of stakeholders to identify and establish specifications;

— Standardizing both the content and format in reports;

— Maintaining and extending the specifications over time.

Out-of-scope for this document are any requirements for specific CE-EMD content or formatting. Also, this document is limited to cardiac examination reporting, and does not encompass other clinical care areas or reporting that have been standardized.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviated terms

3.1 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/

3.1.1
cardiac examination – export measurement data
CE-EMD
numeric and text data that is exported from medical devices and reporting systems during cardiology examinations

3.1.2
reporting system
computer system or software application with function to create a report containing CE-EMD for diagnosis and treatment

3.1.3
secondary use
using data for purposes other than clinical

Note 1 to entry: In this document, cardiac examination data is used for medical research, etc.

3.2 Abbreviated terms

CAG	Coronary angiography
CDA	Clinical Document Architecture
DICOM®	Digital Imaging and Communications in Medicine
ECG	Electrocardiogram
HL7®	Health Level 7
IHE-J	Integrating the Healthcare Enterprise Japan
JAHIS	Japanese Association of Healthcare Information Systems Industry
JCS	The Japanese Circulation Society
LOINC®	Logical observation identifiers names and codes
MFER	Medical waveform Format Encoding Rules
PCI	Percutaneous coronary intervention
SEAMAT	Guideline for Standard export data format by the Japanese Circulation Society
SS-MIX2	Standardized Structured Medical Information Exchange revision 2. Storage specifications for electronic clinical information exchange used in Japan.
UCG	Ultrasonic echocardiography

4 Establishing and maintaining export measurement data standards

4.1 General

There are three key elements for establishing and maintaining a national CE-EMD specifications:

— Stakeholder coalition establishment

— Semantic content standardization

— Specification maintenance

Each element precedes and supports the next element: Semantic content is not standardized until a representative coalition of stakeholders is convened and able to deliberate, identify and establish the needed CE-EMD specifications. Similarly, the maintenance process follows the successful accomplishment of the first two process elements.

The following sections provide general rules for each of these three key elements. Annex A provides more detailed background information for each of these areas.

4.2 Stakeholder coalition establishment, roles and responsibilities

4.2.1 Coalition establishment method

Establishing stakeholder participation can include the following:

— Establishing a committee to identify and analyse CE-EMD specification requirements;

— Committee members comprise broad organizational stakeholder representation and include both clinicians and vendors that handle relevant data;

— Clinicians can be nominated by relevant medical academic societies to ensure that the positions that they advocate represent the consensus opinion for their organization.

With a strong representative stakeholder coalition and committee(s) in place, higher quality specifications and successful implementation are ensured.

4.2.2 Roles and responsibilities of coalition committee members

Each organizational representative can:

— Propose items to be added to CE-EMD specifications;

— Select CE-EMD items (using a consensus process);

— Determine a unified name for CE-EMD items;

— Build consensus on CE-EMD specifications in the relevant medical academic societies.

It can be emphasized that although the expectation is that individuals participating in the work are subject matter experts, their participation is as organizational member representatives and not individuals.

4.3 Semantic content standardization

4.3.1 Unification of name

To advance semantic interoperability, the ultimate objective of supporting secondary use for medical research, CE-EMD has a standardized, uniform name, as well as defined classification, units of measurement and valid ranges for numerical measurements.

See Clause A.3 for examples.

4.3.2 Standardized data element coding

CE-EMD can be encoded by using an established standardized code scheme such as LOINC®[2] or the ISO/IEEE 11073 series. In some cases, especially with medical device parameters, a concept has not been standardized, in which case, a provisional CE-EMD coding can be defined and proposed for inclusion in the appropriate standardized coding scheme. The expert confirmation can be performed in the coding procedure.

See Clause A.3 for examples.

4.3.3 Report formatting

Reports containing CE-EMD can conform to a widely recognized standard. For example, utilizing an HL7®[3] CDA compliant format.

2) LOINC is the registered trademark of Regenstrief Institute. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

3) HL7 is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Example of heart rate example.

```
<section>
    <templateId root="2.16.840.1.113883.2.2.1.5.51"/>
    <code code="29273-0" displayName="Clinical measurements"
        codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Clinical measurement</title>
    <text>
         <table>
              <tbody>
                   <tr>
                       <td>Heart rate</td>
                       <td>60bpm</td>
                    </tr>
              </tbody>
         </table>
    </text>
    <entry>
        <observation classCode="OBS" moodCode="EVN">
            <code code="8867-4" codeSystem="2.16.840.1.113883.6.1"
             codeSystemName="LOINC" displayName="Heart rate"/>
             <value xsi:type="RTO_PQ_PQ">
                  <numerator value="60"/>
                  <denominator value="1" unit="min"/>
              </value>
        </observation>
    </entry>
</section>
```


4.3.4 Additional considerations

Implementation success is also highly dependent on business issues, including licensing costs for use of standardized terminologies or the availability of implementation support resources such as database schemas or XML specifications for conformity assessment. These considerations can also be factored into the standardization of CE-EMD reporting, especially for medical research secondary use.

4.4 Specification maintenance

Once the coalition has completed its first publication of standardized CE-EMD specifications, it can then continue to periodically convene to ensure timely maintenance processes are followed, including:

— Updating any CE-EMD definition (e.g. adding, correcting, extending, deprecating, etc.) as agreed by the member organizations;

— Revision history updated to reflect any modifications;

— Public disclosure of CE-EMD specifications together with the revision history.

Recognized specification maintenance approaches can be considered, including a general means for submitting CE-EMD change requests, both from coalition members as well as general public observers. Also, a small maintenance team could be established to review any change requests or review implementation successes and challenges in a timelier manner.

5 Governance policy establishment

Although, the standardization of CE-EMD semantic content for secondary uses such as medical research is the primary focus of this document, additional aspects need to be addressed in order to successfully achieve the desired interoperability. The combination of specific assessment criteria and approaches as well as the non-semantic content aspects can be established in a coalition governance policy early in the process.