TECHNICAL SPECIFICATION

ISO/TS 22220

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Health informatics — Identification of subjects of health care

Informatique de santé — Identification des sujets de soins sanitaires

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 22220 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/TS 22220:2009), which has been technically revised.

Introduction

0.1 General

The health care system relies heavily on the ability to uniquely and accurately identify a person when they attend for care. The introduction of computerization into this process requires the clear specification of all elements of information used to support the procedural, as well as the computerized, identification of a subject of care so that the present person is associated with previous health information. Computerization is also important in supporting communication between health care professionals.

Developments in the health care system and the emergence of health networks have amplified the importance of collecting, sharing and exchanging data concerning individual subjects of care between different health care providers and between different information systems.

More effective communication between health care professionals is key to securing closer co-operation, improving the handling of subjects of care in terms of quality and continuity of care and prevention, and promoting health system efficiency.

Reliable identification of the individual has always been a critical part of the health care process. The ability of computerized systems to support and enhance the manual process of identification is vital, as is the ability of these systems to identify individuals when communicating patient information electronically. High quality identification is necessary to ensure that health care professionals have access to patient information, facilitating closer co-ordination and continuity of care and improving service in terms of prevention and follow-up. Modern service delivery networks result in greater flows of subjects of care and services across national, functional, jurisdictional, and professional boundaries. However, high quality identification can be very complex in a more integrated health care environment.

Within health care service delivery environments, the process of positively identifying subjects of care entails matching data supplied manually, electronically or through hard documentation by those subjects of care against data the service provider holds about them. This process occurs both manually, increasingly with computer support, and electronically where systems have to communicate information about individuals securely and accurately. Impediments to high quality identification include variable data quality, inadequately considered manual identification processes, differing data capture requirements and mechanisms, and varying data matching methods.

This Technical Specification identifies the data elements and relevant structure and content of the data used to manually identify individuals in a health care setting. In addition, it provides support to the identification of individuals in a consistent manner between systems that will support the natural changes in usage and application of the various names used by people over time.

This Technical Specification addresses the business requirements of identification as well as the data needed to improve the confidence of health service providers and subjects of care identification. It defines the data used to identify subjects of care and the business processes associated with this activity, whether computerized or manual. It is intended to be used both to support the processes of the identification of subjects of care by individuals and computerized identification in automated matching systems.

0.2 Usage

Within a health care service delivery context, the process of positively identifying individuals entails matching data supplied by those individuals against data the service provider holds about them.

The ability to positively identify individuals and to locate their relevant details is critical to the provision of speedy, safe, high quality, comprehensive and efficient health care. The benefits of positive identification include:

— less time wasted and inconvenience generated in hunting for and/or re-gathering information about the individual, which translates to more efficient health care;

— more complete and accurate information on which to base potentially life-critical clinical decisions;

— fewer duplicate entries for an individual leading to less duplication of testing and prescribing;

— safer treatment from having clinical details for the right individual;

— more complete and accurate information on which to base potential data use and disclosure decisions.

The delivery of health care is undergoing a paradigm change, brought about by changing consumer expectations, technological advances, economic pressures, socio-demographic change and changes in the patterns of health and ill health in communities.

These changes include:

a) a shift from institution-centred care to subject-centred care, together with greater empowerment of the subjects of care;

b) greater emphasis on continuity of services supporting quality and safety, health promotion and maintenance;

c) more integrated health care, in which organizational and administrative barriers are invisible to subjects of care.

These new service directions will necessitate a much greater flow of information on subjects of care and services across functional, jurisdictional, administrative and professional boundaries. In a more integrated health care environment, positive identification is no less critical, but is much more complex. Population mobility and multiple points of access to the health care system lead to the accumulation of subject related data in a variety of fragmented, unrelated repositories. Positive subject of care identification is recognized around the world as a critical success factor for health care reform.

Below are some examples of the many barriers to successfully identifying individuals in health care settings.

1) Variable data quality and changes in key identifying information over time.

2) The patient's capacity to provide information. In a health care environment, it is important that the identification system can cope with the fact that people's memories and capacity to communicate vary according to their mental and physical capacity and to their willingness to seek and receive care. Information is often provided by third parties (family and friends) who might know the person by a preferred name rather than by the person's formal name.

3) Differing data capture requirements and mechanisms and varying data matching methods. This Technical Specification provides a framework for improving the confidence of health service providers and subjects of care alike so that the data being associated with any given individual, and upon which clinical decisions are made, are appropriately associated and suited to the flexibility of the health care setting.

4) The need to respect the wishes of the subject of care. The system should be able to accommodate the wishes of an individual who prefers that others not know their full name, or who prefers to be known by a preferred name or nickname. The system should be able to communicate the formal name when required to other systems but also to ensure that the preferred name is used so as not to cause unnecessary stress to the subject of care, or confuse family and friends.

Where permitted by law, data matching can be undertaken in a variety of contexts and settings, including for administrative purposes. However, the specific focus of this Technical Specification is the positive identification of subjects of care for health care service delivery purposes. It is recognized that implementations in different systems and national settings might vary according to local needs.

It is recognized that this Technical Specification can support national client registry projects in health care, but does not represent a registry content or structural specification.

0.3 Responsibilities

The positive and unique identification of subjects of care within and between health care organizations is a critical event in health service delivery, with direct implications for the safety and quality of health care.

It is important that responsibilities for the quality, capture, storage and use of identifying data for subjects of care, including implementation of this Technical Specification are clearly and unambiguously assigned within the organization, and documented in relevant policies, procedures and work instructions.

Users of this Technical Specification should refer to relevant privacy legislation, codes of fair information practice and other guidelines so as not to breach personal privacy in their collection, use, storage and disclosure of subject of care information.

0.4 Training

Relevant staff should receive training that highlights the nature, importance and health benefits of high quality procedures for the capture, storage and use of health identifying data and the safety implications of errors and duplications of subject of care information.

0.5 Business processes

Business processes associated with the capture, storage and use of subject identifying data should be designed and continuously improved to ensure that accurate, consistent and complete data collection, communication and storage practices are used.

Health informatics — Identification of subjects of health care

1 Scope

1.1 General

This Technical Specification indicates the data elements and structure suited to accurate and procedurally appropriate and sensitive identification of individuals in health care in a face-to-face setting supported by computer technology, or through interactions between computer systems. It provides guidelines for improving the positive identification of subjects of care within and between health care organizations.

It defines demographic and other identifying data elements suited to capturing subject of care identification in health care settings, and the wide variety of manual and computer enhanced procedures used for this process.

It provides guidance on the application of these procedures in the manual and the computer environment and makes recommendations about the nature and form of health care identifiers, the management organization to oversee subject of care identification and computer support to be provided for the identification process.

There are additional factors to be considered in providing access to distributed subject of care data, including privacy, security and data transfer mechanisms; these are outside the scope of this Technical Specification.

Application of this Technical Specification will increase the capacity for data access. Authorization of such access is determined by the application of legislation, organizational policies and guidelines, and professional ethics.

It is recognized that specific applications might require additional data to fulfil their purpose. This Technical Specification provides a generic set of identifying information, which is application independent. Implementations in different health care environments and national settings might require the establishment of data sub-sets or priorities.

1.2 Objective

The objective of this Technical Specification is to promote uniform good practice in:

a) identifying individuals in a face-to-face, or paper-based environment, as well as in and between automated systems;

b) recording and reporting of subject of care identifying data;

c) ensuring that data being associated with any given subject of care, and upon which clinical communication and data aggregation are based, are appropriately associated with that individual or organization and no other.

1.3 Application

This Technical Specification is primarily concerned with the use of subject of care identification data to support patient care. It is envisaged that this Technical Specification will be used by health and health-related establishments that create, use or maintain records on subjects of care. It can be used, where appropriate, for collecting data when registering subjects of care or potential subjects of care and when reporting patient information to other systems, clinical and administrative.

Informative guides for business processes associated with capture, storage and use of subject identifying data are included in Annexes A to F.

2 Normative references

The following referenced documents are indispensable for the application 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.

ISO/IEC 2022, *Information technology — Character code structure and extension techniques*

ISO 3166-1:2006, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

AS 4846, *Health care provider identification*

AS 4590-2006, *Interchange of client information*

ASTM E1714-00, *Guide for Properties of a Universal Health Care Identifier (UHID)*

HL7 V2.4, Health Level Seven Standard Version 2.4, *An application Protocol for Electronic Data Exchange in Healthcare Environments*, Health Level Seven Inc., Ann Arbor, Michigan, 2000

HL7 V3, Health Level Seven Standard Version 3, *Core Principles and Properties of Version 3 Models*, Health Level Seven Inc., Ann Arbor, Michigan, 2005

3 Terms and definitions

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

NOTE Individual data elements are defined in subsequent sections.

3.1
capture
deliberate action, which results in the registration of a record into a record keeping system

3.2
subject of care
SOC
subject of health care
any person who uses, or is a potential user of, a health care service

NOTE Subjects of care may also be referred to as patients, health care consumers or subjects of care.

3.3
subject of care identifier
SCI
unique number or code issued for the purpose of identifying a subject of (health) care

3.4
information system
organized collection of hardware, software, supplies, policies, procedures and people that stores, processes and provides access to information

3.5
record
recorded information, in any form, including data in computer systems, which is created or received and maintained by an organization or person in the transaction of business or the conduct of affairs and kept as evidence of such activity

3.6
registration
act of giving a record a unique identity in a record keeping system

3.7
storage
function of storing records for future retrieval and use

4 Components of data elements

4.1 General

This Technical Specification includes recommendations concerning the data elements most likely to affect the quality of identification of subjects of care. Data elements are expressed in terms of the following interrelated components. Individual organizations should identify the elements of most relevance for identification in their cultural and health setting environment.

Data concepts described in this Technical Specification are listed in Figure 1, which does not show the interrelationships between the sections, nor all the data elements that comprise these concepts, nor data structures.

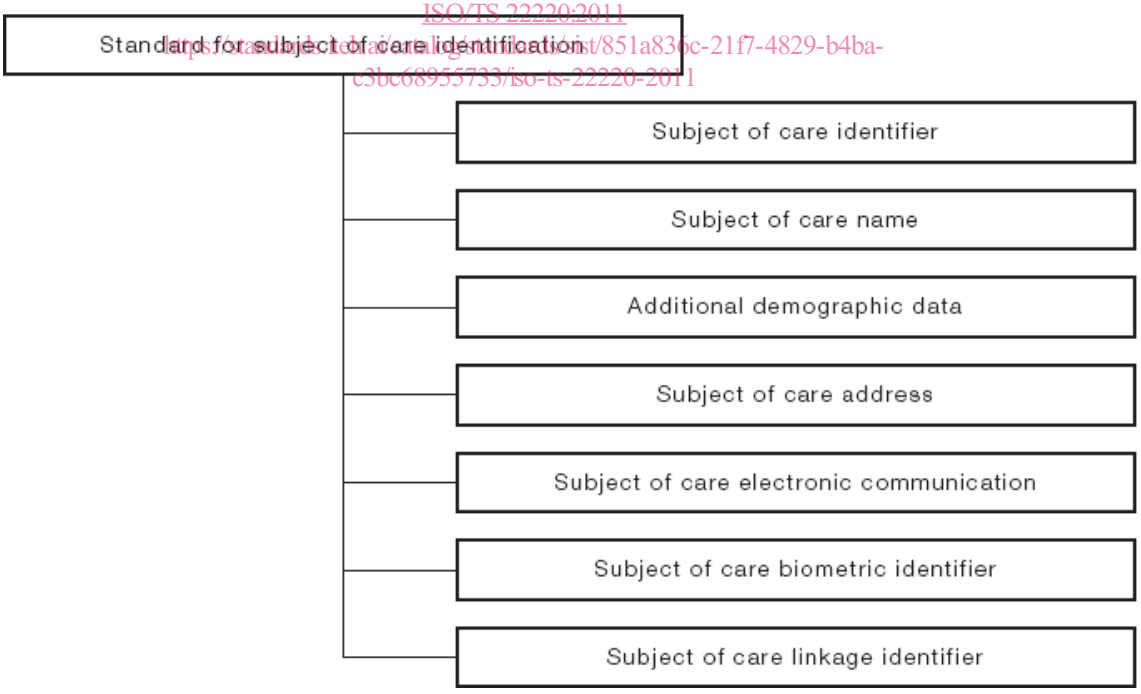

Figure 1 — Data elements and interrelated components

4.2 Data element structure

4.2.1 General

Each data element has been defined according to a set of metadata components based on ISO 11179-3. Most components (definition, data type, representational class, data domain, etc.) describe essential features of the structure of a data element. Some components, such as collection method and comments, describe additional, non-essential features and may be left blank where appropriate.

4.2.2 Synonyms

Synonyms are alternative names for this data element.

4.2.3 Definition

This is a statement that expresses the essential nature of the data element and its differentiation from all other data elements.

4.2.4 Source standards

These are details of established data definitions, or guidelines for data elements, that have been cited in this Technical Specification and are listed in the Bibliography.

4.2.5 Data type

It is recognized that different representations of the values shown in this Technical Specification might be required. Where possible, the data types are described in a manner consistent with HL7 data types. The list below provides examples of data types used in this document.

— Boolean-literal (true/false).

— Number, e.g. ISO/IEC 11404 (only used in this Technical Specification where arithmetic operations are performed).

— Character string.

— Text or unconstrained text.

— Coded text (from an agreed vocabulary or value domain).

— Constrained text (where the text is associated with a formal terminology). The difference between the coded and constrained text is the relationship to a formal, structured terminology, as opposed to a code set, or list of values.

— Unique identifier.

— Dates/times.

Though there are other data types, they are not required within this Technical Specification and thus have not been included.

4.2.6 Data domain

This refers to the values or codes acceptable for representation of the data element. The data elements contained in this Technical Specification are either free text or coded. For each data element that is coded, a code value, a descriptor of the code value and, in some cases, an alternative code (generally an alphabetic code) are provided. The code should be used for communication of this data value, the descriptor is the title of the code value and the alternative code is provided for collection of the data where the use of alphabetic code values is preferred at the point of data collection or for screen viewing. For example, the data domain for the data element “sex” is shown in Table 1 below:

Table 1 — Example of data domain representation

Code	Descriptor	Alternative code
1	Male	M
2	Female	F
3	Indeterminate	I
9	Not stated/inadequately described	N

4.2.7 Guide for use

This is additional guidance to inform the use of the data element.

4.2.8 Verification rules

These are quality control mechanisms that restrict the collection, storage or transferral of non-valid data.

4.2.9 Collection method

This contains comments and advice concerning the actual capture of data for the particular data elements in order to achieve uniformly high quality data.

4.2.10 Comments (optional)

This is any further information relevant to data element collection or storage.

4.3 Summary structure

Table 2 provides a summary guide to the structure of the data elements defined in this Technical Specification. This table indicates that for a given individual there may be multiple identifiers, names, addresses, electronic communications and biometric identifiers, but one set of core demographic data. Each of these data elements is established from a sub-set of data elements.

Table 2 — Summary of data element structure

Section of document	Data elements	Opt.[a]	Data type	Repeat data element[b]
5	Subject of care identifier	R	Text	Y
6	Subject of care name	R	Text	Y
7	Additional demographic data	O	Text	N
8	Subject of care address	O	Text	Y
9	Subject of care electronic communications	O	Text	Y
10	Subject of care biometric identifier	O	Text	Y
11	Subject of care linkage	O	Text	Y

[a] Whether the data element is optional (O) or required (R).

[b] Whether yes (Y) or no (N).

5 Subject of care identifiers

5.1 General

This clause includes data elements that jointly comprise a unique identifier for subjects of care. It also outlines subject identifiers.

The combination of the subject identifier and the health care organization, the type of identifier and the name given to the identifier in the organization is one way to indicate unique identification of the subject of care.

The subject of care identifier may also be known as:

— patient ID (HL7);

— person identifier;

— unit record number (URN);

— medical record number (MRN);

— local subject identifier;

— subject identification number;

— enterprise identifier;

— area identifier;

— province/state/territory identifier;

— unique identifier (UID);

— unique health identifier (UHID).

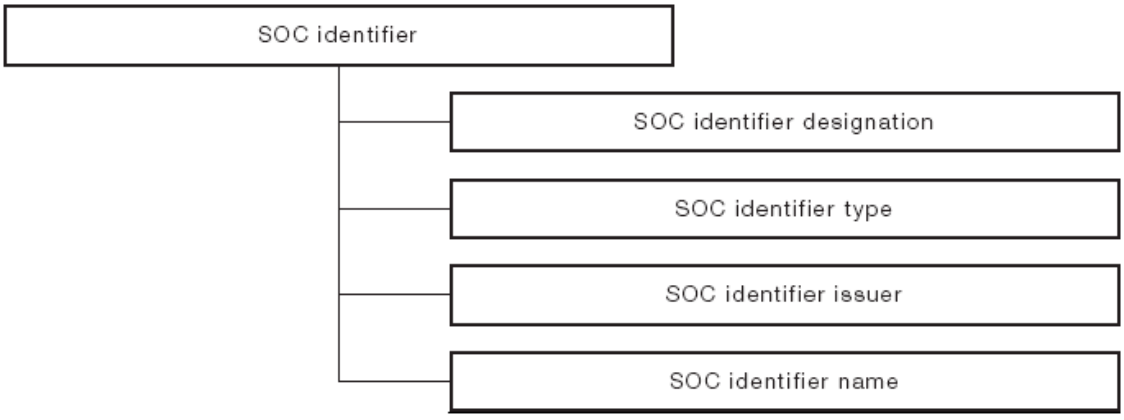

Figure 2 — Data elements for subject of care identifier

Table 3 indicates the data elements used to describe a subject of care identifier. There may be multiple identifiers collected for any one individual. Most subjects of care will have more than one identifier. Each health care organization or health care activity may designate a specific identifier as the one for use in their environment. This identification process would require the specification of the identifier type, identifier issuer and identifier name to be used within that organization/purpose.

Table 3 — Subject of care identifier data elements

Clause/ subclause	Data element name	Opt.[a]	Data type	Repeat data element[b]	Example
5	Subject of care identifier	R	Unique identifier	Y	
5.2	Subject of care identifier designation	R	Unique identifier	Y	12345678
5.3	Subject of care identifier geographic area	R	Coded text	Y	N (National)
5.4	Subject of care identifier issuer	R	Unique identifier	Y	
5.5	Subject of care identifier type	R	Coded text	Y	

[a] Whether the data element is optional (O) or required (R).

[b] Whether yes (Y) or no (N).

Table 4 provides examples of the identifiers used at a number of organizations for Joe Smith.

Table 4 — Example of subject of care identifiers

SOC identifier designation	SOC identifier geographic area	SOC identifier issuer	SOC identifier type
99876543	1 (local)	AB1345 (The Hill Regional Hospital)	01 (unique identifier for issuer)
NCB 913452	1 (local)	AB1345 (The Hill Regional Hospital)	02 (specialty number — pathology)
XYZ123	2 (area)	ABC4 (Northern Area Health Service)	01 (unique identifier for issuer)
998AAB990	4 (national)	SSA (Social Security Agency)	01 (unique identifier for issuer)
99812341	3 (state/province)	ABC (ABC State Department of Health)	01 (unique identifier for issuer)
3344 2256 2235 3	4 (national)	DOHAU (National Department of Health Australia)	01 (unique identifier for issuer)

The combination of any of the items along one line of Table 4 represents a subject of care identifier. For example, at The Hill Regional Hospital, the medical record number may be identified as the number to be used within that organization as the main identifier.

Some identifiers assigned by government agencies or other regulatory bodies to subjects of care may be for special purposes (billing or claiming benefits). Therefore such identifiers should not generally be used for purposes other than these special purposes. The individual requirements of legislation in individual countries should be applied.