

HISO 10040.4:2015 Clinical Document Metadata Interim Standard

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Document information

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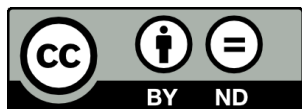
HL7 New Zealand

South Island Information Systems Alliance

Central Region Information Systems Programme

Bay of Plenty District Health Board

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1 Introduction

This is a standard for the metadata used to classify and describe clinical documents stored in clinical data repositories and accessed via clinical workstation and patient portal systems.

1.1 Purpose of the standard

The purpose of this standard is to ensure that clinical documents are identified, classified and indexed in a common way, enabling secure document sharing. This is therefore a standard for the architecture of clinical data repository, clinical workstation, shared care and patient portal systems. It is also a standard for a record locator service used by these systems.

1.2 Scope of the standard

This standard defines the set of metadata elements used to describe any clinical document about an individual patient. This includes documents of many kinds including clinical assessments, test results, referral requests, transfer of care documents, operation notes and shared care plans. The same metadata requirements apply to all clinical document types, regardless of health specialty or content. This standard specifies the required metadata elements and value domains.

HISO 10040 Health Information Exchange Architecture describes how clinical documents are shared between health care providers via federated regional and national clinical data repositories. Under this model, all clinical documents are registered with a record locator service that clinical workstation and patient portal systems use as an index to the collective content of repositories around the country. These systems must implement the metadata standard.

Metadata also drives how clinical documents are secured. Clinical workstation systems are required to implement access controls that are based on the metadata associated with each document.

The key use case scenarios are:

a) Storing a clinical document in a repository	A document is saved to a repository and indexed by the record locator service, which captures the necessary metadata
b) Displaying the list of available clinical documents for the current patient	A clinical workstation or patient portal system queries the record locator service to obtain a list of clinical documents for the patient in context, and allows the user to filter and select from the list, based on the metadata Metadata also drives security controls that clinical workstations patient portals must implement to protect the confidentiality of individual documents
c) Retrieving a clinical document from a repository	A clinical workstation or patient portal system uses metadata from the record locator to direct a query to the correct repository and retrieve the selected document

While this standard is about using documents to represent and exchange health information, solutions that are data intensive or need a fluid data flow might warrant a different approach. This standard does not prevent alternatives.

1.3 Compliance with the standard

Parts of this standard require health provider identities to be recorded. The Health Provider Index (HPI) presently includes health practitioners where a registration authority exists. Until the HPI is extended to all classes of health worker, certain data elements will need to be treated as optional.

1.4 Source standards

The key industry source standards referenced by this specification are:

- IHE Cross Enterprise Document Sharing (XDS) – specifically XDS.b as described by the IHE IT Infrastructure Technical Framework Volume 3 Cross-Transaction Specifications and Content Specifications (www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol3.pdf)
- HL7 Clinical Document Architecture Release 2 (www.hl7.org)
- HL7/LOINC Clinical Document Ontology Implementation Guide (www.loinc.org)
- HL7 Fast Healthcare Interoperability Resources (FHIR).

The set of metadata elements specified here derives from and is compatible with the XDS ‘DocumentEntry’ data set. Mappings to CDA elements and HL7 FHIR ‘DocumentReference’ and CDA document elements are also included.

FHIR is published by HL7 as a draft standard for trial use.

LOINC codes are used to indicate the different clinical document types.

1.5 Structure of data element specifications

Each metadata element is defined as follows, using the framework provided by ISO/IEC 11179 Information Technology – specification and standardisation of data elements, 2004.

Data element	Unique name for the data element (comprising object class, property and representation terms)
Definition	Statement expressing the essential nature of the data element
Source standards	Standards upon which the data element is based
Value domain	The set of valid values for the data element The value domain can be indicated by name, enumerated or described in some other way Data type is implicit in the value domain
Guide for use	How to collect, record and use the data element Includes mappings to the corresponding XDS, CDA and FHIR elements

1.6 LOINC terms of use

This document contains material from the LOINC table and LOINC clinical document ontology, which are copyright (c) 1995-2014 Regenstrief Institute Inc. These resources are available at no cost but are subject to the LOINC terms of use loinc.org/terms-of-use.

LOINC stands for logical observation identifiers, names and codes.

1.7 Retention of personal health information

Metadata entries are subject to the usual retention rules for personal health information:

- Retention of Health Information Regulations 1996
- Public Records Act 2005

1.8 Privacy and security

Clinical document metadata is classed as medical-in-confidence and subject to the usual privacy and security rules for protecting personal health information:

- Privacy Act 1993
- Health Information Privacy Code
- HISO 10029 Health Information Security Framework

This standard is also informed by (1) the National Health IT Board Consumer Panel's 'Protecting personal health information – consumer expectations' document and (2) the Health Information Governance Expert Advisory Group's 'Withholding personal health information' paper.

2 Metadata elements

This section defines the required set of clinical document metadata elements. Together, these data elements identify and describe an instance of a clinical document stored in a clinical data repository.

Each set of metadata element values represents and points to the location of one particular instance of a document in a repository. Where copies of the same document are present in different repositories, each copy will have its own distinct metadata entry (although multiple copies would be unusual under the registry-repository model).

Repository documents may be stored in the same format as they are exchanged. Equally, repository systems may generate documents on demand from content stored in another format. The same metadata rules apply in either case.

A uniform resource indicator (URI) provides the location of each document instance. This URI is the primary key element that is unique to each metadata entry. A secondary, composite key comprises the two elements repository identifier and document identifier.

The defined metadata elements are:

Patient identifier	Health specialty code	Service start datetime
Service finish datetime	Facility identifier	Facility type code
Author identifier	Author clinical role code	Approver identifier
Creation datetime	Repository identifier	Document identifier
Document URI	Document type code	Availability status code
Confidentiality code	Language code	Media type code
Document format code	Document size	Custodian identifier

All data elements are mandatory except as noted below.

2.1 Patient identifier

The patient who is the subject of care is identified.

Data element	Patient identifier
Definition	Identifier for the patient whose care is the subject of the document
Source standards	HISO 10046 Consumer Health Identity Standard
Value domain	NHI number

	<p>Example:</p> <ul style="list-style-type: none"> • 'CHN6824'
Obligation	Mandatory
Guide for use	<p>Identity and contact details for the patient are as recorded in the NHI system</p> <p>Maps to:</p> <ul style="list-style-type: none"> • XDS element 'patientId' • CDA element 'ClinicalDocument/recordTarget/patientRole/id/@extension' (where the corresponding '@root' attribute indicates the above value domain) • FHIR element 'subject.identifier'

2.2 Health specialty

The health specialty or clinical setting associated with the documented service is recorded. Approximately 150 health specialties are recognised.

Data element	Health specialty code
Definition	Code for the health specialty associated with the documented service
Source standards	XDS.b
Value domain	<p>Health specialty code (www.health.govt.nz/nz-health-statistics/data-references/code-tables/common-code-tables/health-specialty-code-table)</p> <p>This code set will be extended to include ambulance as a health specialty</p> <p>It is accepted that the code set should be organised hierarchically</p> <p>Examples:</p> <ul style="list-style-type: none"> • 'G01' – General practice • 'M05' – Emergency medicine • 'S40' – Ophthalmology
Obligation	Mandatory
Guide for use	<p>Maps to:</p> <ul style="list-style-type: none"> • XDS element 'practiceSettingCode' <p>There is no equivalent FHIR element</p>

2.3 Service date and time

The interval of time when the documented clinical service or event occurred is recorded. This is always a completed interval of time, represented by a pair of data elements.

The first data element records the start of the interval.

Data element	Service start datetime
Definition	Date and time the documented service started
Source standards	XDS.b
Value domain	UTC datetime
Obligation	Mandatory
Guide for use	<p>The time component may be omitted if date alone is sufficient to describe when the service was delivered</p> <p>Maps to:</p> <ul style="list-style-type: none">• XDS element 'serviceStartTime'• CDA element 'ClinicalDocument/serviceEvent/effectiveTime/low/@value'• FHIR element 'context.period.start'

The second data element records the finish of the interval.

Data element	Service finish datetime
Definition	Date and time the documented service finished
Source standards	XDS.b
Value domain	UTC datetime
Obligation	Mandatory
Guide for use	<p>The time component may be omitted if date alone is sufficient to describe when the service was delivered</p> <p>Maps to:</p> <ul style="list-style-type: none">• XDS element 'serviceStopTime'• CDA element 'ClinicalDocument/serviceEvent/effectiveTime/high/@value'• FHIR element 'context.period.end'

2.4 Facility identifier

The health facility or sub-facility where the documented service or event took place is identified. Facilities include ambulances and mobile services, as well as medical centres, hospitals and other fixed locations. The Health Provider Index (HPI) is the correct identity source.

Data element	Facility identifier
Definition	Identifier for the health facility where the documented service occurred
Source standards	HISO 10005/6 Health Practitioner Index Standard
Value domain	HPI facility number Examples: <ul style="list-style-type: none">• 'Fo6033-K' – Wellington Hospital• 'FKJ425-6' – Wellington Hospital Clinical Measurement Unit• 'Fo5678-D' – Tirau General Practice
Obligation	Mandatory
Guide for use	The facility that delivered the service is recorded, whether or not the service was delivered on facility premises. Maps to: <ul style="list-style-type: none">• XDS element 'authorInstitution'• CDA element 'ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/id/@extension'

2.5 Facility type

The type of facility where the documented service or event occurred is recorded. There are approximately 60 recognised facility types.

Data element	Facility type code
Definition	Code for the facility type where the documented service occurred
Source standards	XDS.b HISO 10005/6 Health Practitioner Index Standard
Value domain	HPI facility type code Examples: <ul style="list-style-type: none">• '001' – Public hospital• '103' – Community laboratory
Obligation	Mandatory

Guide for use	Maps to: <ul style="list-style-type: none"> • XDS element ‘healthcareFacilityTypeCode’ • FHIR element ‘context.facilityType’
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2.6 Document author

Every clinical document has an identified author or lead author. The author will always be an individual and usually a health practitioner. The author might also be the patient or a support person.

Data element	Document author identifier
Definition	Identifier for the document author
Source standards	XDS.b HISO 10005/6 Health Practitioner Index Standard
Value domain	HPI person number for health workers NHI number for patients Example: <ul style="list-style-type: none"> • ‘53HBNS’ – health worker • ‘JSD1476’ – patient
Obligation	Mandatory
Guide for use	Exactly one author is recorded – a health worker known to the HPI system or a patient known to the NHI system Maps to: <ul style="list-style-type: none"> • XDS element ‘authorPerson’ • CDA element ‘ClinicalDocument/author/assignedAuthor/id/@extension’ (where the corresponding ‘@root’ attribute indicates the applicable value domain) • FHIR element ‘author.identifier’

2.7 Document author clinical role

The broad clinical role the author has with respect to the patient is recorded. Clinical roles include being the nurse, physician, pharmacist or physiotherapist, for example. And patients themselves or their support people might be authors for some document types.

Data element	Author clinical role code
Definition	Code for the clinical role of the document author
Source standards	XDS.b

	HISO 10005/6 Health Practitioner Index Standard
Value domain	HPI clinical role code Examples: <ul style="list-style-type: none"> • ‘NUR’ – nurse • ‘PHY’ – physician • ‘CPH’ – clinical pharmacist • ‘PAT’ – patient/proxy
Obligation	Mandatory
Guide for use	Recorded when available Maps to: <ul style="list-style-type: none"> • XDS element ‘authorRole’ • CDA element ‘ClinicalDocument/author/participationFunction’ • FHIR element ‘Practitioner.role’

2.8 Document approver

Some clinical document types require approval and are recorded with details of the approver. It is assumed that in each such case one person will have designated responsibility for approval.

Data element	Approver identifier
Definition	Identifier for the health worker who approved the clinical document
Source standards	XDS.b HISO 10005/6 Health Practitioner Index Standard
Value domain	HPI person number Example: <ul style="list-style-type: none"> • ‘52GHJB’ – indicating the health practitioner
Obligation	Optional
Guide for use	Recorded for applicable document types and when an HPI person number is available The approver must be an individual health worker and known to the HPI system The approver may be a different person to the document author Maps to: <ul style="list-style-type: none"> • XDS element ‘legalAuthenticator’ • CDA element ‘ClinicalDocument/legalAuthenticator/assignedEntity/id/@extension’ (where

	<p>the corresponding '@root' attribute indicates the above value domain)</p> <ul style="list-style-type: none"> • FHIR element 'authenticator'
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2.9 Creation date and time

The date and time that the document was created at source by the author is recorded.

Data element	Creation datetime
Definition	Date and time that the document was created at source
Source standards	XDS.b
Value domain	UTC datetime
Obligation	Mandatory
Guide for use	<p>Maps to:</p> <ul style="list-style-type: none"> • XDS element 'creationTime' • CDA element 'ClinicalDocument/effectiveTime' • FHIR element 'createdDate'

2.10 Repository identifier

The metadata entry identifies the clinical data repository where the document is stored. Every repository at regional or national level is assigned a universally unique ASN.1 Object Identifier (OID).

Data element	Repository identifier
Definition	Identifier for the repository where the document is stored
Source standards	XDS.b
Value domain	<p>OID</p> <p>HL7 New Zealand OID registry (www.hl7.org.nz/new-zealand-oid-registry)</p> <p>Example:</p> <ul style="list-style-type: none"> • 2.16.840.1.113883.2.18.66.0.100 – OID for the Central Region clinical data repository
Obligation	Mandatory
Guide for use	<p>Maps to:</p> <ul style="list-style-type: none"> • XDS element 'repositoryUniqueId'

2.11 Document identifier

Every document has a universally unique identifier that is assigned at source and is the same for all copies of the document stored in different repositories (usually there would be only one such copy). The document identifier is represented as an OID in the metadata entry. Universally Unique Identifiers (UUIDs) and identifiers from other schemes can be transformed to OIDs.

There is no practical limit on the number of document identifiers possible under this scheme.

Data element	Document identifier
Definition	Identifier assigned to the document at source and the same for all repository copies of the document
Source standards	XDS.b
Value domain	OID Example: <ul style="list-style-type: none">• 2.16.840.1.113883.2.18.66.1.1.945628572 – OID for some particular document
Obligation	Mandatory
Guide for use	Any document identifier that is not an OID at source must be transformed to an OID when the document is copied to a repository UUIDs, for example, can be mapped to OIDs by representing the 128-bit value as a string of decimal characters prefixed with the root OID assigned to the provider organisation – see the HL7 New Zealand OID registry (www.hl7.org.nz/new-zealand-oid-registry) Maps to: <ul style="list-style-type: none">• XDS element 'uniqueID'• CDA element 'ClinicalDocument/id/@extension' (the corresponding '@root' element indicates that this is an OID)• FHIR element 'masterIdentifier'

2.12 Document URI

Every document instance has a URI at which it can be addressed within the repository.

Data element	Document URI
Definition	URI at which the stored document can be accessed in the repository
Source standards	XDS.b
Value domain	URI Example:

	<ul style="list-style-type: none"> • http://interrai.health.nz/assessment/129458323
Obligation	Mandatory
Guide for use	Maps to: <ul style="list-style-type: none"> • XDS element 'URI' • CDA element 'ClinicalDocument/id/@extension' (URI derives from this element) • FHIR element 'masterIdentifier'

2.13 Document type

The precise clinical document type is recorded. There are two data elements.

Data element	Document type code
Definition	Code for the precise type of the clinical document
Source standards	XDS.b LOINC clinical document ontology
Value domain	LOINC code Examples: <ul style="list-style-type: none"> • 74196-7 – interRAI home care assessment • 56445-0 – Medication list document
Obligation	Mandatory
Guide for use	Maps to: <ul style="list-style-type: none"> • XDS element 'typeCode' • CDA element 'ClinicalDocument/code/@code' • FHIR element 'type'

LOINC has a standard name for each coded document type, and this also is captured as a metadata element. The document type name is composed in a structured way and can be used to sort, filter and categorise lists of documents.

Data element	Document type name
Definition	Name for the precise clinical document type
Source standards	XDS.b LOINC clinical document ontology
Value domain	Text

Obligation	Mandatory
Guide for use	Document type name has these components: <ul style="list-style-type: none"> • Kind of document – characterising the general structure of the document at a macro level • Type of service – characterising the kind of service or activity provided for the patient • Setting – describing the facility type or setting • Subject matter domain – naming the health specialty

2.14 Availability status

Whether the document is valid and available for patient care is recorded.

Data element	Availability status code
Definition	The status of the document in terms of whether it is valid and available for patient care
Source standards	XDS.b
Value domain	Values are: <ul style="list-style-type: none"> • ‘A’ (available) – document is available • ‘D’ (deprecated) – document is obsolete or withdrawn
Obligation	Mandatory
Guide for use	Maps to: <ul style="list-style-type: none"> • XDS element ‘availabilityStatus’ • FHIR element ‘docStatus’

2.15 Confidentiality

The confidentiality of every clinical document is recorded. All clinical documents are classed as medical in confidence and the patient may choose any document to have the further protection of a ‘sealed envelope’, for greater confidentiality.

Data element	Confidentiality code
Definition	Code for the confidentiality level of the document
Source standards	XDS.b
Value domain	HL7 confidentiality code: <ul style="list-style-type: none"> • ‘N’ (normal) – document has the usual level of confidentiality and

	<p>should be treated as medical-in-confidence</p> <ul style="list-style-type: none"> • ‘R’ (restricted) – document is protected within a ‘sealed envelope’ and cannot normally be viewed
Obligation	Mandatory
Guide for use	<p>Maps to:</p> <ul style="list-style-type: none"> • XDS element ‘confidentialityCode’ • CDA element ‘ClinicalDocument/confidentialityCode/code’ • FHIR element ‘confidentiality’

2.16 Language

The language used predominantly in the document is recorded. This does not prevent sections such as for patient advice using a different language.

Data element	Language code
Definition	Code for the human language in which the document is written
Source standards	<p>XDS.b</p> <p>ISO 639 Codes for the representation of names of languages</p>
Value domain	<p>ISO 639-1 alpha-2 code</p> <p>Examples:</p> <ul style="list-style-type: none"> • ‘en’ – English • ‘mi’ – Maori
Obligation	Optional
Guide for use	<p>Maps to:</p> <ul style="list-style-type: none"> • XDS element ‘languageCode’ • CDA element ‘ClinicalDocument/languageCode’ • FHIR element ‘primaryLanguage’

2.17 Media type

The Internet media type or MIME type of the stored document is recorded.

Data element	Media type code
Definition	Code for the media type of the document
Source standards	XDS.b
Value domain	Media type code (www.iana.org/assignments/media-types)

	<p>Examples:</p> <ul style="list-style-type: none"> • application/xml • application/pdf • application/atom+xml • image/png • video/mp4
Obligation	Mandatory
Guide for use	<p>Maps to:</p> <ul style="list-style-type: none"> • XDS element 'mimeType' • FHIR element 'mimeType' • Media type for CDA documents is always 'application/xml'

2.18 Document format

CDA document types are structured according to specific templates that determine how documents are processed and displayed. The specific document format is recorded.

Data element	Document format code
Definition	Code indicating the format of the document
Source standards	XDS.b
Value domain	<p>OID</p> <p>HL7 New Zealand OID registry (www.hl7.org.nz/new-zealand-oid-registry)</p> <p>Examples:</p> <ul style="list-style-type: none"> • 2.16.840.1.113883.2.18.7.2 – GP2GP document • 2.16.840.1.113883.2.18.7.20.2 – Home care assessment document • 2.16.840.1.113883.2.18.7.21.6 – Maternity care summary document • 2.16.840.1.113883.2.18.7.21.7 – Ambulance care summary document
Obligation	Mandatory
Guide for use	<p>Document format is used in conjunction with media type to determine how to render or parse a document</p> <p>Document format is presently applicable to CDA document types only</p> <p>The document format code can be used to represent a specific version of a set of CDA templates (or some other format)</p> <p>Maps to:</p>

	<ul style="list-style-type: none"> • XDS element 'formatCode' • FHIR element 'format'
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2.19 Document size

Document size in bytes can be recorded.

Data element	Document size
Definition	Size of the document in bytes
Source standards	XDS.b
Value domain	Integer
Obligation	Optional
Guide for use	<p>Record document size when known (document size will not necessarily be known for documents generated on demand)</p> <p>Maps to:</p> <ul style="list-style-type: none"> • XDS element 'size' • FHIR element 'size'

2.20 Custodian

The health provider organisation that is the custodian of the clinical document may be recorded.

Data element	Custodian
Definition	Custodian organisation identifier
Source standards	XDS.b HISO 10043 CDA Common Templates
Value domain	HPI organisation number Example: <ul style="list-style-type: none"> • GAB432-F
Obligation	Optional
Guide for use	<p>Maps to:</p> <ul style="list-style-type: none"> • CDA element 'ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganisation/id/@extension' (where the corresponding '@root' element indicates the value domain) • FHIR element 'custodian'