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ITK CDA Sender and Receiver Requirements

Document Management

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Reviewers

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Reference Documents

Ref no	Doc Reference Number	Title	Version
•	N/A	CDA Overview - HL7 UK	Info
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Contents

1 Introduction

This document details those requirements which must be met by senders and receivers of ITK CDA documents.

1.1 Purpose of Document

This document defines a set of requirements for sending and receiving CDA's in order that care environments can, on a case by case basis, share information in a clinically safe way.

1.2 Audience

The primary audience are supplier technical and product development staff who are interested in developing an ITK CDA Toolkit Implementation.

1.3 Document Scope

This document covers the ITK CDA accreditation requirements to ensure functional interoperability between sending and receiving systems.

1.4 Document Overview

The rest of this document covers a number of areas of functionality. Within each area the functionality is described, and a number of formal requirements are listed in bold type, with additional detail provided in smaller type below this.

1.5 Reference Implementation

An ITK reference implementation is available as a training and development aid and contains code snippets for typical Healthcare Interoperability scenarios.

- http://developer.nhs.uk/library/interoperability/nhs-interoperability-framework/

2. Background and Context

These requirements have been derived from the CDA requirements issued under the GPSoC contract.

Other requirement sets will almost certainly apply to different parts of an entire solution, in particular:

- The DMS: *Generic CDA Domain Message Specification* provides guidance and requirements on the population of CDA documents .
- The *GPSoC requirement set* provides guidance specific to the implementation systems within primary care, under the GPSoC contract.

2.1 ITK Architecture Specifications and Guidance Documents for Health and Social Care Interoperability

The ITK Architecture Specifications (documents) define the mandatory and optional architecture requirements of an ITK compliant implementation. These documents are message payload agnostic and have no clinical meaning. Their collective aim is to enable assured and auditable delivery of Health and Social Care Information between Health and Social Care IT Systems securely and safely.

Typically they include requirements regarding how systems connect and interoperate, requirements for data security and requirements for payload distribution and routing.

2.2 ITK Domain Message Specifications for Healthcare Interoperability

Domain Message Specifications (DMS) specify message payloads and interaction details for healthcare domains. A DMS contains all the relevant artefacts to build message payloads, which are based on international standards such as HL7 CDA. The payload provides a means to share healthcare information in a clinically safe manner. DMS message payloads are transport agnostic.

DMSs also contain interaction details, which describe behaviours for sending and receiving messages. For example requesting and receiving acknowledgements and messaging configurations.

2.3 ITK Trust Operating Model

The ITK Trust Operating Model provides best-practice guidance that Trusts need to consider when assuring their own Architectures. It provides assistance with the implementation of integrated systems within a local environment. In particular it lays out local responsibilities when connecting to Spine compliant systems. The ITK Trust Operating Model contains a guidance document and best practice checklist which covers the critical operational aspects such as: resilience, performance, installation, configuration etc.

2.4 Resources to aid Development and Deployment of ITK Accredited Software

In order to support the accreditation and deployment of clinically safe interoperable IT systems, there is a need to supply resources that cater for both Vendors and Trusts. Typical resources being:

- Accreditation Support
- Automated Test Workbenches
- Sample Code
- Technical Guidelines.

For Accreditation and Deployment support materials,:

- http://developer.nhs.uk/testcentre/

For the ITK reference implementation:

- http://developer.nhs.uk/library/interoperability/nhs-interoperability-framework/
- https://bitbucket.org/itk/itk-ri

3. ITK CDA Operating Principles

The following principles govern the use of the ITK CDA documents:

- CDA documents are produced in order to summarise an episode of care, they are not intended to capture detailed operational care information.
- CDA documents are generally created in a Healthcare environment, e.g. Hospital, Ambulance, Out of Hours Centre (OOH).
- CDA documents must be viewable from any system sending the document or any system receiving the document provided that the user accessing the document has the necessary access rights to do so.
- CDA documents should serve as freestanding documents and are immutable.
- CDA documents are versioned in order that they can safely be replaced or nullified.
- CDA documents are clinically verified before transmission.

The overarching objective is clinically safe information exchange.

3.1 Completeness and Veracity of CDA Payload

The sender of the ITK CDA Document is responsible for ensuring that the ITK CDA Document contains sufficient and accurate information regarding an episode of care, or encounter.

Sending systems should make available:

- Details of all professionals involved in delivering care during the episode of care, or encounter, to which the CDA Document relates;
- Details of people present, but not involved in the act (e.g. those described as a Witness in HL7).
- All information relating to the encounter that has been recorded locally by these professionals.

To ensure accuracy of the Documents' care content, a verification step must be included in the business process prior to the Document being sent. In many cases, the authenticator will be the author of the document.

A formal specification of the application sending roles is provided within the relevant Business Analysis Models published in the ITK Domain Message Specifications.

3.2 ITK CDA Report Handling Behaviour

Sending systems are expected to handle errors in 2 broad categories, i) the Infrastructure and ii) the Clinical Application.

- The ITK Architecture Specifications define the error handling requirements of the Infrastructure – http, SOAP, Distribution Envelope, Payload Validation, using the ITK Infrastructure Acknowledgement – see the ITK Architecture Specifications.
- The ITK Domain Message Specifications define the error handling behaviour of the clinical application/system and communicates errors using the ITK Business Acknowledgement; the requirements are defined in this document.

Care Professionals need to be informed that a CDA Document has not reached, or is experiencing difficulty in reaching, its intended recipients. Since Business Acknowledgements are only sent on successful receipt of the CDA document, the absence

of such an acknowledgement or the receipt of a transport layer/ infrastructure failure may be used to trigger investigations as to the status of sent messages.

3.3 CDA General Structure

The format of a HL7v3 Clinical Document Architecture (CDA) comprises:

- CDA Header
- Text Sections – which may be nested up to six levels, and must only contain standard CDA mark-up.
- Coded Entry Templates
- Non-XML body parts (e.g. attachments such as PDF or HTML files)

Detailed information relating to the structure and content of each CDA document is provided in the relevant ITK Domain Message Specification.

3.3.1 CDA Attachments

ITK Domain Message Specifications define the allowed attachments (binary objects) to be included within ITK CDA documents.

3.3.2 CDA and Coding Schemes

ITK CDA domains allow many coding schemes to be used together with a mapped /translated SNOMED-CT® equivalent where approved mapping/translations exist.

Systems using the DMS CDA messages may therefore include clinical codes other than SNOMED-CT® subject to the constraints included.

3.4 Messaging Patterns

Message, Interaction and Service patterns are defined in the ITK Domain Message Specifications.

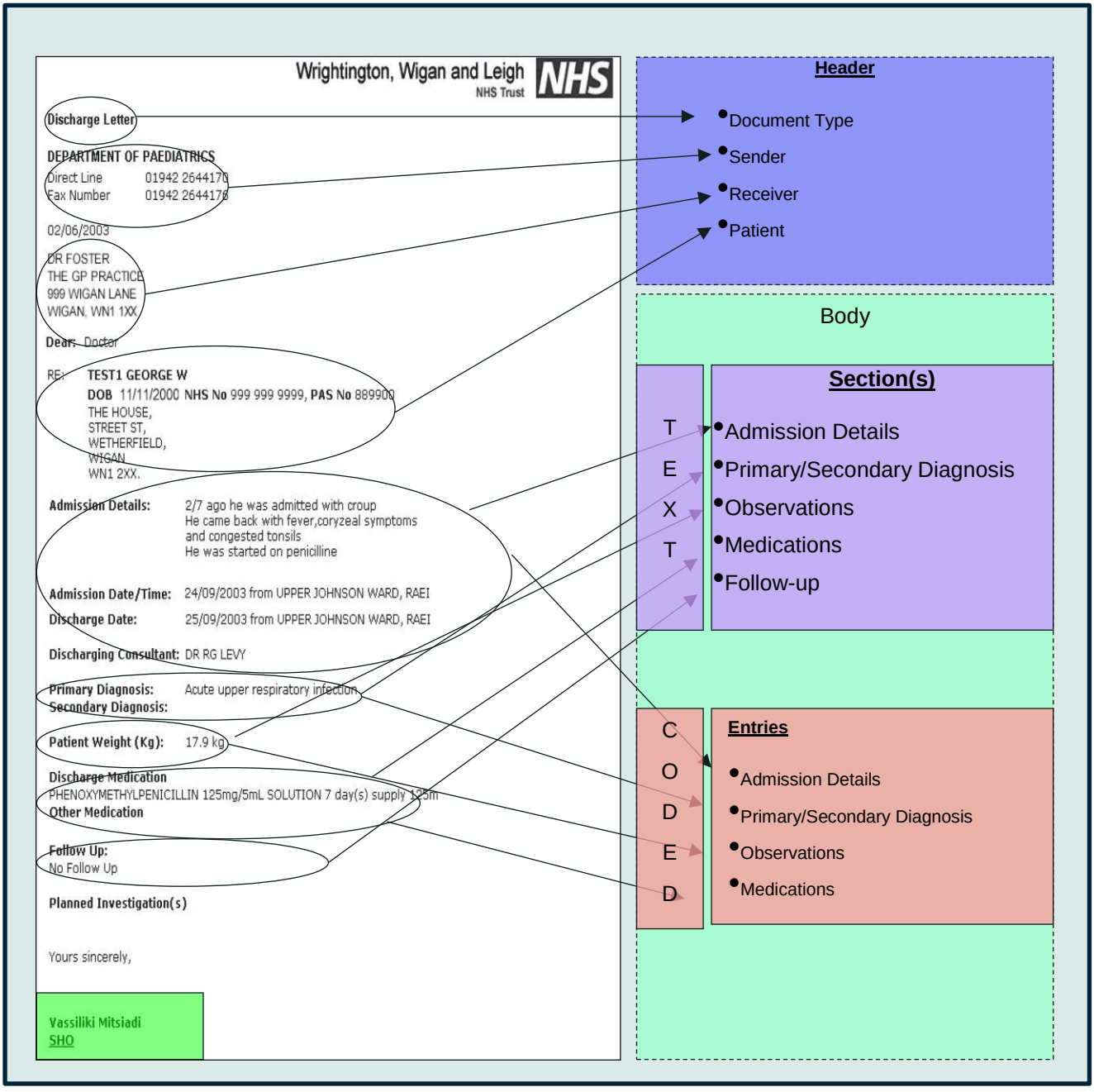
4. ITK CDA Structure

The ITK CDA is created using the formally defined HL7 approach and methodology for the creation and transmission of HL7v3 CDA documents.

A CDA document is a defined and complete information object that can exist outside of a message. With attachments it can include images, sounds, and other multimedia content.

4.1 HSCIC CDA – General Structure

The structure of an HSCIC CDA document is summarised in figure 1 below.



CDA documents are encoded in XML and derive their meaning from the HL7 v3 Reference Information Model (RIM) and use the HL7 v3 Data Types.

The body of an HSCIC CDA document consists principally of a number of text sections, each of which contains mark-up adhering to the CDA standard. In order to support business (document display) needs, text sections are nested in order to provide standardised formatting not available in Standard CDA mark-up.

For the purposes of HSCIC's CDA model, CDA <content> tags are used to delimit text fragments within the original text which contain (as a minimum) information also represented by a coded entry associated with that fragment, also within the document.

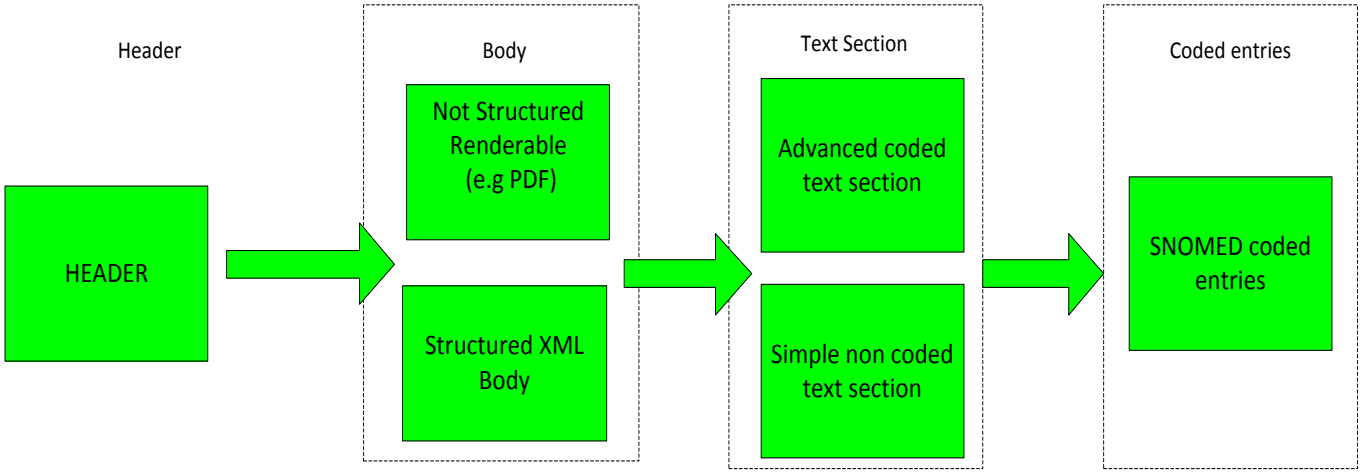
A CDA document will contain the summary of a period of care and may include multiple encounters. Multiple care summaries (e.g. multiple Discharge Reports, ED Reports or Outpatient Reports) must **NOT** be sent in a single clinical document.

4.2 ITK CDA - Construction and Validation

Authority policy requires sending systems and receiving systems to be able to validate CDA Documents against the appropriate schemas. It is recognised that not all systems will operationalise this requirements and so schema compliance cannot be assumed to have been undertaken by the sender before sending a document

4.3 ITK CDA Conformance Levels and Accreditation

The components of an ITK CDA document are shown below :



4.3.1 CDA Level 1 Accreditation

Level 1 CDA profiles use the CDA header and a CDA body that can be rendered but which is not structured. The body is in an alternative format to the CDA structured text. The format can be : XML, Word, PDF, TIFF etc.

There may be major interoperability issues when using non-XML body with formats like Word due to system and document incompatibilities e.g. different versions of Word, loss of formatting, unreadable documents etc.

4.3.2 CDA Level 2a Accreditation

Level 2 CDA profiles use the CDA header, structured XML CDA body and simple non-coded text .For sending and receiving systems the simple non-coded text section will allow headings but will not support coded sections and therefore the sections cannot be safely identified and processed but merely rendered.

4.3.3 CDA Level 2b Accreditation

Level 2 CDA profiles use the CDA header, structured XML CDA body and advanced coded text sections.

4.3.4 CDA Level 3 Accreditation

Level 3 CDA profiles use the header, structured XML CDA body and simple non-coded text or advanced coded text sections and SNOMED coded entries. The advanced coded text section will allow headings as well as coding on text sections; therefore these can also be identified, processed and rendered. Text sections may also have fixed headings and sections, dependant on the business rules

4.4 ITK CDA Conformance - Summary

CDA Level 1	Level 1 CDA profiles use the CDA header and a CDA body that can be rendered but which is not structured
CDA Level 2a	Level 2 CDA profiles use the CDA header, structured XML CDA body and simple non-coded text.
CDA Level 2b	Level 2 CDA profiles use the CDA header, structured XML CDA body and advanced coded text sections.
CDA Level 3	Level 3 CDA profiles use the CDA header, structured XML CDA body and simple non-coded text or advanced coded text sections, and SNOMED coded entries...

4.4.1 ITK CDA Sender and Receiving Systems – Maturity and Compatibility

The following table shows how system interoperability is impacted by having differing levels of maturity at the ITK CDA Sender and Receiving applications.

Key	Description
VB	View Body – e.g. viewing an embedded PDF
VT	View Text
PT	Process Text
VB,PT,PC	View Body , Process Coded Text Sections And Process Coded Entries

	SENDER	1	2a	2b	3

RECEIVER				
1	VB	VB	VB	VB
2a	VB	VB,VT	VB, VT	VB, VT
2b	VB	VB, VT	VB, PT	VB, PT
3	VB	VB,VT	VB,PT	VB,PT,PC

It should be noted that the CDA Levels of either party impact the interoperability of the system as a whole.

4.5 ITK CDA Accreditation Conformance Level and Accreditation Requirements

Sending and receiving systems will be accredited in relation to their conformance capability for creating and processing CDA's.

ID	Description	Sender	Receiver
CDA1	To achieve CDA Level 1 Conformance - Sending and Receiving systems **MUST** be able to create/consume the CDA header and a non-structured though render-able CDA body.	Y	Y

CDA2	To achieve CDA Level 2 Conformance - Sending and Receiving systems **MUST** be able to create/consume the CDA header, structured XML CDA body and simple non-coded text **OR** advanced coded text sections..	Y	Y

CDA3	To achieve CDA Level 3 Conformance - Sending and Receiving systems **MUST** be able to create/consume the CDA header, structured XML CDA body and simple non-coded text **OR** advanced coded text sections, **AND** SNOMED coded entries	Y	Y

4.6 ITK CDA Technical and Clinical Interoperability

Using the Discharge CDA profile as an example, the aim is to illustrate the difference between technical and clinical interoperability. Imagine a sending system uses the discharge profile to send discharge letters and utilises all the SNOMED CT coded entry templates. This defines the system as a level 3 system. If the receiving system can process at least one of the SNOMED CT coded entry templates this also defines it as a level 3 system. This means that both systems are technically interoperable, though have different capabilities.

The templates that are included in the discharge profile sent by the sending system but not supported by the receiving system means there is a problem with actual interoperability.

It is this Clinical interoperability that system suppliers must address. The guidance in this case would be when a receiving system receives a CDA document with template IDs it does not recognise then it should, as a minimum take the only safe option and render the CDA document.

4.7 Verification and Validation

Sending and receiving systems are required to validate messages.

ID	Description	Sender	Receiver
CDA4	Sending and Receiving systems **MUST** provide a means to assure the validity of the HL7 CDA document.	Y	Y
1.	If this validation fails the sending system **MUST- l**og the error in the message or application logs as appropriate		

CDA5	Sending systems **MUST** provide facilities (e.g. a 'verification' step) to ensure the content of CDA Documents is checked/verified by the document author, or other approved user, prior to the sending of the Document.	Y	N

5. CDA Sender Requirements

A CDA Sender has to be aware of a number of constraints associated with sending documents, generally considered in two categories, payload constraints and a patients consent and preferences.

5.1 ITK CDA Number of Payloads Constraint

ID	Description	Sender	Receiver
CDA6	A sending system **MUST** only send the number of CDA document(s) as defined within the ITK DMS.	Y	N

CDA7	If the interaction agreement allows the inclusion of attachments outside of the CDA document then these **MUST** be included within the same ITK Distribution Envelope.	Y	N

5.2 Demographic and Consent Preconditions

It is essential that the identity of the patient is consistently represented by systems that are interacting with one another and that a patients preferences are recognised.

5.2.1 PDS Connected Systems

Ideally, where sending systems are connected to PDS, full PDS Synchronisation will be carried out prior to any messaging interaction and therefore the locally held serial change number will be up-to-date. If the sending system is not connected directly to PDS but synchronises with PDS periodically, e.g. using the PDS Batch service, the latest available details should be sent.

ID	Description	Sender	Receiver
CDA8	Sending systems **SHOULD** synchronise the CDA document with the PDS record.	Y	N

CDA9	The Sender **MUST** include additional patient demographics if the patient's NHS number is not included or the NHS number has not been 'verified'.	Y	N
1	The Sender **MUST**include additional patient demographics if the patient's NHS number is not 'verified': • First Given Name • Surname • Gender • DoB • Address • Post Code		

CDA10	If the Sender is connected to PDS, prior to sending a CDA document, the originating system **SHOULD** check the PDS 'flagged' status of the Patient's record.	Y	N

CDA11	Where a record is marked as 'S' (Sensitive) on the PDS, following an appropriate safety evaluation (*by the local user organisation as data controller*) the Sender **MAY** include Patient address or contact details in the additional demographic data, these items are (PDS data items): • Addresses • Telecom Addresses • Patient Care (All types) • Alternative Contacts	Y	N
NB	The current 'PatientUniversal' template for additional demographics allows Name, Sex, Date of Birth, Address (including Post Code) and Telecom and thus alternative contacts cannot currently be included in the patient element of messages.		

CDA12	Where an NHS number is known to be invalid on the PDS (error code '22' upon a PDS Retrieval), the CDA Document **SHOULD NOT** be sent until the issue has been resolved.	Y	N

CDA13	Where an NHS number is known to be invalid on the PDS (error code '22' upon a PDS Retrieval), CDA documents **MUST NOT** contain the patient's NHS number.	Y	N

CDA14	Where an NHS number is known to be invalid on the PDS (error code '22' upon a PDS Retrieval), if the CDA Document is sent (and this can only be done with ITK DMS messages) other (non- NHS number) demographic details **MUST** be included. • First Given Name • Surname • Gender • DoB • Address • Post Code	Y	N

CDA15	Where a record is marked as 'B' (formerly meaning 'Business Flagged' prior to 2008-B but now meaning 'Under Data Quality Investigation' from spine release 2008-B onwards) on PDS, CDA documents **MUST** be sent as normal.	Y	N

CDA16	Where a Patient dissents from sharing their detailed care records and the document is a routine clinical communication, the originating system **SHOULD** still send CDA documents for that Patient to the Patient's GP Practice.	Y	N

5.2.2 Systems not connected to PDS

If the system is not connected to PDS at all then sufficient identifying attributes should be sent to enable a receiving system to match them to an existing record (if applicable) or create a new record (if applicable). In all cases the status of the NHS number must be indicated using the appropriate OID.

A single check can be used for a series of retrieving or sending interactions associated with a single patient. For user initiated interactions, the check will normally take place at the point that a patient record is selected and remain valid until the patient record is de-selected.

ID	Description	Sender	Receiver
CDA17	If the patient's NHS number is not known the system **MUST** include an alternative local patient identifier with the appropriate OID (see DMS documentation).	Y	N

CDA18	If the patient's NHS number is not known the system **MUST** include additional demographics.	Y	N
1	When a system ONLY sends a local patient identifier it **MUST** also include • First Given Name • Surname • Gender • DoB • Address • Post Code		

5.3 ITK CDA Text Section Exclusions

ID	Description	Sender	Receiver
CDA19	To avoid unnecessary and potentially disruptive duplication, the following items (where present) **SHOULD not be** included in the text section of CDA documents:	Y	N
Source	CDA Document Technical Requirements CT37		
1	Title		
2	Timestamp		
3	DocumentID		
4	DocumentVersion		
5	Author (including all attributes)		
6	Data enterer (including all attributes)		
7	Authenticator (including all attributes)		
8	Recipient (including all attributes)		
9	Custodian organisation (including all attributes)		
10	Patient's NHS Number		
11	Encompassing encounter		
12	Encounter type		
13	Care setting type		
14	Care setting place (including all attributes)		
15	Care setting organisation (including all attributes)		
16	Responsible party (including all attributes)		
17	Effective time		
18	Participants (including all attributes)		

CDA20	**Where an item from the list above is carried in a CDA document, it MUST be carried as an HL7 CDA Class Attribute**	Y	N
	The text sections within CDA documents **MUST** be composed using standard CDA mark-up.		
Source	CDA Document Technical Requirements CT30		

5.4 ITK CDA Coded Entries

Where a Sending System has the functionality to support coded clinical entries for medications, CDA documents created by that system should include coded entries where possible.

ID	Description	Sender	Receiver
CDA21	Where an originating system has the functionality to support coded clinical entries for **medications,** CDA documents created by that system **SHOULD** include coded entries where possible.	Y	N
1	If an originating system has the functionality to support SNOMED CT coded entries for medications, then CDA documents generated by that system and which contain medication information **MUST** include SNOMEDCT coded medication entries.		
2	If the native coding scheme of the originating system is not SNOMED CT, the system **MAY** include medication coded using other approved clinical coding schemes		
3	If the coding scheme used is not SNOMED CT, the originating systems **SHOULD** include a SNOMED CT translated code along with the native code		
4	Where a CDA document contains medication recommendations or medication history, this information **MUST** be carried as text only.		
5	Where an originating system does not have functionality to support coded clinical entries for medications, then CDA documents created by that system **SHOULD** contain medication information as text		

ID	Description	Sender	Receiver
CDA22	Where an originating system has the functionality to support coded clinical entries for **allergies and drug sensitivities**, CDA documents created by that system **SHOULD** include coded entries where possible	Y	N
1	If an originating system has the functionality to support SNOMED CT coded entries for allergies and drug sensitivities, then CDA documents generated by that system and which contain medication information **MUST** include SNOMEDCT coded medication entries.		
2	If the native coding scheme of the originating system is not SNOMED CT, the system **MAY** include allergies and drug sensitivities coded using other approved clinical coding schemes		
3	If the coding scheme used is not SNOMED CT, the originating systems **SHOULD** include a SNOMED CT translated code along with the native code.		

5.5 Multiple Recipients

ID	Description	Sender	Receiver
CDA23	The contents of a CDA document **MUST** be the same for every recipient.	Y	N
Source	CDA Document Technical Requirements CT60		
1	Having the same CDA document for every recipient **MUST** be achieved by addressing an identical clinical message payload (document) to each of the recipients, including identical UUIDs (document, set, coded entry), version number, and content tag IDs.		
2	The payload **MUST** be syntactically and semantically identical regardless of the number of receivers.		

5.6 Withdrawing and Nullifying Documents

The system must support the withdrawing of a previously sent CDA document. This is to support situations where the document was sent in error. It should not be used because part of the information in the original document has been updated – a replacement document should be sent in this instance.

ID	Description	Sender	Receiver
CDA24	The system **MUST** provide a facility for a user to nullify a previously sent document and for the nullify message to be sent to all previous recipients.	Y	N
CDA25	CDA document withdrawal **MUST** be performed by replacing the document to be withdrawn (referred to in parentDocument, relatedDocument.typeCode=”RPLC”) with a Nullify document. This Nullify document contains a coded entry containing reason code and associated text for withdrawal.	Y	N
CDA26	Where a document is withdrawn, the ‘nullify’ document **SHOULD** be sent to all recipients who were sent any version of the original document.	Y	N
CDA27	Those recipients that were primary recipients of the latest version of the document being withdrawn **SHOULD** be included as primary recipients of the nullification.	Y	N
CDA28	Those recipients that were copy recipients of the latest version of the document being withdrawn **SHOULD** be included as copy recipients of the nullification.	Y	N

CDA Document updates are performed by replacement: the submission of a new document which refers to the document it replaces as the parentDocument (with typeCode ‘RPLC’) .

ID	Description	Sender	Receiver
CDA29	Where the author of a replacement differs from the author of the parentDocument, the originating system **MUST** ensure it records the actual author and not the author of the parentDocument.	Y	N
1	Originating systems MUST only allow replacements to a CDA Document to be sent where the custodian organisation of the replacement is the same as the custodian organisation for the parentDocument.		
NB	The ONLY exception to this requirement is where the CDA document is expected to be updated by multiple organisations/users that are each entitled to make updates to it, e.g. an Integrated Care Plan in the HSCI domain.		
CDA30	On creation of a replacement of a CDA document, the version number of the replacement document **SHOULD** be the version number of the document being replaced (the parentDocument), incremented by (integer) one.	Y	N

5.7 UUIDs and Version numbers

In generating CDA documents, the sender must meet the below requirements.

ID	Description	Sender	Receiver
CDA31	A document replacement/revision **MUST** keep the parent document's setId constant (which links a chain of document versions).	Y	N
	The setId of a replacement document **MUST** match the setId in the parentDocument.setId field.		

CDA32	Systems creating new CDA document **MUST** generate a new clinical document ID (UUID) locally, regardless of whether that document starts a new document set, or is a replacement / upissue of an existing document (in a CDA document set).	Y	N

5.8 General Sender Requirements

Users of the system must be able to select who the recipient organisations or systems of a CDA document will be. The system needs to know which organisations or systems are capable of receiving which types of CDA documents.

ID	Description	Sender	Receiver
CDA33	Where it is indicated that a document recipient is required to act on the contents of a document, the originating system **MUST** identify that recipient as a primary recipient.	Y	N

CDA34	Where it is indicated that a document recipient is not required to act on the contents of a document, the originating system **MUST** identify that recipient as a copy recipient.	Y	N

CDA35	The contents of a CDA document must be the same for every (electronic) recipient, this **MUST** be achieved by addressing an identical clinical message payload (document) to each of the recipients, including identical UUIDs (document, set, coded entry), version number, and content tag IDs.	Y	N
1	The payload **MUST** be syntactically and semantically identical		

CDA36	The system **MUST** provide a facility for a user to re-send a previously sent CDA document to one or more of the previous recipients.	Y	N

6. CDA Receiver Requirements

Architectural Layers ensures that error handling is undertaken in line with the layer that the error occurs, for example HTTP, SOAP, Distribution Envelope and Business Application errors are all handled discreetly and in isolation.

This means that error processing falls in the sequence of the layers and processing can halt and report errors at the appropriate point of “failure/error”.

6.1 Recipient – Header Validation

Receiving systems must apply basic header validation to check that the system is the intended recipient.

ID	Description	Sender	Receiver
CDA37	The system **MUST** validate ‘recipient’ information contained in the CDA Document ‘header’ information to check that the identified recipient organisation, or person is supported by the system.	N	Y
1	The system **MUST** either : • Reject the message, ‘reject back to sender’ with an appropriate error code • Accept the message and pass it through to the application for processing		

6.2 Receiving System - Patient Validation

The requirements apply to situations where the patient the document relates to is expected to be present in the receiving system

ID	Description	Sender	Receiver
CDA38	Upon receipt of a CDA document for a patient whose record can be expected to be but is not present and ‘active’ in the system, the system **SHOULD** send a Report Code back to the sender with an appropriate error code.:	N	Y
1	• patient not registered here’ • patient is no longer registered or present		

6.3 Use Of Coded Clinical Content

Template-constrained coded entries (in CDA documents) are the mechanism used to exchange structured clinical information between systems. These are common, agreed structures for clinical data representation, and are the cornerstone of clinical data interoperability.

ID	Description	Sender	Receiver
CDA39	If a local system is not able to construct a coded entry to represent coded clinical information in a document, then that information **MUST** still be represented as text within the clinical document.	Y	Y
CDA40	Coded clinical content within CDA documents **MUST** validate against the set of ITK DMS-specified templates and appropriate constraints.	Y	Y
CDA41	All clinical content within coded entries of a CDA document **MUST** also be	Y	Y

	represented within the text sections of that document.		

CDA42	References to coded entries within a document (for example when using *Problem Link Assertion* or *Link Assertion* templates/coded entries) **MUST** be to coded entries within that same document.	Y	Y

CDA43	A receiving system **SHOULD** process coded entries present in a ITK CDA Document	Y	N
1	Receiving systems that have a lower level of conformance in relation to the sender, must inform them as part of the Business Acknowledgement.- Code 430.		

6.4 Patient Transfer Specific Requirements

ID	Description	Sender	Receiver
CDA44	If the patient has been moved (e.g. they have been 'deducted' or a GP2GP record transfer has recently taken place and a deduction is expected), the system **MUST** following clinical review of the message, notify the new care setting.	N	Y

6.5 Replacement and Nullification

When a replacement CDA document has been received, the system must check that a version of the document it is replacing has been received by the system previously and if not, to flag the document accordingly. The system must also apply the checks to nullification messages received for CDA documents.

Note that there are valid situations where this can occur, e.g. the earlier version of the document was sent by paper, and as such the receiving system must accept the document with a warning to make users aware of the situation.

ID	Description	Sender	Receiver
CDA45	If a Replacement CDA document is received, the system **MUST** check that a version of the document being replaced has been previously received.	N	Y
1	If the check fails the system **MUST** flag the item with a warning indicating that the document being replaced has not been previously received.		
2	If a Replacement CDA document is received the system **MUST** check that the version of the new document is greater than the latest previously received document with the same setId.		
3	If the check fails the system **MUST** return a negative Application/Business Acknowledgement indicating that the 'Document version precedes current version'.		
4	The system **MUST** check that a version of the document (i.e. a document with the same setId) being nullified (withdrawn) has been previously received.		
5	If the check fails the system **MUST** flag the item with a warning indicating that the document being nullified has not been previously received and send back a negative Application/Business Acknowledgement to the sender with an error code indicating 'nullified document setId not recognised'		

If the system does not support replacement or nullification it will still have to acknowledge any messages received.

ID	Description	Sender	Receiver

CDA46	If the Receiving System does not support the receipt of replacement CDA documents, nullification/withdrawal CDA documents, it **MUST** send a negative Application/Business Acknowledgement back to the sender indicating 'no support for replacement CDA documents'	N	Y
1	The system **MUST** log receipt of such messages		
2	The system **MAY** keep such messages and make them available for viewing. When displaying such a document the user **MUST** be informed that the document has been rejected back to the sender		

Receiving systems must check that when a replacement CDA document has been received that a version of the document it is replacing has been received by the system previously and if not, to flag the Document accordingly.

ID	Description	Sender	Receiver
CDA47	. Receiving systems **MUST** check that when a replacement CDA document has been received	N	Y
1	If a Replacement CDA document is received the system **MUST** apply the following validation checks: • Check that a version of the document being replaced has been previously received If the check fails the system **MUST** flag the item with a warning indicating that the document being replaced has not been previously received.		
2	If a Replacement CDA document is received the system **MUST** apply the following validation checks: • Check that the version of the new document is greater than the latest previously received document with the same SetID. If the check fails the system **MUST** return a negative Application/Business Acknowledgement indicating that the 'Document version precedes current version'		
3	If a Nullification message is received for a CDA document the system **MUST** apply the following validation checks: • Check that a version of the document (i.e. a document with the same SetID) being nullified (withdrawn) has been previously received. If the check fails the system **MUST** flag the item with a warning indicating that the document being nullified has not been previously received and send back a negative Application/Business Acknowledgement to the sender with an error code indicating 'nullified document SetID not recognised'.		

6.6 Duplicate CDA Documents

The receiving system must be able to check for message duplicates, that is duplicate document references received from the same source.

ID	Description	Sender	Receiver
CDA48	The system **MUST** perform 'duplicate message' checks on all received messages	N	Y
	If the message ID is a duplicate the system MUST: • NOT forward the message to the host clinical application • Log the error in the message logs.		
	If a duplicate is found, the system **MUST** return a negative Application/Business Acknowledgement with an appropriate error code indicating 'Duplicate Document ID received'.		
	The system MUST flag the item in the message log indicating that it is a duplicate.		

7. CDA General Requirements

There are a number of key characteristics associated with a CDA document : the ability to view documents, the need to acknowledge receipt of a document(s), versioning and compatibility.

7.1 Audit Requirements - Clinical

The sending / receiving of CDA Documents forms part of a patient's record and as such the audit requirements need to be of an equivalent standard.

ID	Description	Sender	Receiver
CDA49	CDA documents that are sent or received MUST be logged.	Y	Y
1.	As a minimum the Distribution Envelope and all its contents must be logged/saved/persisted.		

CDA50	When information from CDA documents has been retrieved or is processed, the local Audit trail **MUST** include entries for the following events: • Clinical Information displayed to a user • Clinical Information stored (imported) in the local patient record • Clinical Information printed.	Y	Y

CDA51	The information stored in the audit record **MUST** include: • Timestamp • Patient NHS Number • User identifier and current role identifier • Clinical data/document identifier	Y	Y

7.2 Business Acknowledgement Processing

The following requirements relate to business acknowledgement processing for CDA's – the business application layer and therefore relate to error responses that are presented in an ITK Business Acknowledgement.

ID	Description	Sender	Receiver
CDA52	The Sending system **MUST** be able to handle all report codes and the Receiving system **MUST** be able to generate all the report codes	Y	Y

7.3 CDA Document Display

The system will need to provide several different views of a CDA document depending on the access rights of individual users and what data they wish to view.

ID	Description	Sender	Receiver
CDA53	Sending and Receiving systems .**MUST** provide a function to render the contents of a CDA Document to an authorised user.	Y	Y

7.4 Document 'Code' and Document Ontology

Systems creating CDA Documents must populate the document 'code' attribute within the 'ClinicalDocument' Act

ID	Description	Sender	Receiver
CDA54	A Sending system **MUST** support the use of the SNOMED CT subsets during the creation of CDA Documents and populate the 'code' attribute of the 'CliniclalDocument' Act with a post-coordinated SNOMED CT expression.	Y	N
CDA55	A Receiving system **MUST** preserve the 'code' attribute of the 'CliniclalDocument' Act when processing the CDA Document whether from the pre-coordinated 'Document Type' subset or the post-coordinated Document Ontology subsets.	N	Y

7.5 General Processing Requirements

The system will need to provide several different views of a CDA document depending on the access rights of individual users and what data they wish to view.

The simplest distinction is to

i) provide an administrative view of the document which does not display any clinical content (except for document type) and

ii) ii) a clinical view which displays all clinical data which may comprise structured coded data and text data.

ID	Description	Sender	Receiver
CDA56	For the purposes of the requirements in this section the system **MUST** regard all contents of the StructuredBody and Non-XML StructuredBody as the parts of a CDA document containing Clinical Data.	Y	Y
CDA57	To separate Administrative and Clinical roles the parts of the CDA document, known as Header information, MUST be regarded as Administrative Data.	Y	Y

7.6 Handling Attachments

Embedded binary objects (files) can be included in a DMS CDA Document. When present the system must be able to detect them, and should inform the user of their presence, display them on demand and add them to the patient record if a user elects to do so.

ID	Description	Sender	Receiver
CDA58	The system **MUST** detect the presence of a NonXMLBody Act.	N	Y
1	The system and **SHOULD** inform the user that there are attachments and display them on demand		
2	When present the system **MUST** be able to detect them, and should inform the user of their presence, display them on demand and add them to the patient record if a user elects to do so.		

7.7 Versioning and Compatibility

This section defines how versions at both document and coded template level provide guidance to connecting suppliers as to what they can and cannot interpret.

7.7.1 Versioning

Multiple levels of versioning exist within CDA clinical documents, these are expressed at:

a) **Document level** – message type and version of that message type are combined into the messageType, whose structure is either:

POCD_MT<message type>UK<message type version>

Or:

POCD_MT<message type>GB<message type version>

This information is represented in CDA document metadata in the 'extension' attribute of the 'messageType' element, for example:

<npfitlc:messageType root="2.16.840.1.113883.2.1.3.2.4.18.17" extension="POCD_MT**000026**GB**01**"/>

b) **Template level,** within a document – includes Clinical content entries and CRE Indexing / Mapping entries, and most other 'Acts' within a document. This takes the form either:

COCD_TP<template type id>UK<template version>

Or:

COCD_TP<template type id>GB<template version>

This is represented within each Act, in the 'extension' attribute of the 'templateId' element denoting the template which is used to derive – and validate – the structure, for example:

<templateId root="2.16.840.1.113883.2.1.3.2.4.18.2" extension="COCD_TP**145201**GB**02**#patientPatient"/>

7.7.2 Backward compatibility

As types of documents and coded templates increase in number, i.e. as they mature as representations of clinical concepts, suppliers will need to maintain document and template level backward compatibility across the lifetime of the data stored in the patient record.

7.7.3 Forward compatibility

HL7 CDA has simplified the problem of providing forward compatibility. Based on the HL7 Reference Implementation Model (RIM) all current and future CDA documents use the same logical structure.

One minor difference between document types is the inclusion/use of the 'Encompassing encounter' element – naturally systems must be designed to handle presence/non-presence of optional structures. It is assured that, structurally at least, systems will be able to parse, and render, any CDA documents in the future and systems should be designed to handle the generic CDA structure.

ID	Description	Sender	Receiver
CDA59	Suppliers **SHOULD** validate against the HL7 generic CDA model.	Y	Y

8. Business Acknowledgement Report Codes

This section defines the codes to be used at a business level between sending and receiving systems, i.e. the error codes included with Application Acknowledgement messages as a result of a business level failure and/or requiring a business level response.

The following table illustrates scenarios generating error responses by a Receiver system back to a Sending system. The 'Remediation' column indicates actions to be taken by the Sending system.

The code system associated with the codes listed below, including both the 3-digit codes and the 5-digit codes is the OID value "2.16.840.1.113883.2.1.3.2.4.17.227" which indicates that it originates from a Point 2 Point domain.

The 3-digit error code is broadly aligned with HTTP error codes as follows:

2xx series: Success – and also success situations with warnings (e.g. awaiting user acceptance)

4xx series: Client Error - the receiving system has been unable to process the message due to a syntax or content related failure. These are permanent errors and resending the message will usually result in the same error again.

5xx series: Server Error – these are unexpected errors and are usually temporary or intermittent. Resending the message again may succeed.

ID	Description	Sender	Receiver
CDA60	All received Business Acknowledgments **MUST** be logged.	Y	Y
CDA61	All received Business Acknowledgments **SHOULD** be appropriately logged and notified to local administrators..	Y	Y
CDA62	A Receiver system **MUST** be able to generate all the Report Codes documented	N	Y
CDA63	Values or text replaced into Business Acknowledgements as described in the table **MUST NOT** contain any patient identifiable information.	Y	Y

8.1 Business Acknowledgment Report Codes

In the error text column below, “{x}” indicates a placeholder for additional values or text to be inserted to provide context and/or references to help investigation into the cause of the problem.

Error code	Source code	Severity	Error text	Description / Receiving Condition (Recipient)	Remediation (Sending system)
200		AA	Success	Success	Success
202	20201	WG	Unrecognised Recipient Person	The Recipient Person is not recognised but the Recipient Organisation is supported and the message has been passed on for local (recipient) investigation/processing.	Report to user/admin. Check person identity in local (sending) system is correctly configured.
202	20202	WG	Unrecognised Sender	The Receiving system does not recognise the Sender but the message has been passed on for local (recipient) investigation / processing.	If this is a regular information flow the receiver should be informed and their system configuration changed.
202	20203	WG	Non Approved file type received as an attachment	The Receiving system has received an attached file whose file type is on the Authorities ‘Black List’. The remainder of the message will be processed.	
400	40012	ER	Control Act validation failure. Detail: "{0}"	Content validation of the Control Act content has failed	
400	40014	ER	Payload validation failure. Detail: "{0}"	Content validation of the SOAP content has failed	
400	40015	ER	CDA 'on the wire' Schema validation failure. Detail: "{0}"	Validation using the generic CDA 'on the wire' schema has failed.	
400	40016	ER	CDA Message Definition Schema validation failure. Detail: "{0}"	Validation using the CDA Document message definition specific schema has failed. Details should include which part(s) has failed e.g. missing mandatory data.	
400	40017	ER	CDA Document content validation failure. Detail: "{0}"	Content validation has failed, e.g. missing/invalid OID, invalid/missing clinical code for terminology, etc.	
400	40018	ER	Attachment file type invalid. Detail: "{0}"	One or more attachments has an invalid file type	Sender (user) could resend with attachment in alternate format (if possible)
400	40019	ER	Attachment file type unsupported. Detail: "{0}"	One or more attachment file types are unsupported by the recipient system.	Sender (user) could resend with attachment in alternate format (if possible)
410	41020	ER	Unrecognised Recipient Organisation	The Recipient Organisation identified in the CDA is not supported by this End Point (Receiving System).	Configuration issue - the ‘transport’ address is incorrect for the intended organisation or the recipient organisation details in the message are incorrect
410	41021	ER	Unrecognised Sender	The Receiving system identified in the CDA is configured to reject messages from unrecognised senders.	If regular communication with this recipient is expected, contact recipient and suggest configuring system to expect

Error code	Source code	Severity	Error text	Description / Receiving Condition (Recipient)	Remediation (Sending system)
					messages from this sender.
410	41002	ER	Patient not known here. (aka 'patient record not present in system')	NHS Number (and/or other identifiers or demographic data to help identify the patient) supplied does not match a locally held patient record in the recipient system.	Report to user – need to check patient identity and registered GP Practice against PDS or other authoritative source and if necessary escalate to National Demographics Back Office.
410	41022	ER	Patient no longer registered here	NHS Number (and/or other identifiers or demographic data to help identify the patient) supplied matches a patient record but the patient has left and registered with a new GP Practice.	Report to user – need to check patient identity and registered GP Practice against PDS or other authoritative source and if necessary escalate to National Demographics Back Office.
410	30307	ER	The NHS Number has been merged.	Local (and PDS) records indicate that NHS# included in document has been merged with another record.	Report to user. This extremely rare occurrence may only happen if a patient has been merged between validating the patient's NHS# and sending the clinical document.
410	41023	ER	The NHS Number is not present or not valid on PDS.	The NHS Number is not present on PDS or not currently valid on PDS and no superseding NHS Number exists.	Local investigation required.
410	41024	ER	This system does not support 'Replacement' CDA Documents	The receiving system is not able to process replacement CDA Documents.	If sending system allows, configure to not send replacements to this recipient. Updates to the previously sent CDA document will need to be handled by other means between the two parties.
410	41025	ER	The system does not support the 'Withdrawal/Nullification' of previously received CDA Documents.		If sending system allows, configure to not send withdrawals to this recipient. Withdrawals of a previously sent CDA document will need to be handled by other means between the two parties.
410	41026	ER	Duplicate Message received - message/transmission ID "{0}" has already been processed.	A message with this message/transmission ID has already been received and processed by this recipient.	
420	41027	ER	Duplicate Document received - Document with UUID "{0}" has already been processed.	A CDA Document with this document ID has already been received and processed by this recipient.	
420	41028	ER	The Document with setId "{0}" being withdrawn is not	The Recipient system has not previously received a CDA Document with the corresponding	Local investigation required.

Error code	Source code	Severity	Error text	Description / Receiving Condition (Recipient)	Remediation (Sending system)
			recognised.	setId.	
420	41029	ER	The Document with setId "{0}" being withdrawn has already been withdrawn.	The CDA Document being withdrawn has already been withdrawn.	
420	41030	ER	The version numbers of replaced/replacing Documents with setId "{0}" are incompatible.	The version number of the replacing CDA Document is the same or earlier than the CDA Document being replaced.	
420	41031	ER	The Document with setId "{0}" and version "{1}" to be replaced has already been replaced.	The Document sent is attempting to replace a document which has been replaced already.	
430	43001	ER	Unexpected Application Acknowledgement or Business Acknowledgement received.	An Application Acknowledgement has been received for a message that is not recorded as originating from this system.	Application Acknowledgement sent to wrong recipient
430	43002	ER	Message Type not supported here	Message type provided in interaction is not supported by this endpoint.	If received over TMS then invoke NASP support to check SDS Accredited system interaction set is correct, otherwise check local configuration and update as required.
430	43003	ER	Document Type not supported here	Document type (SNOMED-CT® coded within document) not supported by recipient system. This should only happen when using the generic ‘Not coded CDA Document’ message or the document type does not match the message type it is within.	Stop process flow. This document will not be received by this version of the destination application.
440	44001	ER	Anti-virus check on CDA attachment(s) failed	Antivirus check on CDA attachments has failed.	
500	30101	ER	Service failure.	Unexpected recoverable error caught in Recipient System. Could not process this message at this time.	Retry message later.
503	50300	ER	Destination application temporarily unavailable.	Local (recipient) application temporarily unavailable	Retry message later.