Chapter 9
Clinical Document Architecture

9.1 Documents and Databases

Worldwide, Clinical Document Architecture (CDA) is the most widely adopted application of HL7 V3. The CDA paradigm takes the document metaphor seriously.

It is illuminating to compare the differences between the database transaction and document metaphors (Benson 1997; Spronk 2007).

Databases are organized for rapid search and retrieval and are updated by transactions. The database structure is designed by a computer professional, updated by various people, who may or may not know each other, and is accessed by others using queries. The person who updates the database is seldom able to control who, if anyone, will read the data, or for what purpose. The person who uses the data may not know who entered them and lack of context makes it difficult to evaluate whether or not they can be relied on.

In contrast, a document, electronic or paper, is organized as a stand-alone artifact mainly to convey human understanding. Each document has a clearly identified set of meta-data stating who created it, for whom, when, where, and about what subject. The author determines the entire content and is responsible for it. If there is any doubt about how to interpret a message, the receiver can contact the author requesting elaboration.

We are all familiar with documents such as letters and invoices, but we seldom notice how much information is contained in each. Some data are fixed and are always present; other data are variable, changing with each document instance.

Consider a typical letter from a company. Fixed data include the company name, logo, address, phone, fax, e-mail, and web addresses; the company's registered name and address, registration number, and place of registration, and may also include tax identifiers (e.g., VAT number), bank information, and lists of directors or partners.

Variable data fall into two types; first, data that are always present on a particular type of document but may vary in every instance, such as the date, reference, recipient name, and address, and the author, including name, job title, and signature. Finally, we have the variable content of the letter, which contains the core of the message.

Even a simple letter contains quite a lot of data that have little to do with the actual message content, but serve to provide context and verification data, allow us

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to trust that it really is what it says it appears to be, and let us check their validity if we have any suspicions.

Documents have a number of properties, which are not shared with databases or transactions used to update database records. These properties include: persistence, stewardship, authentication, wholeness, and human readability.

Persistence is a feature of documents. Every document has a life cycle; it is created, then used, and eventually destroyed (perhaps many years later). While it exists, it remains a single coherent whole. On the other hand, information in a relational database is distributed across the rows of many tables. Different people may be authorized to update the different tables. After numerous updates, it may be impossible to recreate the information as it was originally, without the use of sophisticated roll-back processes.

Stewardship is another document property. At any time, some body or organization is responsible for looking after it. It should always be clear who is responsible for filing, copying, forwarding, or destroying a document. Organizations invariably keep copies of documents they send out. Again, this is not true of a database, where different rules may apply to different types of data.

Authentication is simpler with documents than database records. It is relatively easy to maintain an audit trail for the whole life cycle. Each document may be signed, physically or electronically. Validity can be attested in ways that are difficult to replicate with database records. Only authenticated documents are likely to be of value in medico-legal disputes.

Each document is complete and whole in itself, including context information, such as who created it, when, where, and for what purpose. This makes it easier for others to use it outside the immediate purpose for which it was created. Without strong evidence on the original context, it can be hazardous to place meaning on any statement.

Finally, documents are human-readable. Meaning, as perceived by the human reader, is paramount, even when there is coded machine-readable information within the same statement. Human-readable messages have a long-term value (medical records may have to be preserved for 100 years or more), whereas machine-readable data depend on specific technology, which may not be available many years in the future. For example, few modern computers can read floppy disks or magnetic tapes that were ubiquitous a couple of decades ago.

The need for long-term human-readable persistence was one of the motivations behind the development of XML and its predecessor SGML (Fig. 9.1).

9.2 CDA History

CDA's naming structure can be best understood in reference to its history.

In 1997, XML was the new kid on the block and attracted a lot of interest. Every instance of an XML file is referred to as a document, which is one of the reasons

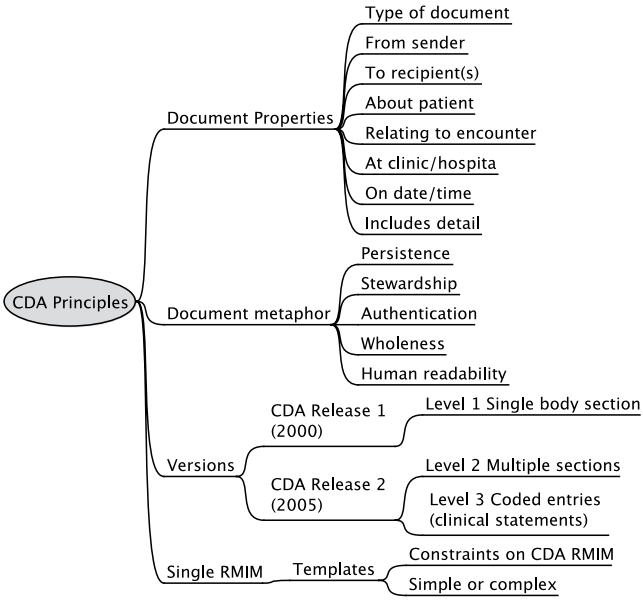

Fig. 9.1 CDA principles

why people began to think seriously about the document metaphor. XML is a simplification of an earlier standard, SGML, which was mainly used for complex documents such as technical specifications and manuals for aircraft and military equipment, which need to be rendered in a variety of different formats. The analogy between complex instruction manuals and medical records was not lost. Both are voluminous and difficult to navigate.

In 1997, a group of people with an interest in both HL7 and SGML/XML met at the Kona Mansion in New Hampshire, where they agreed a three-level plan for using XML in medical documents, along with the emerging HL7 Version 3 reference model. This plan has been largely followed in two main releases.

Release 1, published in 2000, is a simple standard, describing a header and body. Only the header is based on the HL7 V3 RIM, while the body uses a variety of human-readable non-XML formats such as text or images.

Release 2, published in 2005, is more complex and both the header and the body are based on the HL7 V3 RIM, allowing fine granularity of structured data. The body may be non-XML (providing backward compatibility to Release 1) or it may be organized into one or more sections, which may have structured entries.

The development of CDA is continuing, with CDA Release 3 expected in 2010 and the development of a Structured Document Architecture (SDA) with increased flexibility (Spronk 2009).

9.3 CDA Levels

The three levels are:

CDA Level 1 has a header and a human-readable body. The header contains basic meta-data, primarily intended to enable information retrieval, while the body is human-readable text or image. For example, the body can be a PDF document, a jpeg image, or a text document, possibly containing simple formatting markup.

CDA Level 2 allows the body to be either an unstructured blob (enabling compatibility with Level 1) or one or more structured sections. Each section contains a single narrative block, which contains XML markup that can be rendered in human-readable form. The general structure of CDA Levels 1 and 2 was agreed in 2000 and published as CDA Release 1 (ANSI/HL7 CDA R1.0–2000).

CDA Level 3 allows each section to include machine-processed entries at almost any level of granularity. Thus, it offers the benefits of both human-readable and machine-processed documents. Machine-processed data are encoded using the HL7 V3 Clinical Statement pattern.

The relationships between these are shown below:

Release	CDA Release One (R1)	CDA Release Two (R2)
Date	2000	2005
Level 1	CDA R1 Level 1	CDA R2 Level 1
Level 2	CDA R1 Level 2	CDA R2 Level 2
Level 3	Not available	CDA R2 Level 3

Naturally, prior to 2005, all use of CDA used Release 1. Since its release, CDA Release 2 Level 3 has become popular, although it is more complex than Levels 1 and 2.

All levels validate against the generic CDA schema. Additional validation is provided by templates and constraints on the generic CDA schema.

One of the attractive features of CDA is that it lets you start simply, with Level 1 or 2, and then evolve over time. Health care is a long-term business and it is vital that records and documents are kept safely and can be accessed many years into the future. The lower levels of CDA provide rather low technical barriers to adoption, while providing a migration route toward structured coded records.

CDA can be deployed easily to enable web-based access to patient data.

CDA is at the core of almost every standards-based health information exchange architecture, worldwide. Countries that adopted simple CDA level 1 architecture several years ago are now meeting substantial portions of their information exchange requirements with CDA. Resource-strapped countries have adopted CDA because it allows them to immediately share information at the point of care without sacrificing scalability or reuse in the future.

For example CDA is a core component of the National Health Service strategy for interoperability in England. In the USA, institutions like Mayo Clinic that place

a high value on information as an asset have committed to CDA because it provides a single architectural foundation for their clinical information requirements that can be sustained over generations of application development.

A key to this acceptance is the "A" for architecture in CDA, which promotes reusability across a sufficiently wide range of documents to cover clinical information sharing, public health, quality reporting, and clinical trials (Fig. 9.2).

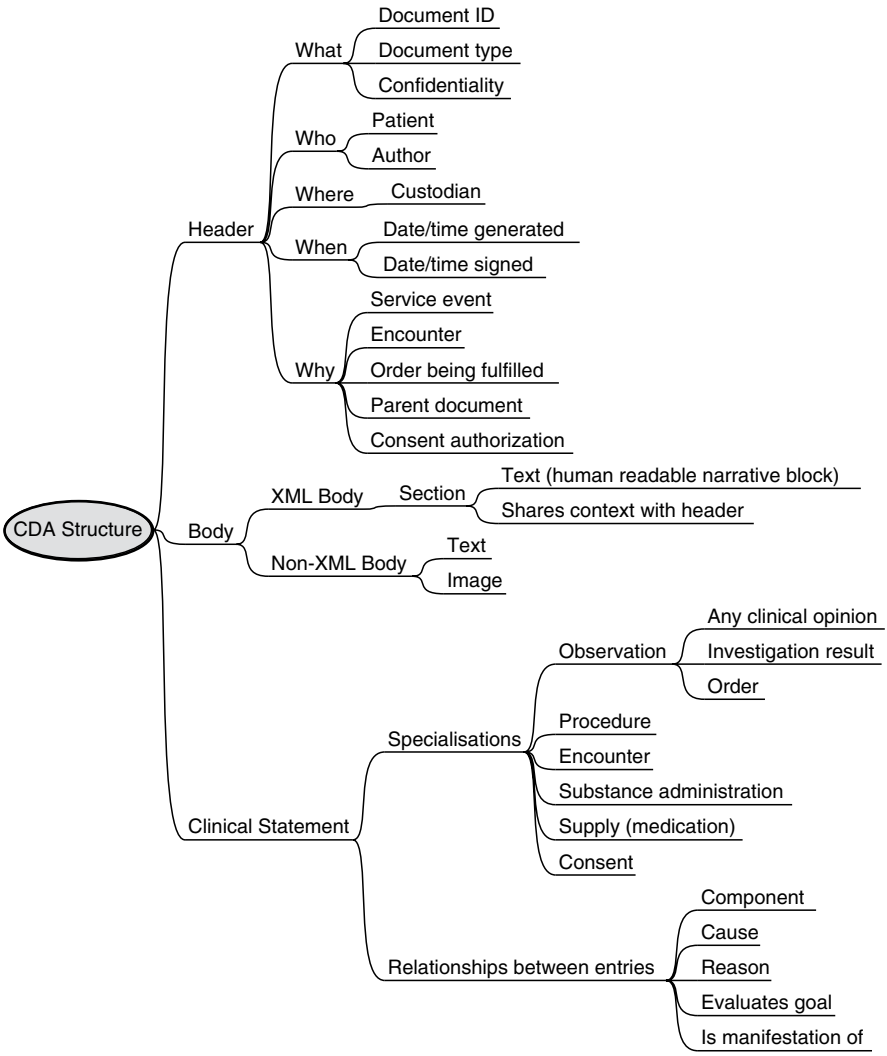

Fig. 9.2 CDA structure

9.4 CDA Header

The CDA header is common to all three levels of CDA.

The primary purpose of the header is to provide unambiguous, structured meta-data about the document itself, which can be used in document registers and databases to classify, find, and retrieve documents. These meta-data include information about what the document is, who created it, when, where, and for what purpose.

The root class of all CDA documents is an Act called Clinical Document.

9.4.1 What?

Identification of the document itself is done at three levels: first, there is a pair of codes which state that this is a CDA document, then there is another code which indicates the type of CDA document (e.g., discharge summary), and finally a unique identifier for the document instance. These are mandatory in all CDA documents.

We state that this is a CDA document using two structural attributes: *ClinicalDocument.classCode* and *ClinicalDocument.moodCode* and these have been allocated predefined values, DOCCLIN and EVN respectively.

The type of document being exchanged is specified using *ClinicalDocument.code*, which is usually an externally specified coding scheme. Use of externally specified coding schemes places no limit on the potential number of different types of CDA document that could be used.

Each specific instance of a CDA document is identified using the *ClinicalDocument.id* attribute. This may be any unique identifier, but is often a UUID (Universally Unique ID).

ClinicalDocument.confidentialityCode is another mandatory attribute in the root class. It defines the overall confidentiality status of the document and has a default value of N for normal.

9.4.2 Times

The time of generation of a CDA document is always recorded in *ClinicalDocument.effectiveTime*.

As well as the time of creation, each document must also include the *author.time*, which is the data and time that the original author is considered to have signed or approved the document. This may be the same as the *ClinicalDocument.effectiveTime*.

9.4.3 Participations

Every clinical document has at least three participations, which are links to specific roles.

- RecordTarget represents the medical record that this document belongs to. In most healthcare organizations this is effectively an identifier of patient.
- The Author responsible for the content of the clinical document.
- The Custodian, which is usually the originating organization which keeps the medical record.

The intended recipient(s) may also be specified.

Other participations, including dataEnterer, Informant, Participant, and Authenticator may be specified, but are rare in practice.

9.4.4 Relationships

A clinical document may have relationships with other documents or events including:

- ServiceEvent represents the main Act, e.g., a colonoscopy or discharge from hospital, which is being documented
- Reference to a parent document, which may be being changed or replaced by the present document
- Fulfillment of an order, for example when a test report references a request
- Authorization of consent
- Reference to an encompassing encounter

9.5 CDA Body

Every CDA document has one header and one body part. The body is either a NonXMLBody or a StructuredBody. NonXMLBody is present to provide upward compatibility with CDA Level 1, and may contain any type of human-readable data including text (txt, rtf, html, or pdf) or image (gif, jpeg, png, tiff, or g3fax). Data encoded using XML may not be put in the NonXMLBody.

StructuredBody is used for XML-encoded data. It is the root node for one or more Sections.

9.5.1 Section

Each Section contains a human-readable narrative block, called *Section.text*. This narrative block is one of the key components of CDA and contains the human-readable content of the Section. One of the responsibilities of the originator of any CDA document is to ensure that the narrative block of each Section accurately conveys the meaning of that Section in a way that can be rendered appropriately for human readability.

Section.text can include special XML markup, which is similar to but simpler than XHTML. However, relatively few documents use markup within narrative blocks other than <paragraph> and
 (line break), although this might change.

The original vision of CDA was for each Section to comprise either a whole document content or at least a significant chunk, such as a composition or section as defined in EN 13606. However, many implementations of CDA, such as the NHS Care Record Service have chosen to implement Sections with rather fine granularity, so each Section is no more than a single line or entry.

Fine-grained sections allow Sections to be filtered, sorted, and rendered in different ways, chronologically, or by author, or by record type, for example, to display all allergies, diagnoses or medication records.

Sections may contain subsections within them, although this is not common, because it adds to the processing complexity.

Sections usually share the same context data as that found in the header, although this can be overridden for each specific Section, although this is not common.

9.5.2 Clinical Statement (Entry)

Each section can contain any number of entries, which are clinical statements, in a structured computer-processable form.

The HL7 Version 3 Clinical Statement is as a common pattern for the development of all types of clinical messages, used for the exchange of information between different computer systems. The same pattern is used in CDA, for complex messages such as the exchange of complete electronic patient records between GPs, and for simpler messages such as prescriptions. HL7 defines a Clinical Statement as:

> an expression of a discrete item of clinical (or clinically related) information that is recorded because of its relevance to the care of a patient. Clinical information is fractal in nature and therefore the extent and detail conveyed in a single statement may vary.

Any clinical statement may have a number of participants, including subject, author, location, performer, participant, and informer.

Each clinical statement is one of the following specializations:

- Observation, which may refer to specimen(s) and reference ranges. Observations cover a very broad range of statements relating to history, examination, tests, diagnosis, and prognosis. It is important to remember that, depending on the mood, an observation can be an actual observation (Event), a requested observation (Request), or a goal set for a future observation (Goal). Also that Observation Events are usually reported using code–value pairs, where the code represents what is being observed and value represents the result. The Observation class may be linked to a specimen and normal range values.
- Procedure, which may refer to a specimen(s) or images and is used for all invasive procedures including surgical procedures and imaging.

- Encounter, which covers most administrative procedures including appointment scheduling and waiting list management.
- Substance Administration or Supply, which may refer to products such as medication and are mainly used for prescribing, dispensing, and administration of drugs.
- Consent.

Several types of associations between clinical statements are provided such as containment, cause and effect, problem linkage, etc.

9.5.3 Relationships Between Entries

The Clinical Statement pattern allows for a rich set of relationships between entries, to reflect the structure of clinical information and links between different items.

CAUS Used to show that the source caused the target, such as substance administration (e.g., penicillin) caused an observation (e.g., a rash), or observation (e.g., diabetes mellitus is the cause of kidney disease).

COMP Used to show that the target is a component of the source (e.g., hemoglobin measurement is a component of a full blood count).

GEVL (evaluates (goal)) Used to link an observation (intent or actual) to a goal to indicate that the observation evaluates the goal (for instance, a source observation of "walking distance" evaluates a target goal of "adequate walking distance").

MFST (is manifestation of) Used to say that the source is a manifestation of the target (for instance, source "hives" is a manifestation of target "penicillin allergy").

RSON (has reason) Used to show the reason or rationale for a service (for instance, source "treadmill test" has reason "chest pain").

SAS (starts after start) The source Act starts after the start of the target Act (for instance, source "diaphoresis" starts after the start of target "chest pain").

SPRT (has support) Used to show that the target provides supporting evidence of the source (for instance, source "possible lung tumor" has support target "mass seen on chest X-ray").

Any clinical statement may inherit context information from the CDA header or context information may be defined within the clinical statement, in which case it overrides the default inherited data. Examples of participations, which can be applied to any clinical statement, are Subject, Author, Performer, Informant, Location, and Participant.

9.6 CDA Templates

CDA Templates are used to specify how CDA is to be used for particular purposes and specific use cases. The development of templates is relatively new and there are likely to be significant changes in this area over the next few years.

A CDA Template is an expression of a set of constraints on the CDA RMIM, which apply additional constraints to a portion of an instance of data. Templates are used in a variety of different ways.

- Narrative – this can be used to reference an implementation guide or pattern "A valid legal authenticator must be provided"
- Schematron assertions "legalAuthenticator and not legalAuthenticator [@nullFlavor]"
- Static Model (RMIM) Publish a new static model making legalAuthenticator mandatory

The CCD specification provides one exemplar of how the *templateId* can be used to reference a template or implementation guide that has been assigned a unique identifier. The following example shows how to formally assert the use of this implementation guide. Use of the *templateId* indicates that the CDA instance not only conforms to the CDA specification, but in addition, conforms to constraints specified in this implementation guide.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
<typeId extension='POCD_HD000040' root='2.16.840.1.1
13883.1.3'/>
<templateId root='2.16.840.1.113883.10.20.1'/>
</ClinicalDocument>
```

In addition to assigning a template identifier to the overall implementation guide, template identifiers can be assigned to other patterns, such as document sections and specific clinical statements within document sections. Using the *templateId* to reference one of these patterns indicates that the CDA instance conforms to the constraints specified in that pattern.

```
<Section>
<templateId root='2.16.840.1.113883.10.20.1.14'/>
<Observation classCode="OBS" moodCode="EVN">
<templateId root='2.16.840.1.113883.10.20.1.32'/>
</Observation>
</Section>
```

Templates allow constraints to be applied to all or any part of a CDA document including the roles (e.g., author or patient details), sections (such as business headings), and entries (such as clinical statements), to say exactly how each is to be specified with a narrower and more focused scope. CDA Templates may be simple, or quite complex.

Multiple CDA Templates can constrain the same portion of a CDA document specification.

A CDA Profile is a set of Templates that correspond to a particular document type.

A Template list provides a set of Templates which provide choices for the user.

The NHS Connecting for Health program has defined a large set of templates, specified using RMIMs, and Schematron schemas for EHR components to be used in CDA messages.

CDA Templates have a *templateId* and may be stored in a repository. The *templateId* is one of the hidden attributes of the HL7 RIM, which can be used in all RIM classes. The *templateId* is used to indicate which template is being used; it is useful in document validation, software, and human-readable specifications. Validators use *templateId* to check that a document complies with the rules specified in the template; computer software uses *templateId* to indicate how this part of a document should be used. Humans use the *templateId* to reference how each part of the specification is to be used. A *templateId* may be a UUID or a locally specified identifier.

Each template has a set of meta-data to describe the purpose and use of the template. The meta-data include a globally unique identifier, a name, description, version, an identifier of the model from which it is derived, the RIM version, and publication details. The use of standard meta-data allows templates to be stored in repositories, which can be queried and the templates shared.

Currently, most CDA Template constraints have been implemented in Schematron, and are used primarily for validating CDA document instances.

9.7 The Continuity of Care Record (CCR)

The ASTM Continuity of Care Record (CCR), also referred to as ASTM E2369-05,[1] has been developed by ASTM to provide a common XML format for a patient health record (PHR) summary of clinical, administrative, and demographic patient data to be sent to the next healthcare provider when a patient is referred or transferred to another hospital, clinic, or other care provider. It can reference one or more healthcare encounters.

The CCR is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's health care, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward them to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient. It supports a variety of coding schemes including SNOMED CT.

The key motivation was to allow data from multiple sources to be brought together in a single format, to enable portable PHRs, needed when more than one care provider is treating a patient. Each data element is data/time and source stamped.

The CCR has a header, a footer, and 17 optional sections, which cover a wide range of functions including detailed insurance and payment-related administrative data that are highly specific to the USA.

The CCR Header defines the document parameters, including its unique identifier, language, version, date/time, the patient whose data it contains, who or what has generated the CCR, to whom or what the CCR is directed, and the CCR's purpose.

[1]ASTM. Specification for Continuity of Care Record, E2369-05, 2006

The CCR Footer contains data defining all of the actors, as well as information about external references, all text comments, and signatures associated with any data within the CCR.

The CCR Body contains the core-patient-specific data, such as current and past medications, problems, and procedures. Data are aggregated into sections based on common clinical conventions. In a typical scenario, pulling in existing data from a variety of sources dynamically creates the body, and no new content is specifically created for the summary. In some cases, the source data will be narrative; in other cases there may be coded data supporting some aspects of the narrative; and in some cases the source data will be fully coded.

Google Health has adopted a pragmatic profile of the CCR for the Google Health PHR.[2] The items supported in the Google Profile (2008) include:

- Patient demographics (e.g., date of birth and sex)
- Problems/diagnoses (e.g., condition or symptom)
- Allergies and alerts
- Medication list
- Immunizations
- Social history (e.g., race)
- Vital signs
- Results
- Procedures
- Functional status (e.g., pregnant or breast-feeding)

The XML structure described in the CCR standard is a simple ad hoc structure, which has the advantage of being simple to use, but lacks some of the flexibility of CDA.

9.8 Continuity of Care Document (CCD)

CCD (Continuity of Care Document) maps the CCR functionality into HL7 V3 CDA format, setting out a set of constraints on CDA, using templates. Although the stated purpose of CCD is to communicate clinical summaries, it is increasingly being used as a framework for developing other types of message (Fig. 9.3).

One way of looking at CCD is to consider it as a set of templates, because all parts are optional and it is practical to mix and match the ones you need. This is the direction of travel for future versions of CCD.

A CCD is the semantic equivalent of a CCR – both are in XML and both adhere to ANSI-based specifications. Implementers must choose either one or the other standard as the primary data format.

CCD has been endorsed by HIMSS and HITSP as the recommended standard for exchange of electronic exchange of components of health information.[3]

[2]See http://code.google.com/apis/health/

[3]HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD)

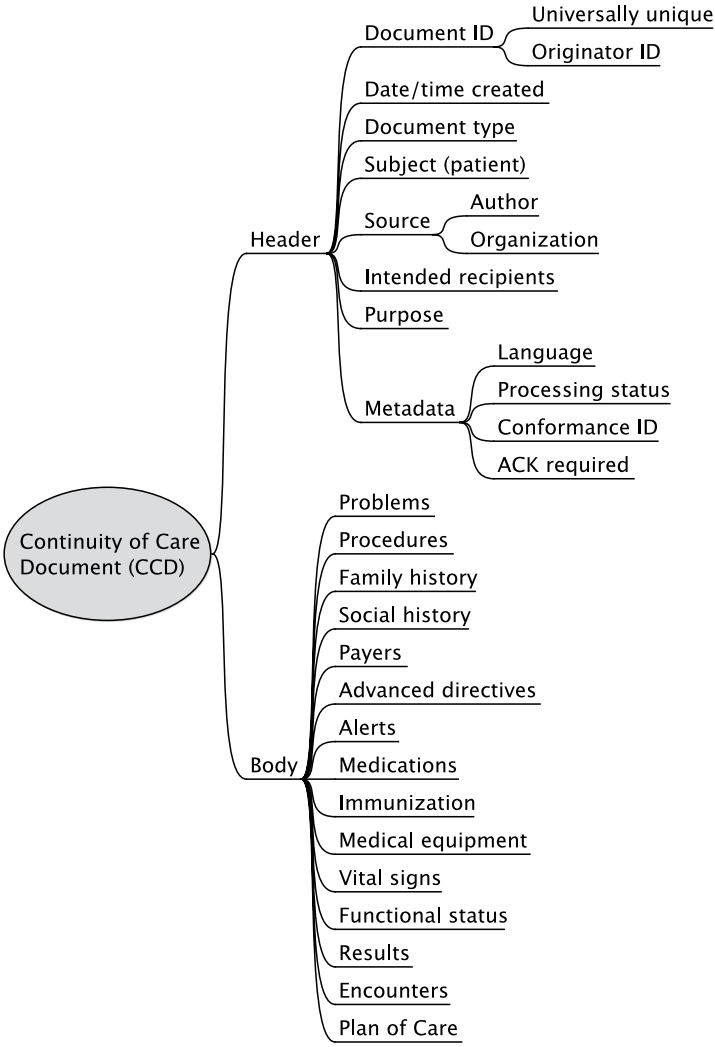

Fig. 9.3 Continuity of Care Document

9.9 CCD Header

9.9.1 Document Identification

Each instance of a CCD document is identified by a universally unique identifier (UUID) generated by the originating system. The use of UUID is mandated as the simplest way to ensure that each document generated is unique and will be understood to be unique by any receiving system.

A separate originator document ID may be provided, which is a human readable identifier for a document, used by the originator. It is not guaranteed to be universally unique, although no such identifier should be used which is known to contain any duplicates. It should be used only in combination with an identified patient and a specific date and time of document creation.

The date/time created represents the exact clock time that the document is created and must include a time zone offset. It is not the time that the document is sent.

The document type is the type or title of the document, e.g., Cardiology Follow-up. Ideally coded, but may be just text.

9.9.2 Document Meta-data

Each CCD document contains several items of meta-data. Meta-data are information about the document which is used to support electronic processing and information retrieval.

languageCode in the form nn, or nn-CC (e.g., en or en-US). The nn portion shall be a legal ISO-639-1 language code in lower case. The CC portion, if present, shall be an ISO-3166 country code in upper case.

processingStatus indicates whether a document is being used in production, testing or training.

ConformanceId is a unique identifier, which identifies the specific version of the clinical document to which conformance is claimed, such as an XML Schema or Schematron.

ACK required specifies the circumstances under which acknowledgment of receipt and or processing is required (always, on success or on error).

9.9.3 Subject

Each CCD refers to a single patient or subject, who is the person seeking to receive, receiving, or having received health care. It can only refer to one patient. Examples: A treated patient, a client of a physiotherapist, each particular member of a target population for screening, each particular member of a group of diabetic persons attending a session of medical education.

Each patient has one or more identifiers. For example, patients may have different identifiers in different units. Patients may also have a full set of demographic details (name, date of birth, sex, address, etc.)

9.9.4 Other Parties

A CCD always has at least one source. Multiple sources may be specified when it is useful to specify the person(s), organization, and or system responsible for generating the document.

There may be any number of intended recipients (and copy recipients) of any document. This is optional, because some documents do not have an explicit recipient. The recipient may be any party (person or organization), including the patient.

9.9.5 Document Purpose

Each CCD document may have one primary purpose, which is the reason that a clinical document is generated, such as patient admission, transfer, consult/referral, or inpatient discharge. It may be associated with an indication (text or code) and a relevant date/time. Each document may also reference any number of other prior documents.

9.10 CCD Body

The CCD Body contains sections corresponding to the main sections of the CCR.

- The Problems section provides a problem list of current and historical clinical problems.
- The Procedures section includes surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient.
- Family history.
- Social history includes administrative data such as marital status, race, ethnicity, and religious affiliation as well as information about the patient's occupation, lifestyle, social, environmental history, and health risk factors.
- For each payer, all the pertinent data needed to contact, bill to, and collect from that payer should be included as well as authorization details.
- Advance directives such as the existence of living wills, healthcare proxies, and resuscitation status.
- Alerts describe allergies, adverse reactions, and alerts related to current or past medical history.
- The Medications section lists the patient's current medications and medication history.
- Immunization lists current immunization status and immunization history.
- Medical equipment includes both durable medical equipment and implanted devices.
- Vital signs may include the most recent, maximum, and/or minimum, or both, baseline, or relevant trends.
- Functional status contains information on the "normal functioning" of the patient at the time the record is created and provides an extensive list of examples. Deviation from normal and limitations and improvements should be included here.
- The Results section contains the results of observations, including abnormal values or relevant trends, generated by laboratories, imaging procedures, and other procedures.

- Encounter lists healthcare encounters pertinent to the patient's current health status or historical health history.
- Plan of Care contains active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient. The plan of care section also contains information regarding goals and clinical reminders.

All sections of a CCD document are optional and may be combined together in any way.