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REFERENCE ARCHITECTURE FOR SHARING DOCUMENTS AND IMAGES

Version 1.0 (English)

National eHealth Authority

June 2012

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Contents

1	Preface	6
2	Summary	6
3	Introduction	7
3.1	What is a reference architecture?	7
3.2	The central concepts of the reference architecture.....	8
3.3	The purpose of a reference architecture for document and image sharing	10
3.3.1	Scope.....	10
3.4	Sharing documents and images (the key content of the reference architecture)	11
3.5	Use	12
3.6	Target groups	13
3.7	Reader guidelines	13
3.8	Development process	13
4	Vision and Goals	14
4.1	Vision	14
4.2	Goals	16
4.3	Value creation from the reference architecture	18
5	Principles	18
5.1	Business principles.....	19
5.2	Information principles.....	23
5.3	Technical principles	25
6	Concept model	27
6.1	Overview	27
6.2	The Concept Model.....	29

6.3	Document concepts	31
6.4	Relations.....	34
6.5	The life cycle of documents and metadata.....	35
7	Processes	36
7.1	Examples of workflows (use)	37
7.1.1	Document consumer searches for documents on a patient	37
7.1.2	Document consumer searches for on-the-fly documents about a patient	38
7.2	Examples of workflows (creation of documents)	39
7.2.1	Document source registers document and metadata at index/registry and repository	39
7.2.2	Document source registers an on-the-fly on-demand document in an index/registry	40
7.2.3	Deletion of documents and document information (metadata).....	41
8	Services / business services	41
9	System-technical goals.....	43
9.1	Technological trends	43
9.2	AS-IS ICT architecture	50
9.3	International system context and experience	51
9.3.1	epSOS.....	52
9.3.2	Austria - ELGA	52
9.3.3	Switzerland.....	53
9.3.4	Compilation of international experience	54
9.4	System image To-Be architecture	55
9.4.1	The international perspective	55
9.4.2	The national perspective	55
9.4.3	The local perspective	57
9.4.4	Connection through the inter-regional image index	57
9.4.5	Examples of other types of connection	58

9.5	Patient identification	58
9.6	Security	59
9.6.1	Existing security models	59
9.6.2	Future security models	60
10	Technical implementation.....	61
10.1	Defined nationwide repositories	61
10.2	Patient identification and identifier-feed.....	61
10.3	IHE profiles and standards.....	63
10.4	Other standards and profiles	67
10.5	Services and service contracts.....	69
10.6	Document formats.....	69
10.7	Document types.....	69
10.8	Metadata.....	69
10.9	Viewer.....	70
	Bibliography	72
	Appendix A Metadata.....	76
	Appendix B - International experience	80
	Austria 80	
	Background	80
	ICT architecture in Austria	81
	Structured documents.....	81
	Switzerland	82
	Background	83
	ICT architecture in Switzerland	84
	Primary standards used in Austria and Switzerland	85
	The rest of the world.....	86

1 Preface

The quality and effect of patient treatment in the healthcare sector depends on physicians and other health professionals having access to up-to-date and relevant information about the patient to aid diagnosis, treatment, care, rehabilitation, etc.

In autumn 2011, the National eHealth Authority (NSI) published a report ¹ which sets the framework for work on establishing a reference architecture and standards for the healthcare sector. The report prioritises a number of focus areas in which there is a need to describe general reference architectures and designate standards which can support the exchange of information.

One of the areas with highest priority is preparation of a reference architecture for sharing documents and images. This choice was made because it supports a number of current projects, including sharing data on chronic patients, the national patient index, and the inter-regional image index. Similarly, the reference architecture will be able to support further development of existing solutions, e.g. electronic referral and prescription distribution.

2 Summary

This reference architecture is to act as the common benchmark for the health areas and ICT solutions relating to document and image sharing.

The purpose of the reference architecture is to form the framework for setting standards for sharing images and documents across organisational boundaries and ICT systems.

The reference architecture is to support the eGOVERNMENT strategy for the healthcare sector which states access to relevant information as an important goal.

Focus is on sharing data which does not necessarily have a fully structured and standardised content. It should be possible to display all types of data content with clinical meaning for the consumers: text, images, drawings, graphs, etc. Use of documents means that the ICT system being used does not have to understand the structure or content of the document; it only has to know how the different types of document are displayed. The consumer puts the clinical information in the document into the correct health context.

This also means that document and image sharing can support the general patient pathway across organisations and sectors, as well as more specialised collaboration on the individual patient.

By standardising the way documents are communicated between specialist systems, the aim is to make it possible to advance digital solutions in the healthcare sector and reduce development costs

¹ National eHealth Authority; Standarder og referencearkitekturer vedr. sundheds-it området
http://www.ssi.dk/Sundhedsdataogit/National%20Sundheds-it/~media/Indhold/DK%20-%20dansk/Sundhedsdata%20og%20it/NationalSundhedsIt/Standardisering/Rapport_standarder_og_referencearkitektur.ashx

of specialist systems. In this way, document and image sharing will supplement traditional web-service-based integration.

The **main recommendation** for the reference architecture is that it be based on IHE standards and profiles which ensure that the reference architecture can also be included in an international context. At national level this means that two domains will be established: a central government domain and a common regional government domain which in the long term can be supplemented by a common municipal domain. At international level, a national contact point will be established which, in a well defined and standardised manner, will ensure communication between the national domains and domains in other countries. In a local context it must be possible to develop own domains, e.g. within a region, but if there is a wish to display documents and images from this domain, it will be necessary to couple it to one of the national domains and comply with the international standards stipulated for these.

The most important overall **consequence** is that a document storage facility can be established across the healthcare sector in which, by using common, standardised metadata, it will be possible to search documents across systems and organisations, without having to have tight coupling (integration) between the ICT solutions being utilised by consumers.

The reference architecture defines a number of business services and corresponding technical services, which can support implementation in different ways.

The reference architecture makes it possible to continuously make data from existing systems available as documents with associated metadata. An existing system can therefore be reconciled with the reference architecture without the need for a fundamental change to the system itself.

The reference architecture makes it possible to make information available relatively simply and cheaply so that the rate of digitalisation within the healthcare sector can be increased significantly.

3 Introduction

3.1 What is a reference architecture?

The report "Standards and reference architectures for the eHealth area" is based on the definition from the National IT and Telecom Agency:

- *"A reference architecture is a well considered method of developing ICT solutions within a specific area.*
- *The reference architecture describes the overall logic structures and concept apparatus for the specific area such that there is a good foundation from which to work when creating cohesive ICT solutions.*

- *In addition to the logic structures and concept apparatus, the reference architecture also describes the fundamental logical business services and concepts within the focus of the reference architecture.*
- *The generic business services and concepts to be used in the interface around the reference architecture are often also described at logic level.*
- *The reference architecture can be described at several levels of abstraction. At a very high level of abstraction, only the basic structures and the adjacent surroundings are shown. At more detailed levels, logic services, core concepts and interactions between these are often described.*
- *A reference architecture sets common indicators and principles for development within the area. The reference architecture provides both the public authorities (orderer) and suppliers (providers) with common targets for development of the area."*²

Therefore, a reference architecture covers a limited area in which, at the highest level, health targets for the area are set and the required properties of solutions in the area are described. After this, the overall principles for solutions are established, solution elements and processes are described, and, on the basis of this, the areas which can be standardised are identified.³ A reference architecture can be described in greater or less detail, depending on requirements.

3.2 The central concepts of the reference architecture

The reference architecture for document and image sharing utilises a number of concepts and terms, which are vital for establishing clarity and understanding. The purpose of the reference architecture is not to be a broad standardisation of concepts or terminology. Therefore, the definitions and explanations used only apply when utilising this reference architecture.

Central concepts in the reference architecture which are important for understanding the core of the reference architecture:

- **Document** is an object containing health information on a given patient, and which is dealt with as a complete entity. The format of documents can be unstructured or structured.
- **On demand documents** are documents generated on-the-fly, which can show an up-to-date snapshot of the data in a given source.
- **Data source** is the source of the health content of documents or images.
- **Document type** describes the health information contained in a document. The document type only describes the content.
- **Document format** describes the document's structure, design and the format in which the content is stored. Format is independent of the health content.

² *Referencearkitektur - best practice anbefalinger* (reference architecture - best practice recommendations)

³ For a more detailed explanation (in Danish) see: <http://ea.oio.dk/referencearkitektur>

- **Document producer** is the producer of the document or image from where the content comes from a data source
- **Document source** is the player (the system), which registers documents and images with associated metadata and possibly displays them via a document repository. The document source can also be a supplier of on-demand (on-the-fly) documents. A document source can also be a data source and a document producer.
- **Document consumer** is the player who establishes access to images and documents in a business contexts
- **Image** is an object composed of health images or graphics in digital format, e.g. an X-ray. The data content of an image is structured according to different standards.
- **Manifest** is a special document in an XDS context which, instead of containing health information, contains references to images and associated documents. Only used for images.
- **Patient** is a person undergoing a course of treatment and who is the object referred to in both documents and images.
- **PatientID** is a unique identification of a patient and is defined nationally.
- **Sharing** means sharing the same document and thereby working on the same basis. If copy registers are established, the authoritative repository must be agreed.
- **Index** explains which documents and images are available and includes references to where they are physically stored (repository).
- **Document repository** is the physical location at which documents and images are stored after creation and from which they can be retrieved for subsequent consumption. A repository has a standardised interface through which the stored documents can be accessed. Via a special document, a repository also contains a reference to the actual document or image.
- **Metadata** is descriptive data about an object, e.g. a document. Metadata is not part of the health content, and can only be used for search and indexing purposes.

The reference architecture works with the following central players:

- **Document source**
- **Document consumer**
- **Index**
- **Document repository**

Chapter 4, Concept Model, contains detailed descriptions of the concepts and relationships between the central concepts in the reference architecture.

3.3 The purpose of a reference architecture for document and image sharing

The purpose of the reference architecture is to **form the framework for setting standards for sharing images and documents across organisational boundaries and ICT systems.**

The aim of the reference architecture is to act as the common reference for sharing images and documents. It may be necessary to update, expand or change the reference architecture, e.g. in the event of changes in the principles on which the architecture is based.

It is important that the reference architecture for document and image sharing can be used in several health areas with the same types of task. Therefore the healthcare sector is endeavouring to perform the same type of task uniformly across ICT systems and organisational boundaries.

The reference architecture should contribute to clarifying **the segregation of tasks between the specialist systems utilised to plan and document patient treatment, and the solutions which enable access to existing patient data through document and image sharing.**

Finally, the reference architecture will be used to **define the overall roles and responsibilities in connection with document and image sharing**, including to describe how interfaces to the outside world are to be managed (for example how to ensure that the documents and images displayed agree with the information in the individual specialist systems).

The business need for a reference architecture for document and image sharing arises from:

- The 2011 budget agreement in which the National eHealth Authority was required to establish a National Patient Index before the end of 2011.⁴
- The guideline targets for the regions under which it was agreed that the regions should be able to exchange images between all the hospitals in Denmark before the end of 2012⁵.

3.3.1 Scope

The reference architecture for document and image sharing deals with access to existing patient data. The architecture only applies to administrative processes directly linked to treatment of patients; not to general administrative management of documents in electronic case and document management systems (ESDH).

The reference architecture does not set a structure for the *content* of documents, but it treats documents as a whole. Therefore the architecture does not deal with searching specific content in docu-

⁴(In Danish)

<http://www.fm.dk/Publikationer/2010/~media/Publikationer/Imported/2010/Kommuneftaler%202011/978-87-7856-954-7.ashx>

⁵ (In Danish) <http://www.regioner.dk/Sundhed/Sundheds-IT/RSI/Pejlem%C3%A6rker.aspx>

ments, combining data content from different documents, or automating functions on the basis of specific content/data in a document (e.g. alarms if medication is suggested which conflicts with the patient's laboratory values). The reference architecture describes a level at which complete documents or images as a whole are included in workflows in which they are considered by health personnel.

The reference architecture currently does not deal with possibilities to subscribe to incidents, for example changes in underlying registers. This subject is relevant, but not specifically with regard to document and image sharing. This topic will be discussed more generally in connection with describing a reference architecture for national services (planned for 2012). If a model for subscribers is established in this context, there may be cause to revise the reference architecture for document and image sharing.

3.4 Sharing documents and images (the key content of the reference architecture)

Exchange of information in the healthcare sector is carried out in many different ways. There can be direct exchange or transfer of structured data between two ICT systems, structured messages, or information shared between several parties in the form of more or less structured documents. Similarly, common registers have been established in which data is reported and retrieved, e.g. in the Shared Medication Record (FMK).

The reference architecture will define guidelines for how to establish a standardised method of making different types of information (text, images, graphs, ultrasound etc.) available for several parties, without being dependent on the internal structure of the systems communicating with each other.

Document and image sharing enables a decoupling, so that the sender and recipient do not need to know of each other's existence to be able to exchange information.

A set of structured metadata describing documents will be established for searching and processing documents, see the figure below.

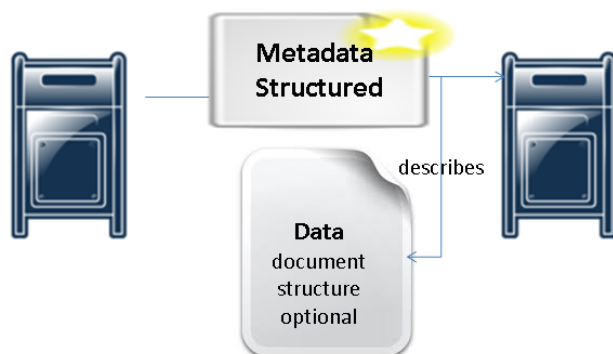


Figure 3 1 Sharing documents

3.5 Use

The reference architecture can be used in connection with specification of requirements for solutions. The reference architecture can also be used in connection with standardisation of interfaces between systems to manage documents and images.

The reference architecture can be used with other reference architectures, e.g. reference architectures for reporting to national registers.

The reference architecture is the general framework for solutions based on document and image sharing. With regard to the specific use, there will have to be a national profiling of the standards selected.

If the reference architecture is not consistent with other reference architectures, standards or project needs, the National eHealth Authority will enter into dialogue with the parties so that the necessary assessments and choices to establish consistency can be made collaboratively.

In order to further develop and improve work on reference architectures, we would like to receive feedback on how the reference architecture is being used and any issues arising in this context. Comments on the reference architecture can be submitted to soaafdelingsposti@ssi.dk.

3.6 Target groups

The reference architecture will be utilised in requirements specifications for ICT solutions in the Danish healthcare sector and therefore it is primarily directed towards ICT decision takers at the Ministry of Health and associated agencies, regions and municipalities, Danish Regions with RSI, Local Government Denmark, Kombit, the eHealth portal sundhed.dk, and MedCom.

In addition the reference architecture is relevant for project managers, architects and developers at public authorities and providers tasked with specifying requirements and designing solutions based on document and image sharing.

3.7 Reader guidelines

The three introductory chapters (Introduction, Vision and Goals, and finally Principles) make up the strategic framework for the reference architecture and these are relevant for both the target groups mentioned above.

The following chapters provide more detail on the health architecture and the technical architecture and these are primarily intended for project managers, architects and developers.

The business-oriented part of the reference architecture is described in chapters 4-6, while the technical part is described in chapters 7-8.

3.8 Development process

This report has been prepared by the National eHealth Authority in collaboration with a number of partners from the health sector and suppliers of ICT solutions to the health sector.

The work group held five workshops during the period 26 August 2011 - 13 January 2012. The work group included:

Jan Thomsen, Capital Region of Denmark (1st meeting)

Søren Zachariassen, Capital Region of Denmark (2nd-4th meetings)

Birgitte Seierøe Pedersen, Capital Region of Denmark (2nd-4th meetings)

Frederik Endsleff, Capital Region of Denmark (5th meeting)

Jonas Lindhardsen, Region Zealand (1st-4th meetings)

Jens Henning Rasmussen, Region Zealand (5th meeting)

Finn Kristian Mathiesen, Region of Southern Denmark

Henrik Tholstrup, Danish Health and Medicines Authority

Johann Brend, sundhed.dk

Jens Rahbek Nørgaard, MedCom

Rikke Andersen, Logica (ITB)

Niels Husted Kjær, Medical Insight (Confederation of Danish Industries (DI) Association of IT, Telecommunications, Electronics and Communication Enterprises (ITEK))

Jens Hvidberg, National eHealth Authority

Thor Schliemann, National eHealth Authority

Esben Dalsgaard, National eHealth Authority

Helle Torp Eklund, Strand & Donslund

Kurt Hansen, Strand & Donslund

Esben Poulsen Graven, National eHealth Authority (chairman until 15 October 2011)

Pia Jespersen, National eHealth Authority (chairman from 15 October 2011)

4 Vision and Goals

4.1 Vision

The digitalisation strategy for the healthcare sector⁶ states access to relevant information as one of the most important goals for IT development.

The strategy points to a step-wise development of digital communication in the healthcare sector and step-wise convergence between local solutions. The strategy is to ensure ongoing migration towards a greater degree of convergence within the areas which provide the greatest benefits, and this migration should contribute to ever greater information-sharing across local solutions.

⁶ *National strategi for digitalisering af sundhedsvæsenet 2008 -2012, December 2007*
(In Danish) http://www.nsi.dk/sitecore/content/Nsi/~media/omNSI/SDSD_Strategi_2008_12.ashx

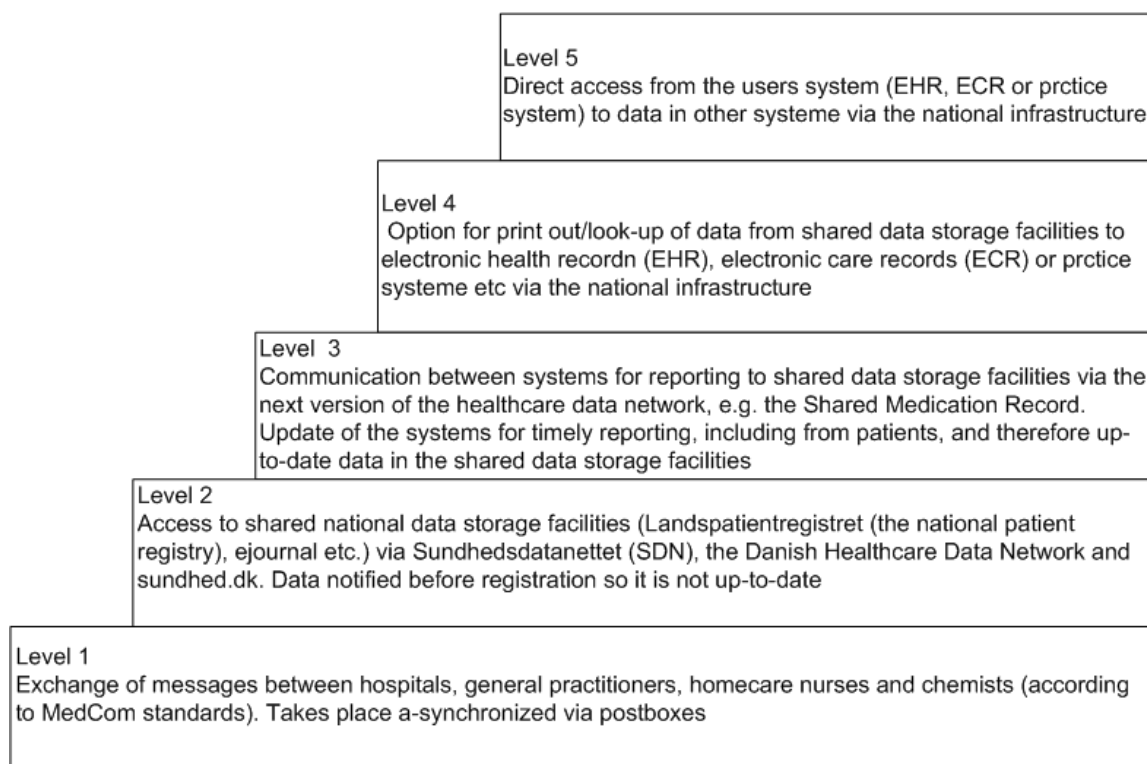


Figure 4-1 Development of digital communication across the healthcare sector. The figure shows how a common communication model is composed of several steps based on MedCom's message-based model (level 1) and in which new initiatives build on and reuse elements from lower steps.

Most ICT solutions in the healthcare sector today utilise communication at level 1 or 2. New common national solutions such as the Shared Medication Record are at levels 3 and 4.

Solutions utilising document and image sharing based on indexing and metadata provide for the first time opportunities to establish digital communication at level 5 in the above model, as healthcare staff will be able to retrieve information from each other directly from their own ICT system.

The architecture proposed makes it possible to share data with content which is not necessarily fully structured and standardised. In documents, it will be possible to display all types of data content with meaning for the consumer: text, images, drawings, graphs, etc. Use of documents means that the ICT system being used does not have to understand the structure or content of the document; it only has to know how different types of document are displayed. The consumer puts the clinical information in the document into the correct health context.

This also means that document and image sharing can support the general patient pathway across organisations and sectors, as well as more specialised collaboration on the individual patient.

Use of indexing and metadata will make it easier to search and retrieve relevant information. An index makes it possible to search for relevant information, independent of the data source or ICT system from which the information originates.

It must be possible to search for all metadata across systems and data sources, and this requires semantic standardization and metadata within the domain in which documents are to be shared.

By basing some of the exchange of information on document and image sharing, it will be possible to increase the rate of digitalisation in the healthcare sector significantly, because it will not be necessary to have a high degree of structuring from the start.

Although the strategy will initially also aim at being able to make unstructured information available, in areas where data is more structured it will be possible to agree to use documents with a higher degree of structuring, and, where it is relevant and creates greater benefit, it will be possible to develop new documents in which data is more structured.

A greater degree of structuring will make it possible in the long term to transfer data to a consumer's own ICT solution and to not just display data in the consumer system, but also compare and process data and thus more directly support the clinical work process. Use of existing standards such as HL7 for structuring will also enable reuse of solutions which have already been exchanged and will increase possibilities to communicate and collaborate internationally.

It should be possible to support the reference architecture for sharing documents and pictures with several standards. The epSOS project⁷ aims at providing access to patient data and enabling management of prescriptions across national borders and it uses the IHE/XCA standard, which is an interface used when there are several existing parties and which is comparable with the IHE/XDS standard used between local registries. This is the background for adopting parts of the IHE/XDS architecture in this reference architecture.

Similarly, a number of countries, including Switzerland and Austria, use IHE/XDS in projects aiming at presenting patient data across organisations⁸.

Adopting parts of the same architecture opens for the possibility to establish collaboration on further development of the standards, and to establish collaboration on development and implementation of solutions based on sharing documents and images.

The proposed architecture will also make it possible to use on-the-fly documents, i.e. access a data source and create a document which contains a snapshot image of the content in the data source. In turn, this will make it possible to retrieve data in systems which do not have actual document storage, but in which the document is created 'on the fly'. For example, there could be a need to collate and display an appointment booking list for a specific day or period.

4.2 Goals

This section describes the health goals for the reference architecture which are to underpin the vision.

⁷ epSOS – Smart Open Services for European Patients
<http://www.epsos.eu/>

⁸ Medicare

The figure below describes how, by establishing a common standardised infrastructure, it is possible to standardise the way in which documents are communicated. The infrastructure makes it possible to search and retrieve documents across specialist systems.

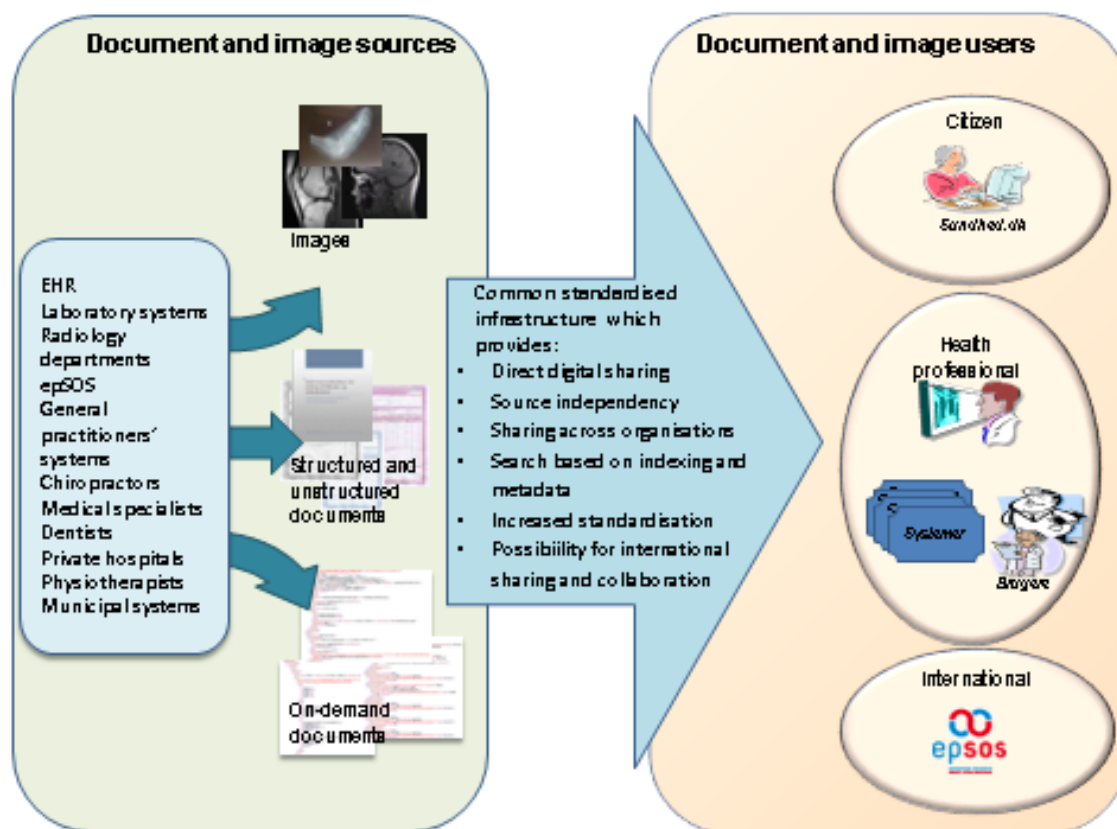


Figure 4-1 Goals

Parties

The reference architecture will support all relevant parties, i.e. health professionals and citizens. Health professionals in this context cover a wide group, as they can be employed at many different locations (hospitals, the probation services, municipalities, etc.) in Denmark or in other countries, although they have in common that they provide health services for the public.

Presentation

The reference architecture will support display of data with as few constraints to existing technical solutions as possible.

Main processes

Document and image sharing will support the main processes described in section 6 and thereby contribute to simplifying, and making more efficient, exchange of information within the individual sector of the healthcare system and across sectors.

Business services

A number of business services will be established with well defined operations which support workflows in connection with searching and displaying documents and images. Business services are described in section 5.

Metadata

Search and retrieval are based on a structured set of metadata which ensures that all relevant information is displayed and available.

4.3 Value creation from the reference architecture

Standardising the way in which documents are communicated between specialist systems will make it possible to reduce the costs of (further) development of specialist systems, as it will no longer be necessary to establish closer integration to other ICT solutions if there is only a need to retrieve and see information. Document and image sharing is therefore a supplement to traditional web-service-based integration, which still requires special development for each specific data interface.

Moreover it will be possible to simply and efficiently make the same information directly available to health professionals and individuals, thereby contributing to patient involvement in their own treatment (patient empowerment).

5 Principles

This section reviews the principles of the architecture forming the basis for the design of the reference architecture. The basis for selecting the principles originates from the architecture principles adopted for the health sector⁹.

Business principles
Realisation of a national architecture and infrastructure is to be step-wise and determined by needs.
Data/documents to be made available digitally with as few constraints as possible.
Delimitation of formats supported must be governed by what is widely supported by the market (now and in the future).
Types of document to be determined on the basis of clinical relevance.
Read only.
Support use of international and national standards.
Information principles

⁹ The architecture principles for the health sector (in Danish) Arkitekturprincipper for sundhedsområdet, Sammenhængende Digital Sundhed i Danmark, 2009 <http://digitaliser.dk/resource/833256>

Standardization of metadata is a national task.
The document sources are responsible for data content.
The document consumer is responsible for use of the document.
Technical principles
High availability/up-time.
Search/display must be independent of document source.
Use of national infrastructure.
Transparent search across indexes.
Standardization of document index and repository is a national task.

5.1 Business principles

Title	Realisation of a national architecture and infrastructure is to be step-wise and determined by needs
Description	The proposed architecture makes it possible to establish sub-elements of the same architecture and infrastructure which have independent utility value.
Rationale	Document and image sharing enables increased rate of digitalisation in the healthcare sector. This gives an immediate utility value, but can also form the basis for step-wise implementation of standards, which makes it possible to establish a higher degree of structuring in the documents.
Implication	The reference architecture should account for the long-term perspectives and describe how step-wise development can be supported.
References ¹⁰	F6 Realisation of national architecture and infrastructure should be step-wise and determined by needs, with focus on continuous supply and immediate utility value.

¹⁰ The architecture principles for the health sector (in Danish) Arkitekturprincipper for sundhedsområdet, Sammenhængende Digital Sundhed i Danmark, 2009

Title	Data/documents to be made available digitally with as few constraints as possible
Description	Using metadata, the reference architecture is to support availability of existing documents, without special requirements for technology, and without having to establish the necessary functionality.
Rationale	By making information available digitally as documents, it will be possible to provide clinicians with access to information required for planning and performance of patient treatment. As far as possible, access to documents should be independent of specific technical solutions. It should be possible to search and retrieve relevant information using metadata which describes the content of the documents and metadata should help retain the individual patient in context so that information on several patients is not mixed.
Implication	The reference architecture should only point to specific technical solutions or limitations as necessary. When setting metadata, account should be taken of how availability and context retention can be ensured.
References	

Title	Scope of formats supported to be determined by what is broadly supported by the market (now and in the future)
Description	The reference architecture should contain the foundation for designating the formats that can be used for documents made available across the healthcare sector.
Rationale	The reference architecture should point to the document formats which can contribute to ensuring broad market support, including in the longer term, and thereby increase the rate of dissemination of solutions based on document and image sharing.
Implication	A list of all the document formats supported should be prepared. The list is to be revised regularly in line with technological possibilities.
References	

Title	Types of document to be determined on the basis of clinical relevance
Description	Displaying documents which do not provide important information for the consumer, but which could make searching more complicated should be avoided.
Rationale	In order to ensure that clinicians use document-based solutions, it should be ensured that the types of documents displayed have clinical relevance.
Implication	Individual solutions based on document and image sharing should set guidelines for the types of documents that can be displayed.
References	

Title	Read only
Description	The reference architecture exclusively relates to search and display of existing documents.
Rationale	Sharing documents and images is a supplement to web services or common data storage (e.g. Shared Medication Record - FMK). This makes it possible to share both unstructured and structured documents without constraints from existing ICT solutions.
Implication	Existing documents are to be made widely available for others through browser-based solutions.
References	

Title	Support use of international and national standards
Description	This is a general architecture principle which for this reference architecture means that it should also point to any standards which can contribute to increasing dissemination and rate of dissemination of solutions based on document and image sharing.
Rationale	The use of national and international standards ensures that it is possible to communicate with parties within other sectors in Denmark and with parties abroad. Use of international and national standards also means that there will be a wider range of suppliers and that Danish suppliers can establish a larger market for their solutions.
Implication	It is necessary to assess whether there are international and national standards which are relevant in supporting the goals of the reference architecture. Profiling the existing (mature) standards requires consensus between the parties who are to use the standard. In this connection it will be relevant to incorporate the profiling work completed previously by Med-Com, the National Board of Health, Denmark and others in connection with the CEN standards (equivalent to HL7).
References	Overall architecture principle F2: International, national and local initiatives are to be coordinated with a view to reusing both new and established solution elements, standards and infrastructure.

5.2 Information principles

Title	Standardisation of metadata to be set nationally
Description	A model is to be made for use of metadata in searching and classification of information in documents.
Rationale	The metadata to be used for searching documents should be standardised within the individual domain and across domains, if it is to be possible to manage transparent searches across indexes. It is important that metadata is designed so that the historical information can also be managed.
Implication	An organisation will be established responsible for development and maintenance of common metadata.
References	Overall architecture principle I2: real cohesion via information sharing requires establishment of semantic interoperability in relevant areas, taking into account the required utility value.

Title	Responsibility for data content in documents is with the owners of the document sources
Description	The owner of the individual document source should ensure that the content of the document is correct and readable by other consumers as well as that relevant metadata is in place which complies with common standards.
Rationale	The reference architecture is not concerned with the actual content of documents, but only how to ensure that documents can be retrieved and displayed across the healthcare sector. Requirements for the content of documents exclusively related to quality in terms of health science.
Implication	Responsibilities are to be designated. It should be possible to see in which context a document has been created or is part of. If the document cannot be put in the right context, there is a risk that information will be lost or can be misunderstood.
References	Overall architecture principle I1: for information sharing, clear definition of data-ownership, maintenance responsibilities and consumer policies must be set.

Title	The document consumer is responsible for use of the document
Description	The owner of the document source determines the purpose of the document (as mentioned above). If the document consumer uses the document for other purposes, this will be at his/her own risk.
Rationale	There is a relationship between the objective of an examination and the reply given. Therefore it is not possible to just use a document without ensuring the correct context.
Implication	Responsibilities are to be designated. It should be possible to see in which context a document has been created or is part of. If the document cannot be put in the right context, there is a risk that information will be lost or can be misunderstood.
References	Overall architecture principle I1: For information sharing, clear definition of data-ownership, maintenance responsibilities and consumer policies must be set.

Title	Security of information
Description	Access to documents and images should be in accordance with requirements in the Danish Health Act and the Act on Processing of Personal Data.
Rationale	It should be possible to specify who can have access to what information.
Implication	Security solutions should be established which support authentication and authorisation of consumers and validate that there is an existing treatment relationship.
References	Overall architecture principle I1: For information sharing, clear definition of data-ownership, maintenance responsibilities and consumer policies must be set. Overall architecture principle T1: Security related to cross-cutting workflows must be supported by the national infrastructure.

5.3 Technical principles

Title	High availability/up-time
Description	Sharing images and documents should support day-to-day work at the clinic and a high level of availability of relevant information should be ensured. There are therefore performance requirements, e.g. regarding up-time and response times.
Rationale	High consumption-rate is a success criteria for document and image sharing, and therefore consumers should be confident that they can rapidly and effectively access relevant and up-dated information.
Implication	Access to registries/indexes has higher priority than access to individual repositories. Decoupling from local systems so that break-downs do not block primary work processes.
References	Overall architecture principle T4: availability is to be incorporated from the start in national architecture elements at all levels of the architecture. Overall architecture principle T5: it should be possible to decouple support of cross-cutting work processes from local systems.

Title	Search/display should as far as possible be independent of document source
Description	The individual document source should not have significant influence on the possibility to search or display a document.
Rationale	There should be as few technological constraints as possible, but for some types of document (images), because of large amounts of data, it may be necessary to introduce special technical conditions.

Implication	There should be an assessment of the individual sources in order to ensure that their design does not lead to constraints which may give availability problems.
References	Overall architecture principle T2: technical interoperability is to be achieved through use of widespread, open standards. Overall architecture principle F8: primary work tasks should not be obstructed or delayed by supporting ICT tools.

Title	Use of national infrastructure
Description	The reference architecture for sharing images and documents must use the common national infrastructure.
Rationale	Document and image sharing should be able to act as an integrated part of the national infrastructure and ensure reuse of solutions.
Implication	The reference architecture should incorporate use of the national infrastructure and security infrastructure in describing frameworks and use of standards.
References	Overall architecture principle T1: security related to cross-cutting workflows to be supported by the national infrastructure.

Title	Transparent search across indexes
Description	It must be possible to search for documents across different indexes.
Rationale	If there are several indexes (nationally or internationally), there is a need to be able to search and display documents located in another domain.
Implication	There should be clarification of how it can be made possible to search across indexes (possibly by mapping metadata). Standardization of metadata is a requirement to ensure transparent searches.
References	Overall architecture principle T4: availability is to be incorporated from the start in national architecture elements at all levels of the architecture.

Title	Common standards for national document indexes and repositories
Description	Design of national document indexes and repositories, including format requirements etc., is to be uniform across domains. This does not apply for documents which are only to be used locally.
Rationale	Standardization will increase availability and improve usability for document and image sharing.
Implication	The reference architecture has to designate the infrastructure elements which need standardization. Responsibility for maintenance of document indexes and repositories must be clearly defined.
References	Overall architecture principle T2: Technical interoperability is achieved through use of widespread, open standards.

6 Concept model

6.1 Overview

The model is a concept model for document and image sharing at conceptual level. That is, a model which is not linked to specific implementation. It is a model outside any specific technology or platform. The concepts, relations etc. have been raised to conceptual level so that the model can form the basis for many different implementations of document and image sharing.

Basically, document and image sharing comprises health information represented in a *document* which may have associated descriptive specialist information. The various health objects are represented by a *document* object.

Conceptual model

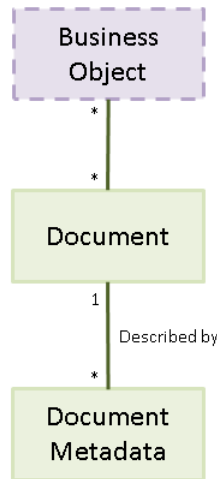


Figure 6-1 Simple concept model

Documents are regarded as independent objects and are not included as sub-documents of each other. However, documents can refer to each other and the same document can refer to different health objects. For example it may be an image document connected to a description (text and graphs) which exists as an independent document, but is linked to the same patient and examination.

The reference architecture, and thus also the concept model below, describes the architecture around the documents and document exchange (including associated metadata), as well as how different concepts around documents are linked together.

On the other hand, the reference architecture does not involve how the health-specific data and health objects are modelled and described, for example the data content around an X-ray image. This is left for the specialist systems. However, the system-technical goals affect the exchange formats and standardization of these.

The concept model describes the concepts and their mutual relations, but it does not describe processes, players, flows or specific instances of concepts when sharing a document and using it.

On the basis of IHE XDS.b and XDS, the figure below shows an example of a close-to-implementation specification, which includes a set of system players between whom there is interaction (called transaction in IHE XDS). The arrows in the figure indicate the interaction between the players and the direction of the initiative.

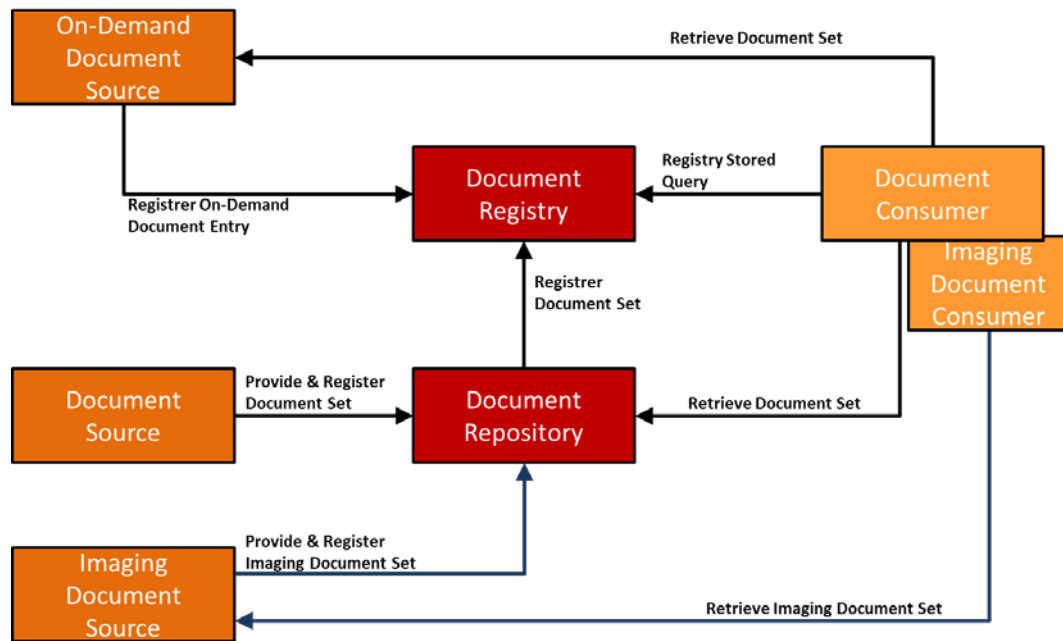


Figure 6-2 IHE XDS player-interaction diagram

The IHE XDS operates with three types of document source (Imaging Document, Document and On-Demand Document). Imaging Documents and On-Demand Documents both store displayed documents and images for consumers where indexes are used so that a consumer can search documents and images and subsequently receive information on where they can be retrieved. On the other hand Document Source uses a Repository to store available documents. This is also where the consumer retrieves documents.

Details regarding IHE XDS players and interaction are described in more detail in the sections on System Goals and Technical Implementation below.

6.2 The Concept Model

The basic model is built up around the central concept, "Document", which contains the health information and covers both text and image documents. The concept model is shown graphically in the figure below, which also shows the relationships between the concepts.

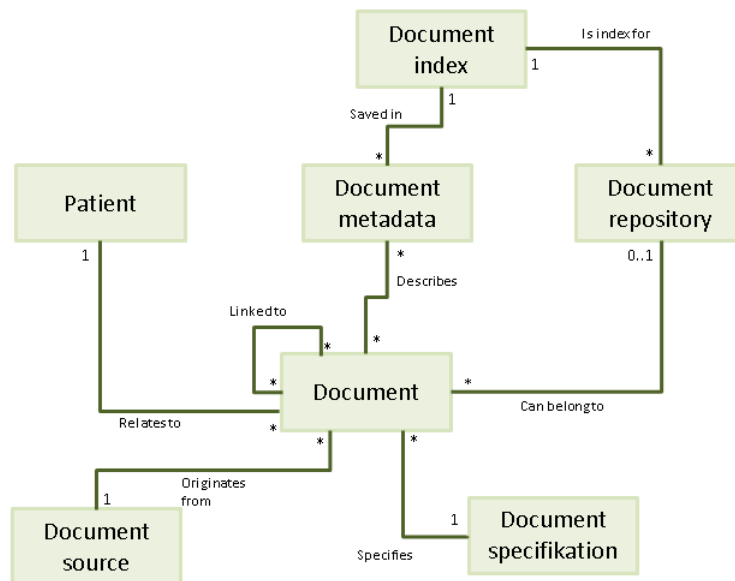


Figure 6-3 Extended concept model

A document pertains to one patient, and many documents linked to the patient can be created in connection with one or more treatments. The documents can be related (linked) with other documents. Relations will primarily be of a more technical nature, including describing the relationships between new and old versions, transformed versions, as well as supplements and addendum to existing documents. Relations cannot be used to describe a patient pathway with associated documents.

A document is described by a series of metadata which can be used to search documents. This metadata is stored in a document index (document registry) in which it is possible to search for documents. A document index includes one or more document repositories, so there does not have to be a dedicated index for each document repository. A document can physically be located in just one document repository.

Document sources are a unique identification of the system (or equipment) which has generated the document and possibly stored it in the document repository.

The document specification contains information about the structure of the document, e.g. the document format, type etc. For example there is the CDA specification which Austria has developed for letters of discharge in which the CDA specification would be an example of a document specification.

6.3 Document concepts

This section defines and describes all the concepts included in the concept model for the reference architecture.

Document

Definition:	The object is the digital document	
Description:	The object is the central object in the concept model and it is a collection of health information containing text or images. Digital documents can be on-the-fly (on-demand), i.e. the content is not generated until the time it is read/retrieved. A document can be described as a collection of data which together make up an entity.	
Examples:	epicrisis, X-ray images	
Information content:	Identification:	Unique identification
	Content:	Health information in structured or non-structured format

Document source

Definition:	A health system, storage or equipment which generates documents	
Description:	The source is where the document is created. X-ray equipment and other scanners will be sources of images, for example.	
Examples:	X-ray equipment, laboratory system, medical-practice system	
Information content:	Identification:	Unique identification
	Type:	Type of document source, system/type of system, equipment. Will possibly be included in metadata for document

Document specification

Definition:	Specification of content, structure and quality for the various types of document
Description:	Documents should be uniform in terms of content, structure and quality so that they can be exchanged, read and understood by the

	recipient	
Examples:	DICOM, CDA specification	
Information content:	Identification:	Unique identification
	Name:	Name on document specification
	Type of content:	Type of document
	Structure:	Format specification for structure and content
	Set of attributes:	List of attributes with associated set of values for the various types of document

Document metadata

Definition:	Data which describes document, document specification and document relations	
Description:	Data which makes it possible to identify a document, search for it and, using metadata, determine whether a document is relevant for the document consumer	
Examples:	Patient ID, X-ray, time	
Information content:	Set of attributes:	List of attributes (key in key-value pair)
	Values:	Values for attributes (value in key-value pair)

Document repository

Definition:	Collection and storage of physical digital documents
Description:	A document repository is a physical collection, location and storage facility for documents. A document repository contains the physical documents. There are also possibilities to generate on-the-fly documents from a repository. With regard to images, this means that there are two repositories in an IHE XDS configuration, a repository which stores the document manifest (XDS Document Repository) and a PACS system which stores the actual images ¹¹ .

¹¹ IHE XDS definition of repository: A document repository is responsible for storing documents in a transparent, secure, reliable and persistent manner and responding to document retrieval requests.

Examples:	"Image library",	
Information content:	Identification:	Unique identification of document
	Name:	Name on document
	Physical document:	The physical digital document

Document index

Definition:	A document index is a list of registered documents with associated metadata.	
Description:	A document index contains an overall list of documents located in the document repository(ies) linked to the index. In order to find a relevant document it is necessary to search in the document index in which the registered reference can be used directly or indirectly to retrieve the document.	
Examples:	Metadata and reference to document in the document repository	
Information content:	Identification:	Unique identification of document
	Document reference:	Direct or indirect reference to document in the document repository
	Date of creation:	The date the document was registered in the index
	Metadata:	Metadata for the document

Patient

Definition:	The person described by the content of the document, or on whom the document contains information	
Description:	A patient is a person who is part of a treatment and for whom health information has been collated in documents or images	
Examples:	Person identified through civil registration number (CPR)	
Information content:	Identification:	Unique identification of patient, e.g. CPR number
	Name:	Name of patient
	Address:	Address of patient

6.4 Relations

Documents *relate* to a patient

Definition:	Documents are linked to a specific patient through a relation to the patient
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A document specification *specifies* a document

Definition:	Documents linked to a given specification which defines the structure and content of the document
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Document metadata *describes* a document

Definition:	Through this relation, descriptive metadata can be linked to a document
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A document *originates* from a document source

Definition:	A document originates from a document source which has created the document, or will be able to create the document on request
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A document *can belong* to a document repository

Definition:	A document can belong to a document repository in which it is stored. For on-the-fly documents this relation does not exist (implies further logging requirements)
-------------	--

Document metadata *is stored* in a document index

Definition:	Metadata is stored in a document index, but only in one index
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A document *is linked* to other documents

Definition:	Documents can be linked so that if the documents which are perceived as objects are related to each other, a link can be created between them. E.g. an addendum to an existing document or between versions of documents
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A document index is an index for a document repository

Definition:	A document index is an index of the documents registered in a document repository. A document repository can only have one document index, whereas a document index can index several repositories.
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6.5 The life cycle of documents and metadata

This section describes the life cycle for the central concepts in the reference architecture from the health perspective.

Concept	Description of life cycle
Document	When a document is made available for consumers, the content of the specific document cannot be changed. If there is a need to add information or change the existing content of a document, a new document has to be created containing the changed information. Although the document content itself cannot be changed, the status of the document is not subject to the same restrictions. A document can have the following status: • Draft • For comment • Approved • Obsolete (deprecated) The on-the-fly documents have a different life cycle, as the status above applies for the document template registered in the index, but not the documents themselves. The document sent to a consumer is a snapshot of the data in the document source. Immediately after it is generated, the document source will consider this version of the document as deprecated, but there will be no stored version of the document with this status.
Document metadata	Metadata for a document can be changed as a whole in real time. However, there will be specific metadata which can only be designated a value after creation of the document in the index. This is specified in more detail in the section below on technical implementation

7 Processes

Document and image sharing can be an advantage in workflows when the health professional needs to retrieve information about the patient from many different sources in order to assess the general health of the patient or to assess which examinations and treatment are relevant in the given situation.

The following lists a number of processes in which document or image sharing would be able to improve the decision basis for clinicians even though the information is not structured and standardised, or at least is only slightly structured and standardised.

- Medical examination of a patient referred to the hospital by a general practitioner when insight into the patient's general condition is required. In this context the examining physician will usually search for the previous epicrisis from relevant hospital contacts, laboratory test results, image diagnostics and medication data.
- On admission, when patients are not always able to give the necessary information regarding their health and medication, it will be relevant for the physician to be able to see information from the patient's own GP, from previous contact with the hospital, from the Shared Medication Record (FMK), etc.
- Within image diagnostics, the radiologist uses the referral as well as X-rays to prepare his report for the treating physician. In connection with his report, he can have to access previous X-ray reports in order to fully understand a patient's condition or to assess whether the disease has developed.
- According to the Executive Order on X-rays, (*røntgenbekendtgørelsen*) personnel in image-diagnostics departments should ensure that patients receive a little radiation as possible. When planning patient examinations, it is important to be able to retrieve previous images in order to assess whether these can be used instead of taking new images.
- For patients with long-term contacts with the healthcare sector and many different players, it is important that the information necessary is available, e.g. in connection with transfer or referral to another hospital, possibly in another region, which does not have direct access to existing data on the patient. In this context, access to relevant information can contribute to having the necessary resources in place so that examination and treatment of the patient can be immediately initiated.
- Increasing specialisation in the healthcare sector means that there is a need to be able to organise multi-disciplinary conferences between specialists from several medical specialities from different regions in order to plan diagnostic evaluation or treatment for the patient. This applies both for patients with complex needs (e.g. patients with a cancer diagnosis or cardiological illnesses), and for patients whose treatment is local, but where there can be a need to confer with specialists on future treatment.
- If a patient has many appointments with different health professionals, e.g. chronic patients or cancer patients, it will be possible to compare an overview of all the patient's existing appointments in order to coordinate booking other appointments for the patient.

- Support for cross border mobility in Europe. In the epSOS pilot project, patient summaries and medication information are already being exchanged, but the goal is to expand the volume of information that can be exchanged.

7.1 Examples of workflows (use)

As described above, document and image sharing is primarily about being able to retrieve existing patient data so that it can be incorporated in a decision basis. Therefore it is possible to present process support with the following generic use cases, the first of which deals with searching documents placed in a repository, while the second involves searching for on-the-fly documents from sources which enable generation of a document on demand.

7.1.1 Document consumer searches for documents on a patient

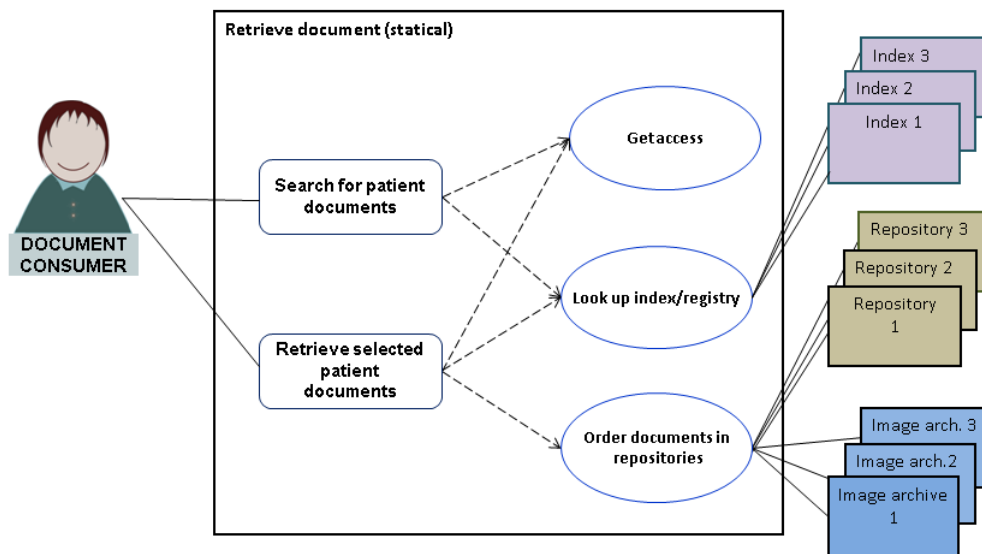


Figure 7-1 Retrieve documents on a patient

In the first case (figure 7-1) the document consumer is searching for documents for a specific patient. The document consumer has the required rights and gets access to look up in an index in which he can see an overview of the documents available on the relevant patient (via metadata). After this the document consumer chooses which documents are relevant for him, and these are re-

trieved from the repository and made available for the consumer. If there are images, there may be two repositories, one of which contains a "manifest" of references to the image in PACS (the actual image archive).

7.1.2 Document consumer searches for on-the-fly documents about a patient

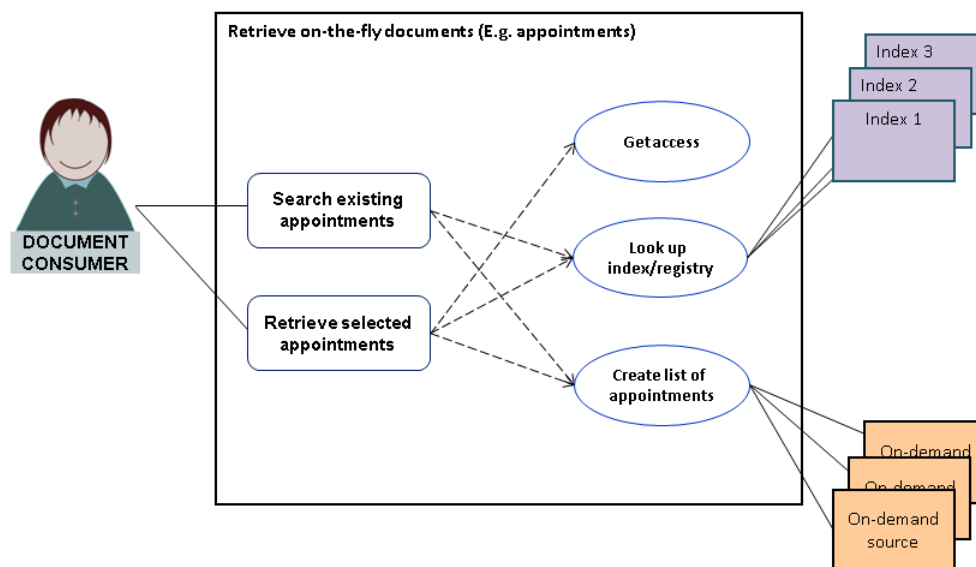


Figure 7-2 Retrieve on-the-fly documents on a patient

In the second use case (figure 7-2), the document consumer wants to book a new appointment for a patient. As the patient's illness requires examinations and treatment with different health professionals, and therefore it is likely that the patient has already booked appointments, the document consumer wants an overview of the patient's existing appointments. The document consumer has the rights necessary and is granted access to look up in the index (via metadata). On the basis of the information in the index, the document consumer retrieves the selected appointments for a required overview (this may be for a given period, for example). On the basis of the information in the local booking systems which are registered in the index, an on-the-fly document is created on-demand, which shows a list of appointments as they are at the moment the list was created.

7.2 Examples of workflows (creation of documents)

7.2.1 Document source registers document and metadata at index/registry and repository

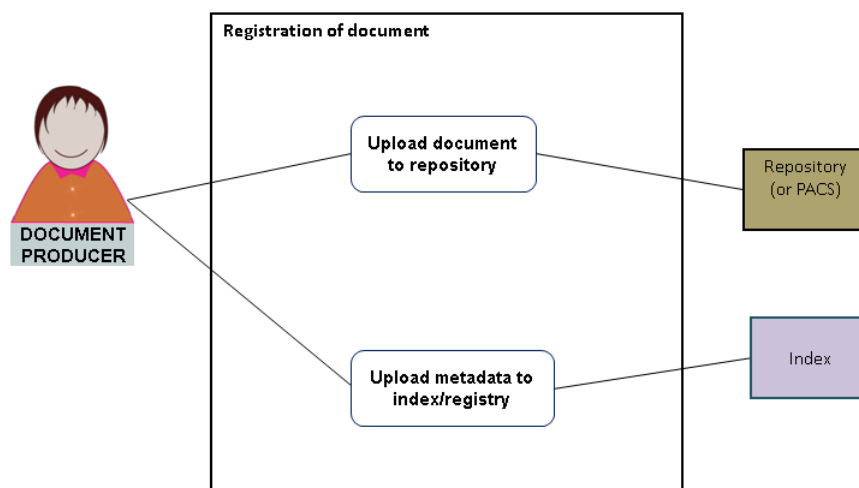


Figure 7-3 Register document about patient

An owner of a document source makes a document and associated metadata available (figure 7-3). The document is placed in a repository which is integrated with an index/registry which enables searches for the document. Images are registered in the usual Pacs systems and a manifest is placed in the repository. This will be apparent from the information registered in the index about the document.

7.2.2 Document source registers an on-the-fly on-demand document in an index/registry

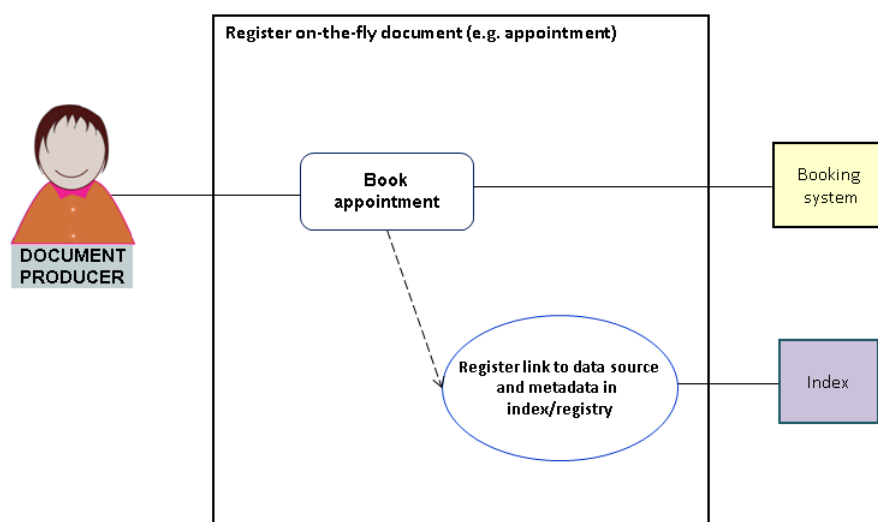


Figure 7-4 Register on-the-fly document about patient

An owner of a document source makes data available in an index/registry (figure 7-4), but without uploading the document itself to a repository. A link is registered in the index which makes it possible to access the information in the document source itself by creating an on-the-fly on-demand document.

7.2.3 Deletion of documents and document information (metadata)

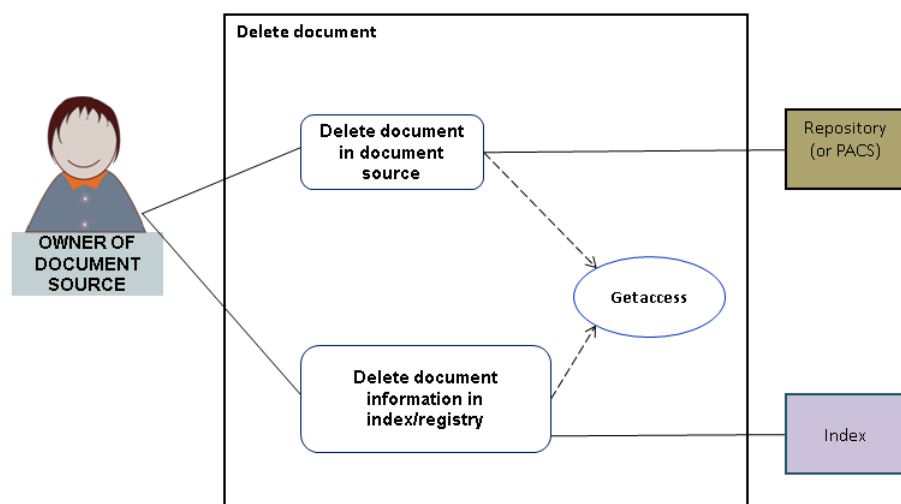


Figure 7-5 Delete document about patient

An owner of a document source may need to delete a document in a repository and the associated metadata in the index, e.g. if the document contains errors (figure 7-5).

8 Services / business services

The reference architecture describes a set of business services to be displayed and implemented by solutions which realise all or part of the described reference architecture.

Business services are derived with a view to supporting the concept model and to support the processes described above. Finally the result of a completed bottom-up process is included, in which the IHE XDS specification is reviewed in order to identify the health-oriented services which are either directly or indirectly described in this. The bottom-up process has primarily used the IHE

documents "IHE_ITI_TF_Rev8-Vol1_FT_2011-08-19" and "IHE IT Infrastructure Technical Framework Supplement On-Demand Documents Trial Implementation".

Business services	Description
Search documents	Search is based on various criteria, e.g.: Patient ID, document-type or other metadata
Retrieve selected document	An identified document is retrieved by a document consumer.
Show document	A document is displayed for a consumer in readable form.
Publish document	A document is published by storing it in a repository and registering it in an index or only by registering it in an index.
Publish metadata	Metadata which describes the document is published in an index so that it is available for document consumers.
Update metadata	Metadata for a document is updated without the document being updated.
Update document status	Life cycle status of the document updated.
Remove access to document.	Access to document removed from repository.
Delete document.	Document deleted.
Create document "link".	Two or more documents linked to each other. <i>IHE operates with the following links:</i> - o <i>Replacement</i> - o <i>Addendum</i> - o <i>Transformation</i> - o <i>Transformation-Replacement</i>
Create Patient ID	Make patient ID available so that all documents relate to one, and only one, patient.
Search for document in ex-	Search for documents in another community than the

ternal community	community in which the document consumer is located.
Retrieve selected document from an external community	Retrieve selected document from another community than the community in which the document consumer is located.

9 System-technical goals

This section describes the system-technical goals for the reference architecture for document and image sharing which make it possible to support the vision and health goals described above.

As part of the system-technical goals, the technological trends and current ICT situation is described for areas with a direct influence on the reference architecture or which cover aspects the reference architecture must take into account.

9.1 Technological trends

This section is a review of selected technological trends which are relevant for the reference architecture. A number of technological trends have been incorporated directly into the current version of the reference architecture or have been secured future incorporation.

Below is a description of the selected technological trends and a brief review of the most important consequences for the reference architecture.

	Description and consequence
Semantic search	The general purpose of semantic search is to improve the accuracy of searches by understanding the intentions of the person/consumer making the search and contextualising the meaning of expressions as they are stated/input, regardless of whether this is on the internet or on a more restricted domain, in order to generate more relevant results. This means that: • Metadata must be set up and defined taking into account semantic search. I.e. uniform tagging of the content in the document. • Index/repository requirements to support this extended type of search. This could be according to the same solution concept as images with a manifest, but where semantic search itself will be a subsequent process in relation to XDS. • The context of the consumer and client must be forwarded to an index in standardised form. Consequences • It is recommended that future work within this area be under IHE.
Workflow	Documents are often part of a workflow-like process, in which the workflow is an integrated part of a clinical, or other health system, or the workflow is more cross-disciplinary flows, possibly controlled manually. Documents and images are included in workflows as information or decision-supporting data. IHE is currently studying this area with a view to preparing a future profile. The reference architecture will not incorporate or prepare for future support of workflows, as these are currently supported by the health systems. It should, however, be possible to incorporate shared documents and images in workflows already implemented. Consequences

	• Documents and images utilised and retrieved in relation to the given step in the workflow. This means more, and more-specific, searches. • Prefetch for documents/images could be an option where this can be anticipated. The document consumer is responsible for this. • Data made widely available.
epSOS – Semantic significance and standardisation, including management of ID for patients and clinics	epSOS deals with profiling within semantic significance and categorisation. epSOS works with the following components and techniques: • CDA (Clinical Document Architecture) and PCC (Patient Care Coordination), i.e. the structure in which the clinical information is located. • epSOS MVC (Master Value Set Catalogue), is the set of valid values used to represent the clinical values. • epSOS MTC (Master Translation/Transcoding Catalogue) is the translations of the codes into text. • epSOS Ontology is a way of representing the relationship between the clinical fields. The rationale behind epSOS Ontologi is to provide a linguistic reference in relation to the epSOS MVC. Source: http://www.epsos.eu/technical-background/semantic-issues.html Consequences • The above epSOS material should be highly integrated into definition, specification and standardization of metadata. • If the content of documents is to be standardised completely or partially, the epSOS material

	should also be incorporated. • Standardization of the document content should be managed outside of the reference architecture.
IHE/HL7/ISO dissemination - both suppliers and customers (installations)	IHE/HL7 is becoming increasingly more widespread within the health sector, and IHE/HL7 is now considered as the most dominant and commonly used method of standardization/profiling in the sector, both for suppliers and customers. This trend, with specific focus on IHE XDS, is apparent in Denmark, in Europe and in the US. IHE does not itself prepare actual standards, but it takes its start point in existing standards from ISO, HL7 etc. and it then prepares profiles of these. The profiles are prepared collaboratively between the parties and are realised in specifications/agreements. Therefore, IHE should not generally be perceived as the dominant and most common standardization. The reference architecture only focuses on document and image sharing. Consequences • The reference architecture should follow the standards as much as possible. • The reference architecture should use IHE profiles where these are available with the status "final text" • Danish participation and influence on standardization/profiling is recommended so that Danish perspectives and Danish conditions are supported in the profiles as far as possible. Outside the scope of work on the reference architecture.
Shared archives (local)	Data and information to be made more available through establishing shared archives. This will be done both nationally and at local level, where local initiatives can be within a hospital or at regional level. Data is moved out of specialist systems and into shared archives so that it is possible to share and access this data without having to go through the specialist system.

	Consequences • It should be possible to use the reference architecture at both national and local levels. • State options for dimensioning shared archives.
Web services	Web services are increasingly becoming a de-facto standard rather than a technological trend to display functionality and data, and this is important with regard to migrating away from proprietary solutions and communication towards a more standardized degree of technology support. Consequences • The reference architecture, and the standards/profiles designated under this, should be based on web-service technology as the underlying communication mechanism.
Developments in the volume of data (increasing exponentially "Big Data")	Technological developments within the health sector mean that volumes of data stored and to be transferred are growing all the time. Regarding images, resolution and number of images in a recording/scanning are increasing. 3D images will also accelerate this trend. Consequences • The reference architecture must address the challenges in increasing volumes of data and support redimensioning.
More focus on security / privacy	More data in significantly greater volumes will be made available and this will lead to more focus on security and privacy. Citizens must be confident that only health professionals for whom their information is relevant can access such information. They must be confident that the same security requirements apply, irrespective of the channels through which information is accessed. Consequences

	• Security should be an integrated part of the reference architecture, including consent. • Security should be cohesive and not isolated to solutions implemented in accordance with the reference architecture. • Implies stricter security requirements for information. This is both in terms of attitude and fact.
Patient empowerment/active patients	Patients themselves take part and are actively asked for advice, and they want insight into registered data and images. Consequences • Patients must be able to access their "own" documents and images. This will usually be through the health portal, sundhed.dk, or similar common portals for patients, who should therefore be able to use a viewer, either included in the portal, or via a remote session.
Telemedicine and chronic patients	Telemedicine, whereby modern technology is used to monitor and treat patients in their own homes, entails remote access to data and that data sources are located remotely compared with traditional health-sector solutions. Documents and images are created at the patient's home and this means that these have to be delivered for use by practitioners and for sharing with others. Examples of applications of sharing images and documents within telemedicine include summarising laboratory test results collected locally/at home and video recordings of consultations between physicians and patients. Consequences • Document and image sources can be located remotely in contrast to "normal" sources • A national repository may be relevant to collate data on citizens, but there should be consideration as to whether XDS is appropriate with regard to collection of monitoring data.

	• A national index will give an overview of treatment of chronic patients taking place at several locations.
Cloud computing	Cloud Computing, IAAS, PAAS and SAAS¹², is currently one of the fastest growing ICT areas. Consequences • It is important to ensure that the reference architecture does not cement conditions that block future use of cloud computing. • The reference architecture prescribes that images and viewers are physically located close to each other because of response times and band width. This conflicts with cloud technology principles by which physical location is immaterial (therefore the term "cloud"). • Cloud technology and suppliers must comply with legislation.

¹² IAAS - Infrastructure as a Service, PAAS – Platform as a Service, SAAS – Software as a Service

9.2 AS-IS ICT architecture

Today, the architecture is characterised by a number of national as well as local and regional initiatives regarding the infrastructure and solutions. The reference architecture and physical realisation of this should therefore be balanced against the other national initiatives and it should be possible to integrate it with existing regional and local solutions.

The existing solutions and initiatives also make up a large part of the architecture framework within which the system-technical goals are to be placed. The existing solutions and initiatives in progress which make up this framework, or are closely related to the reference architecture, are described in the table below, with a description of the relation and significance for the reference architecture.

In the table, relation means documents and information entities and not the transactional part in an inter-active perspective. This is specifically relevant for potential on-demand sources.

Solution/initiative	Description	Relation
NPI	National Patient Index	NPI will include a central index based on IHE XDS
FMK	Shared Medication Record	Potential candidate for document source
IBI	Inter-regional image index	Future solution for document and image sharing to co-exist with IBI and amongst other things share documents and images with IBI
Prescription server	National shared prescription server	Potential candidate for document source
Laboratory systems	Laboratory systems	Potential candidate for document source for specific searches and on-the-fly documents
LPR	<i>Landspatientregistret</i> (the national patient registry)	Potential candidate for both statistical and on-demand documents
PAS/EPJ electronic health record	Patient Administration System/electronic health record	Potential candidate for document source and can already generate documents. Potential candidate for document consumer.

eJournal (eRecord)	Shared electronic record	Potential candidate for document source.
Practice systems	Medical practice systems and practice records	Will act as document consumer in relation to document and image sharing. Potential candidate for document source.
The Danish Healthcare data network (SDN)	Secure network which can only be used by health-sector players.	Solutions implemented in accordance with the reference architecture will initially communicate via the healthcare data network. Performance is an important issue with regard to the healthcare data network
NSP	National Service Platform	Service platform which displays common services and provides access to basic data. NSP also provides a number of security components which can support and be included in the architecture for document and image sharing.
DGWS	<i>Den Gode Web Service</i> (the good web service)	Standards and profiles for web services.
CPR	Danish Civil Registration System	CPR contains allocation and maintenance of civil registration numbers which are used as a common ID for patients with a national-register address in Denmark.
eCPR	Service to extract replacement civil registration numbers.	Allocation of replacement civil registration numbers for patients without a civil registration number or where this is not known.

9.3 International system context and experience

The reference architecture must ensure that international experience is incorporated in the design of the reference architecture, partly through incorporating best practice solutions dealing with document and image sharing, and partly by ensuring that the reference architecture can be included in an international interplay as well as support international system contexts and environments through use of standards and associated profiles.

As described in the following section, to a high degree the international system context will follow IHE standards and profiles, including XDS.

9.3.1 epSOS

epSOS is a European collaboration aiming at designing, building and evaluating a service infrastructure which demonstrates the inter-operability between electronic health-record systems in Europe across national borders through exchange of patient data. For example, it could be possible to exchange patient summaries and electronic prescriptions across EU member states. Exchange of this information and these documents requires a standardised set up. The figure below is an outline of the technical solution used by epSOS. Each pilot country has a national contact point (NCP) which can act as both country A (the patient's own country) or country B (the country the patient is visiting). A contact point must therefore be able to both send information (as country A) and receive information (as country B).

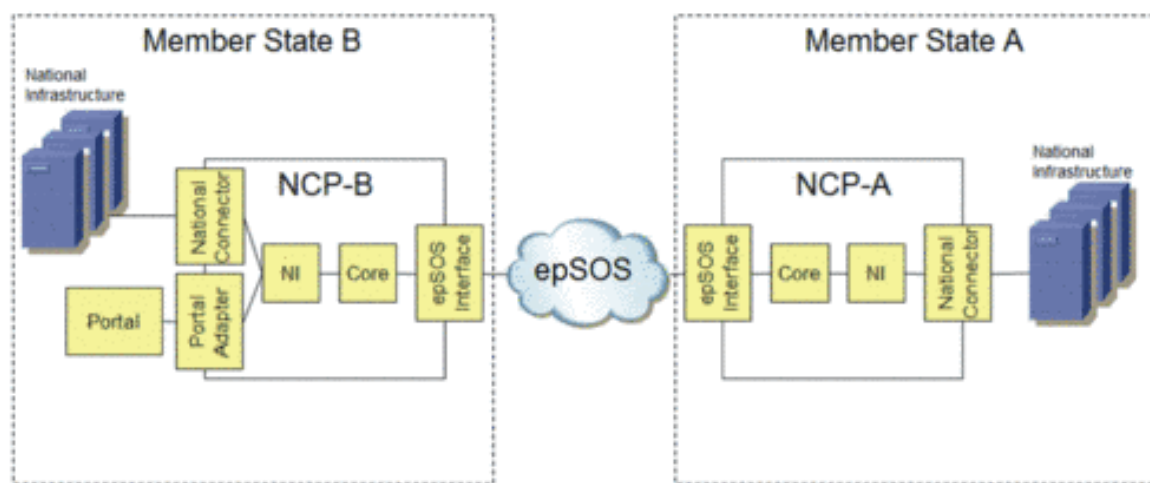


Figure 9-1 epSOS infrastructure

Work in epSOS is ongoing and it is expected to base interfaces for document exchange and associated document content on IHE standards and associated profiles.

9.3.2 Austria - ELGA

In 2006, the Austrian government and provinces decided to set up ELGA (Elektronische Gesundheitsakte = electronic health record), with responsibility for:

- Development/further development of ICT architecture and standards.
- International collaboration. ELGA is a partner in epSOS.
- Programme management for national implementation.

In 2008 national development and implementation of solutions for the following areas was approved and launched:

- Patient index, which is an important requirement for a coherent electronic health-record system.

- Health provider index, which is a fundamental requirement for ELGA and which can also be used by members of the public to find a physician.
- Document register for text and images. The register is based on an index.
- Rules for access which define who can access documents.
- A portal, which is the central access for members of the public to important health information (quality-assured information, health policy, organisational and scientific information).

The ICT architecture is based on IHE XDS profiles which support the objective of ELGA to establish access for health professionals to existing documents by linking them to decentral systems. The most important factors regarding the ICT architecture are:

- Decentral storage of documents (in ELGA repositories and in hospital systems).
- Only selected documents included.
- Standardised documents.
- Standardised document retrieval.

Guidelines have been prepared for the standardised documents to develop CDAs with clinical content. At the moment HL7 CDAs have been developed for the following documents:

- Letters of discharge
- X-ray descriptions
- Laboratory test results
- Medicine

The ICT architecture is further described and illustrated in appendix B.

9.3.3 Switzerland

Switzerland has an overall goal that by the end of 2015 access to electronic health records (ePatient dossiers) will be introduced for all Swiss citizens. Access includes treatment-related information independent of time and place. In 2009 the steering group approved adhesion to the IHE philosophy and 12 fundamental guidelines were adopted for development of patient dossiers.

1. Centre on the individual
2. Greater expectations for access to data
3. Voluntary for patients to use eHealth

4. Protection of information
5. Access without additional cost
6. Collaboration
7. Realistic steps
8. Information and transparency
9. Incorporation of international experience
10. Legal foundation
11. Other applications
12. Contracts

ICT architecture in Switzerland

In Switzerland it has been decided that each state (canton) is to implement local infrastructures based on IHE XDS.

A gateway will be established between document-registry players in states based on the IHE XCA profile, so that documents can be shared across borders between states.

On the basis of requirements in Switzerland and experience from other successful eHealth projects, a number of specific choices for use of standards have been made.

The standardisation process is based on Integrating the Healthcare Enterprise (IHE) use cases, and especially the integration profiles from the IHE domain IT Infra structure (IHE ITI):

- XDS for document exchange
- PIX/PDQ for patient identification
- XUA for authentication
- ebXML as web service profile

9.3.4 Compilation of international experience

The most important experience and similarities from the above projects, which have either been implemented or are under implementation, and therefore have been included as the basis for preparing the reference architecture, are use of IHE/XDS and IHE/XCA for profiling and to link across domains at national and international levels.

9.4 System image To-Be architecture

This section describes the required system image and addresses three perspectives and application scenarios:

- The international perspective
- The national perspective
- The local perspective

9.4.1 The international perspective

Sharing documents with foreign health professionals is supported through a single national contact point which will implement IHE XCA (Cross Community Access). A national contact point is also in full agreement with the preferred architecture in epSOS. Utilisation of IHE XCA also gives a well defined, standardised and player-independent interface. The national index (and document retrieval service) must be reachable from this contact point and the national contact point must make the international index-search and document-retrieval services available on the healthcare data network and the national service platform.

9.4.2 The national perspective

The structure for affinity domains, indexes and repositories etc. should take into account the architectural framework of the reference architecture, technological trends as well as existing solutions and anticipated future solutions.

Therefore, the following apply:

- There are existing solutions for document and image sharing, including IBI (inter-regional image index). IBI is defined as an affinity domain.
- Support for the upcoming NPI which is developed around an index which allows for optional linkage to a repository.
- Based on standards. The principles state that components and interfaces should be based on standards.
- International experience and collaboration with specification that IHE standards and interfaces be used.
- Compared with typical target groups for standards, Denmark is a small area, and this can be exploited to achieve as flat a structure as possible.

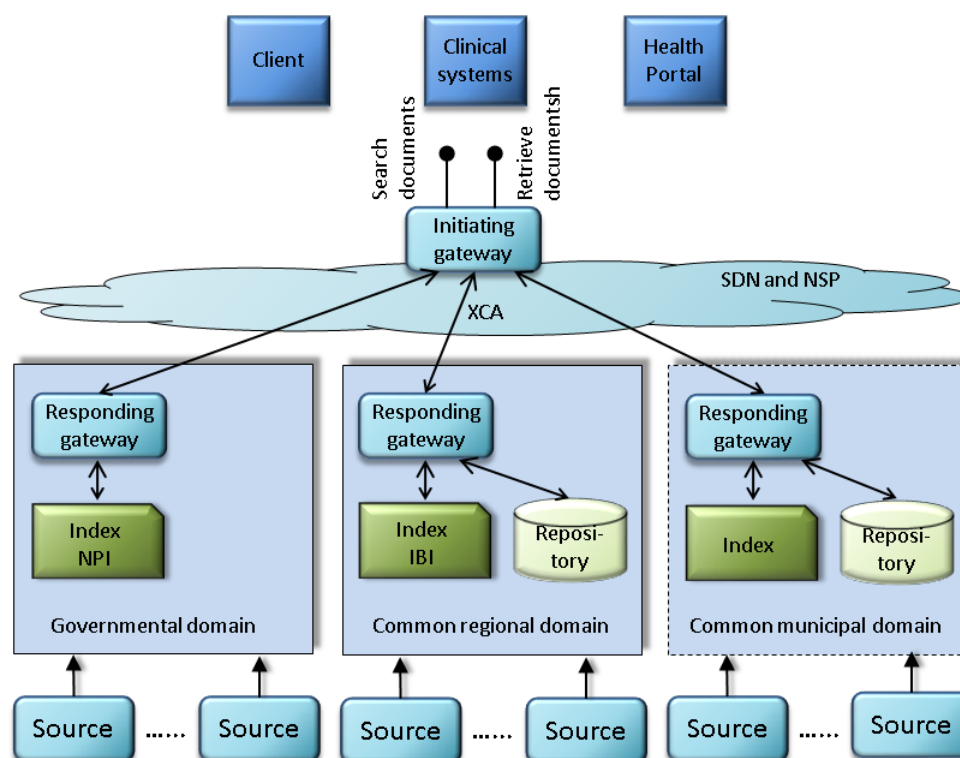


Figure 9-2 The national perspective

The national structure for indexes and repositories currently includes two nationwide indexes.

- An index established under the NPI project, including a number of central registers and solutions. The state is responsible for this.
- An inter-regional index which supports documents and images, including the existing IBI. The regions are responsible for this.

In an IHE context, this means that the structure at national level currently includes two affinity domains, as an affinity domain only has one index. In the slightly longer term it is possible that the municipalities (local government) will also want a common affinity domain in which documents relevant for municipal cooperation can be shared. Furthermore it is important to decide whether data from private-sector players should be linked to one of the existing affinity domains or whether a new one should be set up (and if so, who is to be responsible?). Similar clarification is required with regard to collection of citizens' own data.

Although the individual document consumers must have access to search and retrieve documents from several affinity domains, in practice this will be as if it were from one domain. Affinity domains existing at national level will be subject to nationally adopted guidelines and standards for interfaces, documents, types of documents, metadata etc. Furthermore national search services can be established on the national service platform which searches across these national affinity domains such that the individual consumer

systems do not themselves know about the number and location of the individual affinity domains and do not themselves perform searches across these.

IHE's "Cross Community Access" (XCA) profile can be used as a standardised interface for the individual affinity domains. More precisely, the individual national affinity domains should have an XCA "responding gateway" established. This could possibly be made available in a future version of the national service platform (which can be set up in each affinity domain).

In order to secure operational stability and efficiency, a service level agreement (SLA) will be established for each affinity domain. Moreover, the number of affinity domains will be kept low (2-5). This means that if documents from a source are to be shared nationally, these will have to be "connected" to one of the existing national affinity domains. Therefore a new national affinity domain will be established for each local index or repository in existence at a hospital, in a region or in a municipality.

9.4.3 The local perspective

If a person or an organisation has a local document source or repository containing documents which are to have national access, it will be necessary to contact a person responsible for a nationwide affinity domain. This means that regional parties should contact the IBI (inter-regional image index).

The nationwide indexes for documents and images will generally contain registrations which can also be found in local indexes, but it is possible for the local indexes to contain registrations which have not been forwarded to the nationwide index.

Only document consumers belonging to the local affinity domain can search in the local index. If a document or image registered in a national affinity domain is to be displayed, the document consumer has to search and retrieve the documents in the national affinity domain. It is not possible to search directly in other parties' local index. This should be done through national indexes (for example the inter-regional image index on the health data network, or through national services on the national service platform).

The nationwide affinity domains themselves are responsible for determining how such document sources, repositories and local indexes are to be "connected" to the domain. The domain simply has to meet national standards (including SLA, see section above).

9.4.4 Connection through the inter-regional image index

As an example of how connection can take place, the following describes how regions have decided that local repositories are to be connected to the inter-regional image index.

The idea is that documents in the local repository are replicated to a common regional repository. The local repository acts as document source for the common regional repository (registration in repository is in accordance with IHE XDS). See figure below:

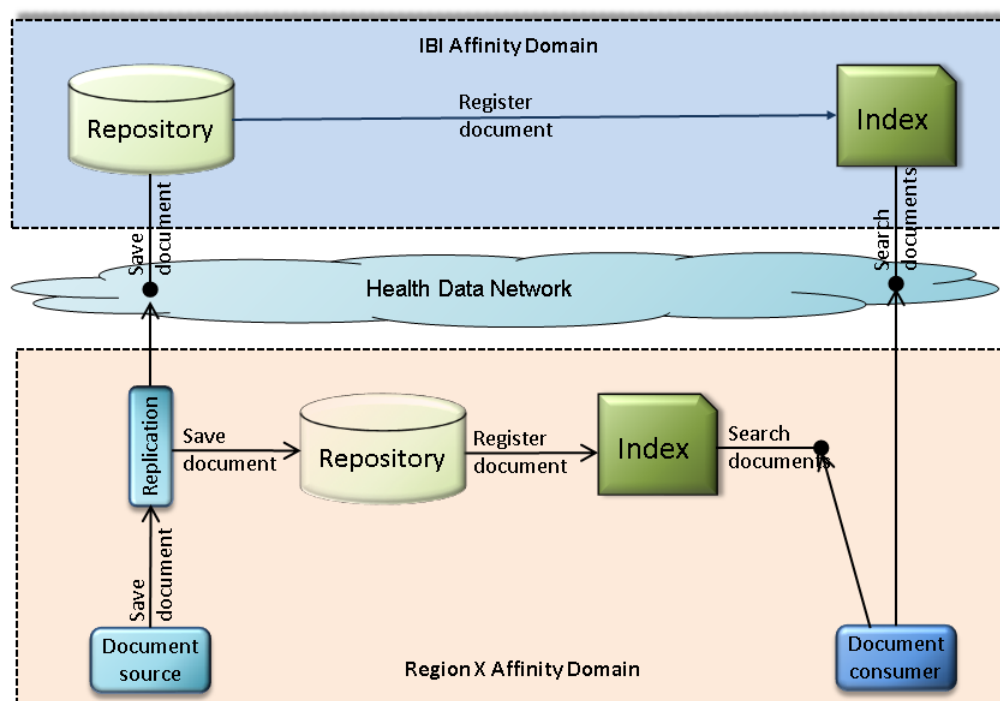


Figure 9-3 The local perspective

In order to control the content of indexes and repositories, only the document source which has created a document or an image in the index is allowed to upload new versions, correct metadata or deprecate a document or an image. If others wish to change metadata, for example, the creator of the document/image must be notified, who will then implement the change. For example, a document has to be deprecated in the local index/repository first and the action must then be “replicated” to the national level.

9.4.5 Examples of other types of connection

A nationwide affinity domain can choose to grant access to local information through “redirection” (e.g. using XCA) in contrast with (or as a supplement to) replication of documents from a local affinity domain to the nationwide affinity domain. This is irrelevant for this reference architecture, as long as the nationwide domain follows national standards and complies with the national SLA.

9.5 Patient identification

In the Danish health sector, civil registration numbers are used as unique identification of a patient. In the event that a civil registration number cannot be retrieved, a replacement civil registration number will be assigned, and this can later be replaced with the correct

civil registration number. In this way, patients can always be identified via a civil registration number or a replacement civil registration number.

It must be ensured that the Patient Identity Feed to the XDS index is the same whether it is used at national or local level. In order to accommodate this, national services are made available which can supply updated and unique civil registration information and replacement civil registration information (with the option to connect replacement civil registration numbers to original civil registration numbers, if the patient's identity becomes known at a later stage).

As the source systems are responsible for registrations in one index, the source systems must decide whether changing a replacement civil registration number to an original civil registration number in local systems should give rise to changes in the index. If this is not the case, searches on the index must include requests for civil registration number as well as associated replacement civil registration numbers.

XCPD (Cross Community Patient Discovery) is used in relation to the international perspective. This is recommended because epSOS requires that XCPD be used across national borders.

9.6 Security

9.6.1 Existing security models

This reference architecture points at IHE XDS and IHE XCA as the profiles of standards which support document sharing at local, national and international levels. These profiles describe a number of web services to be used to register documents, search for registrations and retrieve documents.

Such web services must comply with national requirements for security. Over the years, requirements for this area have been laid down by various fora (the National Board of eHealth, *Sundhedsvæsenets arkitekturråd* (the architectural council of the healthcare sector), *Det nationale informationssikkerhedsråd* (national information security council), *Det nationale begrebsråd*, (national concept council), etc.). The National eHealth Authority is currently summarising the national security requirements in a reference architecture for information security. This will be accompanied by a reference architecture for national services, which will describe how to implement the reference architecture for information security in web service profiles based on SOAP¹³ and SAML¹⁴.

Web services in the reference architecture for document and image sharing are also based on SOAP and SAML and must therefore follow the guidelines in the reference architec-

¹³ Simple Object Access Protocol. A specification of a message format to exchange structured information based on XML.

¹⁴ Security Assertion Markup Language. A standard for exchanging security information between different parties based on XML.

ture for national services and for information security. As part of the standardisation work, it will be appropriate to make a national profiling of IHE's web services, which is based on national standards for security and for document-metadata (or perhaps more generally metadata regarding patient information).

The following applies specifically for document and image sharing:

Data in index (document-metadata) contains information directly related to a person (or perhaps personal information), and this is why the same requirements apply for protection of this data as for other patient data (access control, logging etc.). For example, this means that rules regarding treatment relationship, consent etc. must be enforced in connection with requests on an index.

Therefore, the index must not return references to documents which concern matters about which the patient does not want others to retrieve information (instead the index should return information that references to such documents have been left out).

Thus it must be possible to determine solely from the index whether a given consumer has access to the document to which the index holds a reference. In connection with national standardisation of metadata, it must therefore be ensured that this objective is taken into account. If it is not always possible to determine solely on the basis of metadata (and the consent registration) whether a person is to be granted access to a document, by default this should be treated as if there is no consent. This may be in situations in which the document content is composed of both data to which there is consent and data to which there is no consent.

As the individual source systems are responsible for registrations in the index and thus for ensuring that the index always reflects the documents available, the source systems are also responsible for registrations to be deprecated when data in the sources is deleted according to statutory regulations for limitation. In connection with notification of an index to the Danish Data Protection Agency, it should be determined whether it is sufficient that consumer systems do not have access to such registrations or whether data has to be deleted from the index.

9.6.2 Future security models

Disconnecting searchable keys in the index (civil registration number etc.) and registered keys in repositories etc. (entry UUID etc.) is a step towards alternative security models, in which data is not registered as relating to specific persons, but the identity is set at the time when access to the data is relevant.

However, nothing prevents connection of registration and identity in the individual document.

10 Technical implementation

This section about technical implementation describes the more close-to-implementation aspects which the reference architecture specifies for solutions that offer document and image sharing. The section focuses on interfaces and connection between solution components, for example by specifying the IHE profiles that are to be supported and the profiles that should not be used, as well as the services to be used from the existing infrastructure. In connection with laying down standards, requirements for the technical implementation are clarified.

10.1 Defined nationwide repositories

The reference architecture does not prescribe a specific or final number of repositories at national level, but states those which have initially been suggested to be established.

- A state repository
- A common regional repository
- A municipal repository
- A possible repository for private businesses (medical practices, private hospitals and similar)
- A possible repository for citizen's own data

The following bullets state some areas and conditions which may assist in analysing and deciding establishment of other repositories.

- Legislative reasons for a new repository, for example that other acts and regulations apply
- Data-relevant reasons for separate repositories, for example other requirements for service level, response times, up-time etc.
- Data responsibility for data content
- Ownership of documents and images, for example images for private health professionals
- Conditions for projects and tendersInternational guidelines
- Changes in standards or profiles

10.2 Patient identification and identifier-feed

As mentioned above, civil registration number is the unique patient identification in Denmark. This is consistent with the fact that within an XDS affinity domain, there must

be a unique identification of the individual patient. In IHE XDS terms, this identification is named XDS Affinity Domain Patient Identifier (XAD-PID). In addition, the index alone uses and validates patient ID, whereas the repository does not use this ID.

In principle, all national and local document and image sources can share documents and images with all consumers. This is why it is optimal to use the same patient-feed and subsequent updates for all indexes regardless of whether they are local or national. NSP provides access to, and load of, the full basic data set in the Civil Registration System. NSP also provides subscription to changes in information in the Civil Registration System so that additions and deletions are propagated to the XDS indexes. In order to ensure that indexes are synchronised, the NSP CPR service must be used, and it must not be possible to add false patient IDs.

Replacement civil registration numbers must be retrieved via the NSP CPR service. Merging replacement civil registration numbers and the actual original civil registration number poses a challenge in relation to document and image sharing, as IHE only supports changes from temporary patient ID to permanent patient ID by deprecating documents and registering them again, as this metadata attribute cannot be changed in the index. In previous versions, XDS supported merging of patient IDs, but this is not supported in the current XDS version. However, it is expected that this will again be supported in the future version. At present, this will not be supported, but must be analysed when IHE XDS has this functionality again.

IHE does not specify any profiles or standards for how this feed is to take place; it leaves this as an implementation-specific detail. How CPR data from NSP is to be read in to the index is up to the individual implementations of indexes and repositories.

With regard to the international perspective, the solution model from epSOS will be followed where it has been decided to use the IHE XCPD profile which localises where there is relevant data on a patient, and at the same time translates the patient identification across communities. Patient-feed must therefore contain as much information as possible to conduct the translation mentioned above. In addition to civil registration number as patient ID, patient-feed must contain full name and address.

10.3 IHE profiles and standards

The table below shows the different IHE standards and profiles reviewed. The table also describes their relevance for the reference architecture and states whether a standard or profile is to be used or supported. Where it has been specified that specific standards and profiles must not be used, these must not be used at national level, and it is recommended that they are not used in local XDS solutions, as compatibility with national setups is no longer secured.

In connection with implementation of the recommended standards, how the standards are supported on NSP must be described.

Standard/profile	Description	Relevance	Used
Retrieve Information for Display (RID)	Profile to provide read-only access to patient data. Supports access to documents in CDA (level 1), PDF and JPEG formats etc.	Not relevant as document sharing for the document formats mentioned above is supported in a different manner. Patient data which cannot be displayed as documents is out of the scope of this reference architecture	No
Enterprise User Authentication (EUA)	Profile to support single signon. Describes use of Kerberos tokens etc.	Not relevant as login is supported by national security infrastructure	No
Patient Identifier Cross-referencing (PIX)	PIX supports cross-reference between patient IDs in different ID domains	Not relevant as civil registration number is used both nationally and locally for patient identification. In the international perspective, epSOS has selected XCPD	No

Standard/profile	Description	Relevance	Used
Patient Synchronised Applications (PSA)	Supports seeing data from several different applications/sources in the same solution	Not relevant in relation to the reference architecture. Compiled display of patient data is partly in specialist systems, NPI and health portal	No
Consistent Time (CT)	Synchronisation of time between players. Profile is based on NTP as underlying protocol.	XDS, XCA and ATNA require this profile	Yes
Patient Demographics Query (PDQ)	Request to a Patient Information Server to get a list of patients on the basis of stated search criteria. A form of directory look-up for patient information	Not relevant. This type of functionality will be supported by NPI etc.	No
Audit Trail and Node Authentication (ATNA)	The Audit Trail and Node Authentication profile determines characteristics for a Basic Secure Node. The profile describes security and environment (user ID, approval, authorisation, access control etc.) which are assumed to be valid for a node. The profile defines the basic security requirements for communication with the node using TLS or similar functionality. In addition, the profile defines the basic audit requirements for a node.	XDS and XCA require this profile and are relevant in relation to audit trail and logging. See also above section on security	Yes
Cross-Enterprise Document Sharing	Profile for document and image sharing. XDS-b is the forward-looking profile	The bearing profile in the reference	Yes

Standard/profile	Description	Relevance	Used
(XDS)	used (XDS-a is deprecated)	architecture	
Personnel White Pages (PWP)	States a method to find directory information about consumers. The PWP profile is the first step on an IHE roadmap, which includes digital certificates, encryption, digital signatures, medical credentials and roles	Relevant in relation to information about consumers/practitioners. See section on security above	Yes
Cross Enterprise User Assertion (XUA)	Exchange of claims in relation to authorisation.	Relevant, as the reference architecture describes use of XCA etc.	Yes
Patient Administration Management (PAM)	Exchange of patient master data between solutions in the health sector	Not relevant, as the same patient-feed is used for all indexes, so that everyone is working on the same set of patient master data.	No
Cross-Enterprise Document Media Interchange (XDM)	Basic profile for exchanging documents between two parties, typically through physical media such as USB and DVD. Specifies common file and folder structure etc.	Not relevant, as document sharing is through XDS. Exchange of documents on physical media is outside the scope of this reference architecture	No
Basic Patient Privacy Consents (BPPC)	IHE profile which supports patient consent.	Relevant in relation to consent. See section on security above	Yes

Standard/profile	Description	Relevance	Used
Scanned Documents Integration Profile (XDS-SD)	Profile specifies coupling of health-specific metadata to non-standard health document formats	Will be relevant depending on the type of document to be shared through XDS	Perhaps
Imaging (XDS-I) –B	Profile to exchange images including documents in DICOM format. The profile builds on basic XDS	Must be supported as images are shared through this profile. IBI is based on XDS-I etc.	Yes
Lab report (XDS-LAB)	Describes standardised content in a clinical laboratory report. Content description contains readable content as well as machine-readable content (fully structured). Content in this profile has been incorporated in XD-Lab v2.1 volume 3 'Content' which is a continuation of this profile	May be relevant as specification of format and structure for laboratory reports, if these are to be shared as documents.	Perhaps
Cross Community Access (XCA)	Search for and exchange of documents across communities, where this could be affinity domains, etc.	Used to access documents and images located internationally and to grant international access to images and documents. There are clear indications that XCA will be the future IHE basis for exchanging documents across communities/affinity domains and the standard is used in epSOS, for example. XCA development must be monitored carefully for possible use at	Yes

Standard/profile	Description	Relevance	Used
		international level as well.	
The Cross-Community Patient Discovery (XCPD)	Describes functions to localise communities that hold health data relevant for patients as well as functionalities to translate patient identification across communities	Must be supported as this profile has been chosen by epSOS, and this profile must be used by the NCP (National Contact Point)	Yes

10.4 Other standards and profiles

The table below contains other standards and profiles relevant for document and image sharing. These may be standards and profiles which either support the standards and profiles above, or which are included in the necessary underlying infrastructure.

Standard/profile	Description	Relevance	Used
DGWS 1.01	NSI profile of WS-I	Part of NSP	Yes
OIO-IDWS-H	ITST profile of ITST to support identity-based web services	Relevant for maintaining security credentials during several web service calls	Yes
SAML-2	The public sector NemLog-in (EasyLog-in) solution is based on SAML-2	Relevant to be able to utilise public sector solutions, including NemID, and log in to the common portals	Yes
SOAP	SOAP is a protocol with which to access	IHE displays SOAP-based web ser-	Yes

Standard/profile	Description	Relevance	Used
	web services	vices and the NSP also uses this type	

10.5 Services and service contracts

IHE XDS web services are specified as synchronised as well as asynchronised services and both forms must be supported by the parties that implement one or more XDS players. The reference architecture does not prescribe the use of one form over the other, but that both forms must be supported.

As a general rule, the IHE XDS standard WSDL will be used as the service contract, and changes in relation to the standard must be approved at national level, as all parties must support same standard web-service interface, if document and image sharing is to be a real possibility.

Participation in international collaboration also prescribes use of standard interfaces.

10.6 Document formats

Documents and images which are registered in an index must always be in a format specified on the current positive list. The positive list is developed and maintained nationally, but outside the reference architecture. This list is also expected to change over time according to technological developments.

For document formats on the positive list, the reference architecture includes the principle that a viewer must exist for the relevant format and that this is generally available.

With regard to international perspectives, document formats should use standards and profile specifications where these exist, so that sharing across national borders can be realised. To a great extent, epSOS uses CDA-2 specifications for document formats where there is no standard or profile.

Standards are used in a broad sense and not only in connection with the health sector. Industry standards are also suitable as document formats, for example PDF and JPEG.

10.7 Document types

The reference architecture does not have any guidelines and standards or limitations for the document and image types that can be registered and shared, other than that health documents and images should only be registered where sharing adds value to others than the document source. The document and image source is responsible for this assessment.

10.8 Metadata

Compared to IHE XDS, metadata is data for the document as an object and not for the health content in the document. Therefore, metadata contains very little health information to be searched on.

It is a national task to categorise metadata, where this has not been specified by IHE XDS. If an attribute has been specified in the XDS profile, this is valid. As a general rule, there are no extensions of the set of standards of metadata. This is to be able to use new versions of the IHE XDS profile in the future, for example by acquiring new systems, and to be compatible with international parties that use the IHE XDS standard. However, it is technically feasible to extend with extra metadata, if necessary, or if specialisation of standard metadata is necessary. Extensions are also part of the national task regarding metadata. Local extensions are therefore not allowed.

Appendix A has a table of standard metadata for XDS.

10.9 Viewer

An important aspect of document and image sharing is that there is a viewer available, so that all document consumers are free to use available documents and images. A viewer is also closely coupled to document formats, see section 10.6 Document formats.

Document viewers are established at national level in connection with determining national document types. However, it is a local responsibility for source and consumer systems to meet the standards laid down. In principle, how the viewer is made available falls outside the scope of the reference architecture, but depending on the document or image size, how to optimise response time in the best possible way must be considered when implementing the viewer. For example, IBI offers image viewers as an SAAS solution in which this is offered through remote session. This is illustrated in the figure below.

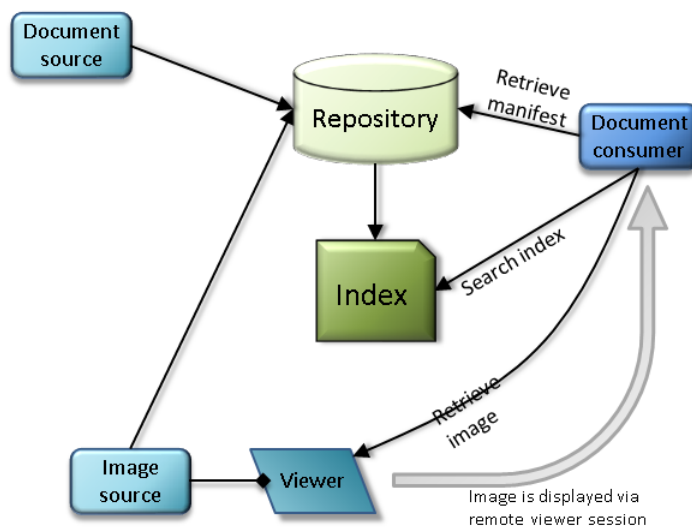


Figure 10-1 Document viewer

A document viewer will be operated locally in relation to the document consumer, typically on the local PC, and must therefore be easily accessible.

For display of documents and images on portals, including sundhed.dk, this can be supported via a browser viewer plug-in (for example Adobe Reader plug-in) and with the above alternative to display images via a remote viewer session.

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Appendix A Metadata

Source for the table below is "IHE IT Infrastructure Technical Framework White Paper 2007-2008, XDS Affinity Domain Checklist". Table contents have not been processed in any way, but have been included to inform about content and scope of standard XDS metadata.

XDSDocumentEntry Attribute	Specialization of Attribute	Source/Query (Bold and Underline if specialized)	Data Type
authorInstitution	Provide a translation if necessary. Define whether or not the XDS Affinity Domain specializes this Attribute in any way. If not then the comment "No Specialization" will suffice. Otherwise, point to the sub-section of X.9.2.1 that specializes this Attribute for the extension. If the Attribute is specialized by defining a Source or Query value that is different from the Technical Framework (i.e. by requiring a value whereas it is optional in the Framework) then bold and underline the altered value and provide an explanation in the sub-section. Same applies for the remaining Attributes.	R2/R	Provide a reference to the sub-section of X.9.2.1 that specifies the list of permitted XON data type authorInstitution values for the of this attribute. For this example, "Refer to X.9.2.1.1 for the XDS Affinity Domain specification of this Attribute".
authorPerson		R2/R	XCN
authorRole		R2/O	Refer to the sub-section of X.9.2.1 that specifies how the authorRole should be specified. If the XDS Affinity Domain wishes to standardize upon a restricted list of possible values then this should be provided in this sub-section.

authorSpecialty		R2/O	Refer to the sub-section of X.9.2.1 that specifies how the authorSpecialty should be specified. If the XDS Affinity Domain wishes to standardize upon a restricted list of possible values then this should be provided in this sub-section.
availabilityStatus		Cg/R	Refer to the sub-section of X.9.2.1 that specifies the list of possible availabilityStatus values.
classCode		R/R	Refer to the sub-section of X.9.2.1 that specifies the list of possible classCode values.
classCode DisplayName		R/P	Refer to the sub-section of X.9.2.1 that specifies the list of possible classCode DisplayName values.
comments		O/P	Refer to the sub-section of X.9.2.1 that specifies how the comments attribute shall be used for this XDS Affinity Domain.
confidentialityCode		R/P	Refer to the sub-section of X.9.2.1 that specifies the list of possible confidentialityCode values
creationTime		R/R	DTM
entryUUID		Cg/P	UUID
eventCodeList		O/R	Refer to the sub-section of

			X.9.2.1 that specifies the list of possible eventCodeList values
eventCodeDisplay NameList		O1/P	Refer to the sub-section of X.9.2.1 that specifies the list of possible eventCodeDisplay NameList values
formatCode		R/R	Refer to the sub-section of X.9.2.1 that specifies the list of possible formatCode values
Hash		Cp/P	SHA1 hash
healthcareFacility Type-Code		R/R	Refer to the sub-section of X.9.2.1 that specifies the list of possible healthcareFacility TypeCode values
healthcareFacility Type-CodeDisplay Name		R/P	Refer to the sub-section of X.9.2.1 that specifies the list of possible healthcareFacility TypeCodeDisplay Name values
languageCode		R/P	
legalAuthenticator		O/O	XCEN
contentType		R/P	
parentDocumentId		O/P	ebRIM Association
parentDocument Relationship		R/P	Use one of the following values (provide a translation of these if necessary to the XDS Affinity Domain language): APND RPLC XFRM signs
patientId		R/R	CX

practiceSettingCode		R/R	Refer to the sub-section of X.9.2.1 that specifies the list of possible
practiceSettingCode DisplayName		R/P	Refer to the sub-section of X.9.2.1 that specifies the list of possible practiceSettingCode DisplayName values
serviceStartTime		R2/R	HL7 V2 DTM
serviceStopTime		R2/R	HL7 V2 DTM
size		Cp/P	Integer
sourcePatientId		R/P	CX
sourcePatientInfo		R2/P	
title		O/P	
typeCode		R/R	Refer to the sub-section of X.9.2.1 that specifies the list of possible typeCode values
typeCodeDisplay Name		R/P	Refer to the sub-section of X.9.2.1 that specifies the list of possible typeCodeDisplay Name values
uniqueId		R/R	
URI		Cp/P	URI

Appendix B - International experience

In early 2011, the National eHealth Authority commissioned a report on the use of IHE XDS from the consultancy firm Mediq. The report especially accentuated Austria and Switzerland as frontrunners in Europe.

Austria

Austria covers a total of 84,000 km² and had a population of 8.3 million in 2009.

The Austrian healthcare system is characterised by a great number of providers:

- 270 hospitals (64,500 beds)
- 20,300 hospital physicians
- 12,700 general practitioners
- 18,500 medical specialists
- 80,000 nurses
- 2,200 chemists

The healthcare system is based on a social insurance model which guarantees Austrian citizens equal rights to treatment. Patients are free to choose their own physician and/or treatment at hospitals, at specialists etc.

Background

In 2006, the Austrian government and provinces decided to establish ELGA (ELGA = Elektronische Gesundheitsakte = Electronic health record). In 2009, ELGA was converted into a private limited company (GmbH), and is owned by the government, the provinces and the social insurance companies. ELGA GmbH is responsible for:

- (Further) development of the ICT architecture and standards
- International collaboration (ELGA is a partner in epSOS)
- Programme management for national implementation

In 2010, 11 people were employed in ELGA, and in 2011 this number increased to 18 people. ELGA grants access to information about its tasks via the website <http://www.elga.gv.at>.

In 2002, IHE's profiles (radiology) were introduced at the Medical University Hospital in Vienna. In 2005, an electronic insurance card was introduced, which forms the basis for ELGA's work. In the north-eastern province (Niederösterreich), the NÖGUS Patient In-

dex project was launched, which aimed to build an index based on IHE XDS for document sharing between the 27 hospitals. Together the hospitals had a total of 270 ICT systems from 70 different suppliers. In 2008, five hospitals were attached to the project, and 500,000 documents were registered for 350,000 patients.

In 2007, ELGA conducted a preliminary study and developed an ICT architecture for the healthcare sector. This preliminary study was subsequently used for detailed planning of a coherent electronic health record system. Moreover, politicians decided to use IHE XDS as the standard for the national electronic health record system.

In 2008, following a cost-benefit study, it was approved to initiate national development and implementation on the basis of the systems below:

- Patient index; an important requirement for a coherent electronic health-record system.
- Health provider index; a fundamental requirement for ELGA and which can also be used by members of the public to find a physician.
- Document register with text and images. Registered on the basis of an index.
- Rules for access which define who can access documents.
- Portal; the central access for members of the public to important health information (quality-assured information, health policy, organisational and scientific information).

ICT architecture in Austria

The ICT architecture for ELGA is shown on **figure B-1**. Patients have access to their own documents via a portal using the identification on their health insurance card. Health professionals have direct access to ELGA and can retrieve documents via local ICT systems. The ICT architecture is based on IHE XDS profiles.

The ICT architecture supports ELGA's goal to create access for health professionals to existing documents (data) by combining existing decentralised systems:

- Decentralised storage of documents (in ELGA repositories, in hospital systems)
- Only relevant documents
- Standardised documents and standardised retrieval of documents

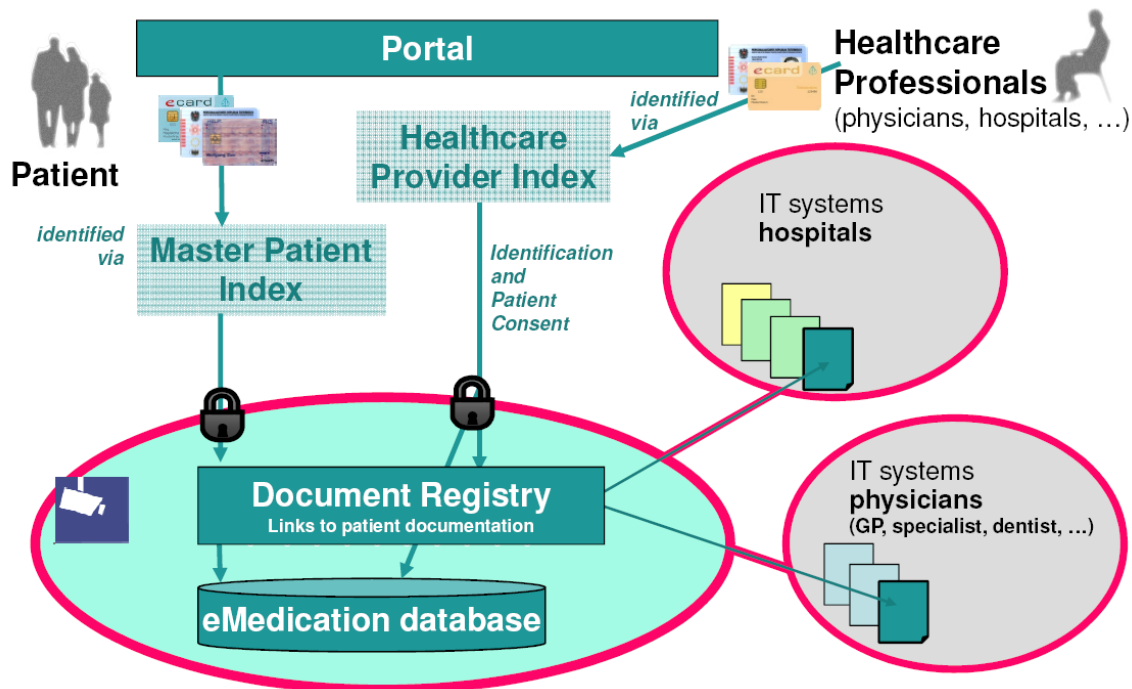
Structured documents

ELGA has drawn up guidelines for developing CDAs with clinical content. HL7 CDAs have been developed for the following documents:

- Letters of discharge

- X-ray descriptions
- Laboratory test results
- Medication

The work has been extensive and has involved more than 150 general practitioners and hospital physicians.



B 1High level ICT architecture for Austrian healthcare system

Switzerland

Switzerland covers an area of 41,300 km² and has a population of 7.4 million (2010). Switzerland is made up of 26 cantons (states) which all have a very high degree of self-governance with their own constitutions.

The hospital service comprises 318 hospitals with between two and 2,167 beds. Furthermore, in 2006 Switzerland had 2,313 nursing homes, rehabilitation centres etc. The hospital service employs 177,100 people (about 4% of the labour force), and nursing homes, rehabilitation centres etc. employ 97,420 people.

In Switzerland, the private health sector constitutes 40%, and the public health sector constitutes the remaining 60% of the total sector. The public healthcare service is financed by 40% from private funds, 17% from public funds, while the remaining costs are covered by social insurance and public donations. Healthcare sector costs in Switzerland amount to 10.8% of the country's BNP, which is among the highest in the world.

Background

Switzerland's overall goal is to introduce access to electronic health records (ePatient dossiers) for all Swiss citizens by the end of 2015. Access includes treatment-related information independent of time and place. The introduction of electronic health records is complex and involves many areas of the healthcare sector. Moreover, it is necessary to clarify and agree on the political, legal, organisational and technical issues. In 2008, initial activities began with the setting-up of IHE Switzerland. In 2009, the steering group approved adherence to the Integrating Healthcare Enterprise (IHE) philosophy on the basis of recommendations from the sub-project on standards and architecture: a transparent test process of systems on the basis of integration profiles will guarantee interoperability.

In 2009, the steering group for coordination of eHealth adopted 12 guidelines for developing ePatientdossiers.

13. **Centre on the individual:** Builds on the eHealth strategy to centre on the individual, and eHealth in order to promote an open and transparent healthcare sector.
14. **Greater expectations for access to data:** Health professionals are increasingly using electronic applications, and the demand for access to electronic records is assumed to increase.
15. **Voluntariness:** Patients themselves can choose whether they want to use eHealth services.
16. **Protection of information:** Health professionals must document treatment, and patients must be entitled to have insight into transmission of their data and to protect transmission of their data.
17. **Access without additional cost:** Members of the public must have access to electronic data without additional cost.
18. **Cooperation:** Stakeholders are to prepare the minimum framework conditions for introducing electronic health records.
19. **Realistic steps:** The introduction of eHealth must be based on documented advantages and respect Swiss political, cultural and organisational traditions.
20. **Information and transparency:** Strategic eHealth projects using basic components from the architecture are to be supported financially. The projects are to be evaluated and the results (and any negative results) published.
21. **Incorporation of international experience:** Incorporation of international work and experience (for example standards and interoperability).
22. **Legal foundation:** Provision of the necessary legal foundation for introducing an electronic health record.

23. **Other applications:** The technical and legal foundation developed for the electronic foundation is also to be applicable for other applications.

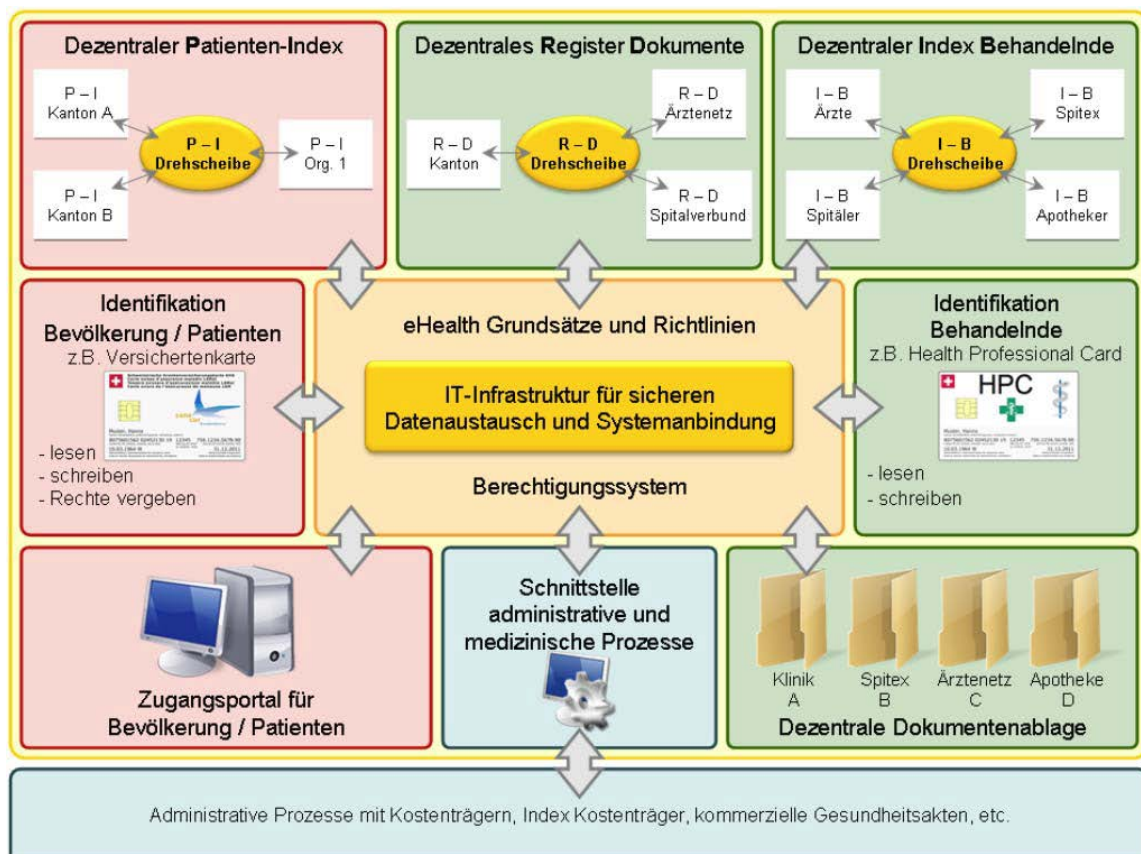
24. **Contracts:** The social partners (employer and employee organisations) are to be able to incorporate electronic submission of documents in collective bargaining.

ICT architecture in Switzerland

The ICT architecture in Switzerland consists of 10 main elements as shown in the figure below. Switzerland has decided that each canton is to implement local infrastructures based on IHE XDS.

A gateway has been established on the basis of the IHE XCA profile between the document registry players in each canton.

The eHealth projects are at different development stages in the sub-stages. Some projects have already been completed, and experience will thus rub off on other projects which are in the planning stages.



B 2 ICT architecture in Switzerland

Primary standards used in Austria and Switzerland

Technical standards for the infrastructure of the documents which are to be exchanged:

- Integrating the Healthcare Enterprise (IHE), Technical Framework
 - o IT Infrastructure Technical Framework Revision 3.0, December 9, 2006, Final Text Version
 - o Patient Care Coordination Technical Framework Revision 1.0, Final Text
 - o Laboratory Technical Framework, Revision 1.1, August 10, 2004, Draft for Public Comment
 - o Radiology Technical Framework, Revision 7.0, May 15, 2006, Final Text Version
- Health Level Seven, Version 3, RIM
 - o ISO/HL7 21731:2006(E), Health informatics – HL7 version 3 – Reference Information Model – Release 1
- Health Level Seven, Clinical Document Architecture, Release 2
 - o ANSI/HL7 CDA, R2-2005
- Logical Observation Identifiers Names and Codes(Laborteil)
 - o LOINC® 2.19:2006-12-22
- DICOM 3.0 und WADO
 - o ISO 12052:2006(E), Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management
 - o ISO 17432:2004(E), Health informatics – Messages and communication – Web access to DICOM persistent objects

The following IHE profiles are used to develop:

- CT – Consistent Time
- ATNA – Audit Trail and Node Authentication
- PIX – Patient Identifier Cross Referencing

- PDQ – Patient Demographics Query
- BPPC – Basic Patient Privacy Consent
- XUA – Cross Enterprise User Assertion
- XCPD – Cross Community Patient Discovery
- XDS.b – Cross Enterprise Document Sharing

The rest of the world

In recent years, use of the IHE XDS profile has gained more and more ground, which is underpinned by the many suppliers who have had solutions tested at IHE's Connectathon.

Large IHE XDS implementation projects are taking place in:

- The UK (Wales)
- France
- The Netherlands
- Italy
- Canada
- USA