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Boundaries between structuring applications and messaging

The rise of two-level model based EHR systems

Gerard Freriks

zaterdag 19 juni 2010

Why EN13606?
When there is HL7?

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INFORMATION DOCUMENTATION

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Topics

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1. **Introduction**
2. **Standards, Norms, Policies**
3. **EHR. What is it?**
4. **HL7 messages and EN13606 Objects**
5. **Conclusions**

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Introduction

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- **Gerard Freriks**
- **Trained as GP**
- **40 Years Health Informatics**
- **Chairman CEN/TC251 wg1**
- **Electronic Record Services B.V.**

Topics

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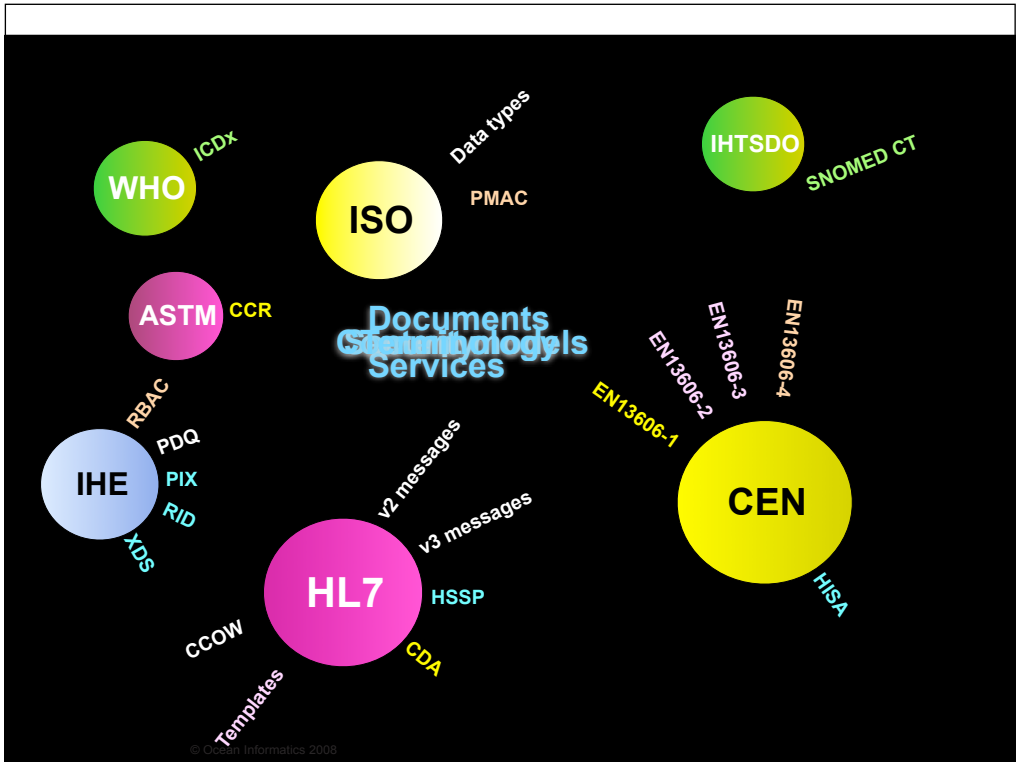

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FIrst some information about EHR related standards.
Many complain there are so many.
We need many in order to have an eHealth Infrastructure.

Many think that there are too many competing standards (e.g. HL7 and EN13606)

European Standardisation

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European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

2. Aims

CEN, as the integrated system for European standardization, aims to:

1. support and strengthen the achievement of the **European Single Market**;
2. enhance the **competitiveness** of European players in the global market;
3. **foster** the European **economy** and the **welfare** of European **citizens** under the global concept of sustainable development;
4. ensure the most efficient **input** of **Europe** to international **standardization** activities and cooperation;
   through the delivery of formal standards, other deliverables and related services needed by interested parties in Europe, working as closely as possible with CENELEC and ETSI to achieve all sectoral market needs.

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Some history of European standards.

Standards play a formal role in Europe

European Standardisation

European standards play a special role:

- Only National standards derived from European standards can be used in *legislation*
- National and European standards play a role in *procurement*

European Standardisation

Trading within the European Union

- Four basic freedoms:
  - Free movement of goods
  - Free movement of persons
  - Free movement of capital
  - Freedom of establishment and free movement of services
- Barriers to trade:
  - Traditional barriers such as tariffs or quotas
  - Technical barriers such as differences in standards and conformity assessment

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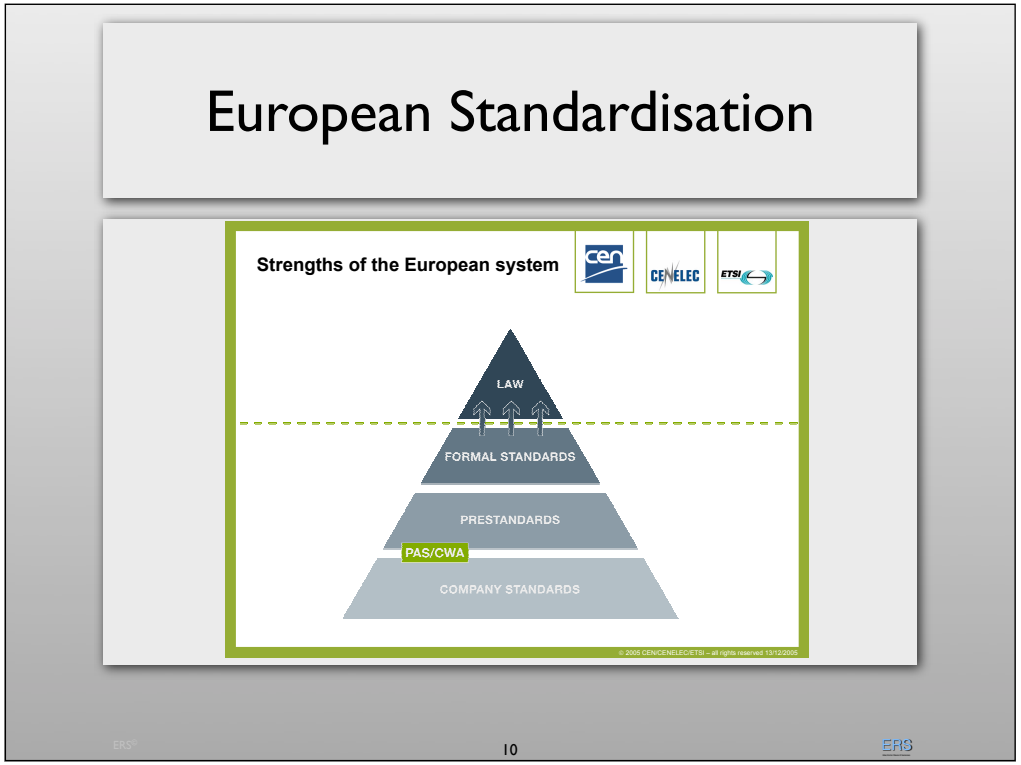
The reasons why we have a European Community

And why we need attention for the FREE MOVEMENT of data and Information



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Only European standards play a formal role in legislation:
ENvirionment, medical devices, Electrical appliances, etc, etc.

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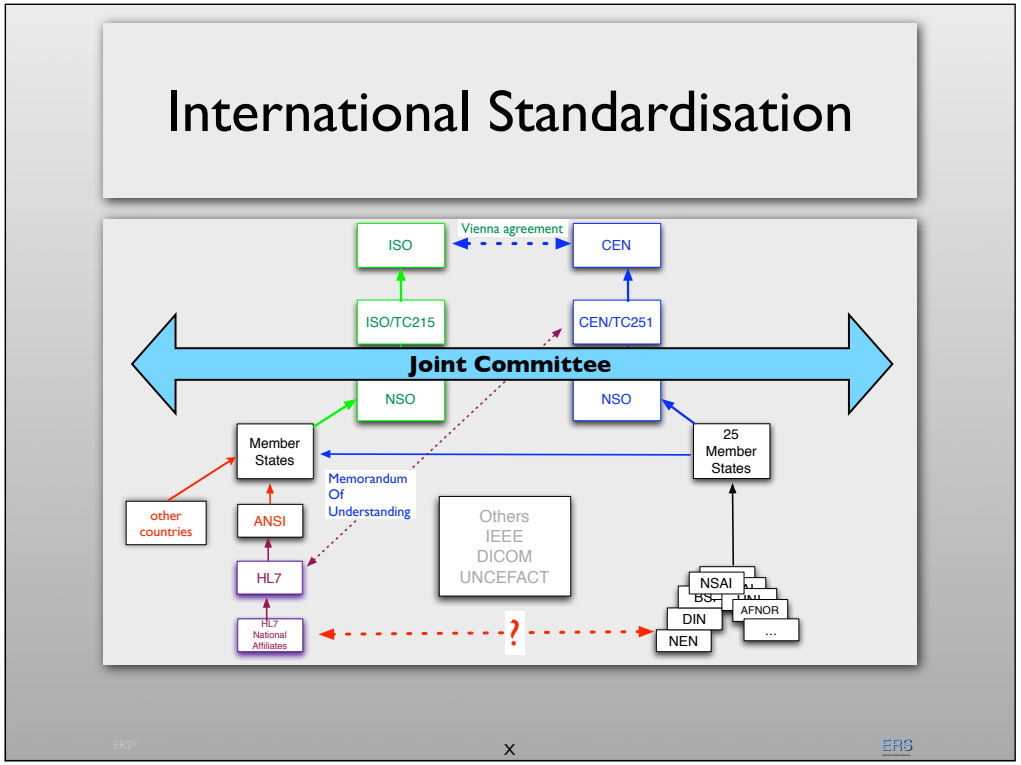
European and ISO standards are free of IP problems



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The relations between CEN/ISO
And the place of HL7 in this scheme.
SDO's co-operate

European Policies

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European
Recommandations and announcements

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European Digital Agenda

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Communication: A Digital Agenda for Europe

1. Lack of investment in networks: ...

2. Fragmented digital markets: Europe is still a patchwork of national online markets even though the problems are fixable.

3. *Lack of skills: ...*

4. *Fragmented answers to societal challenges:* Europe misses out on much of the potential of ICT because it does not give common answers to challenges facing society (such as the ageing population, rising health costs, climate change).

5. *Rising cybercrime and low trust:...*

6. *Insufficient research and innovation efforts: ...*

7. Lack of interoperability: Europe does not yet reap the maximum benefit from interoperability. Weaknesses in standard-setting, public procurement and coordination prevent digital services and devices used by Europeans from working together as well as they should.

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European Digital Agenda

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Communication: A Digital Agenda for Europe

ACTIONS

The Commission will work with Member States competent authorities and all interested stakeholders to:

- **Key Action 13**: Undertake **pilot actions** to equip Europeans with **secure online access to their medical health data** by 2015 and to achieve by 2020 widespread deployment of telemedicine services;

- **Key Action 14**: Propose a **recommendation** defining a **minimum common set of patient data** for interoperability of patient records to be accessed or exchanged electronically across Member States by 2012;

- **Other actions**:

  - **Foster EU-wide standards, interoperability testing and certification of eHealth systems by** 2015 through stakeholder dialogue;

  - Reinforce the AmbientAssisted Living (AAL) Joint Programme to allow older people and persons with disabilities to live independently and be active

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European Commission

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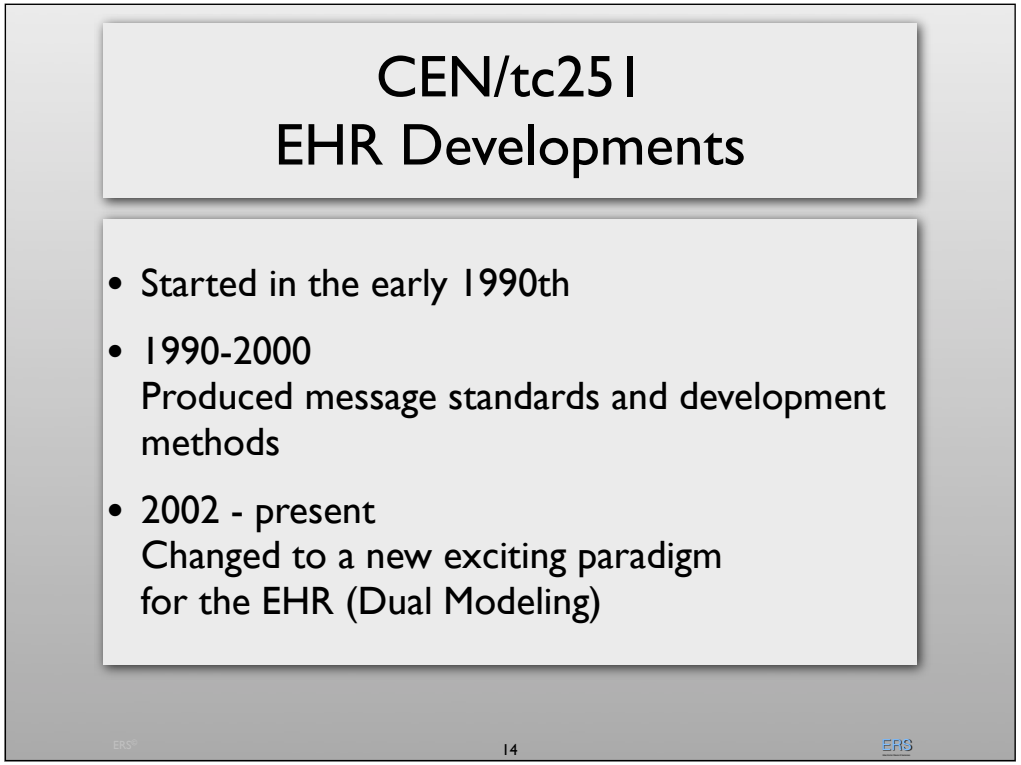
A **Recommendation** of the Commission (July 2, 2008):
On on cross-border interoperability of Electronic Health Record systems

1. An **Announcement** COM(2004) 356 (April 30, 2004) of the Commisssion to the Council:
e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area

2. An **Announcement** COM(2008) 689 (November 4, 2008) of the Commissie to the European Parliament, The Council:
On telemedicine for the benefit of patients, healthcare systems and society



The history of the EN13606.

CEN/tc251 EHR Challenges

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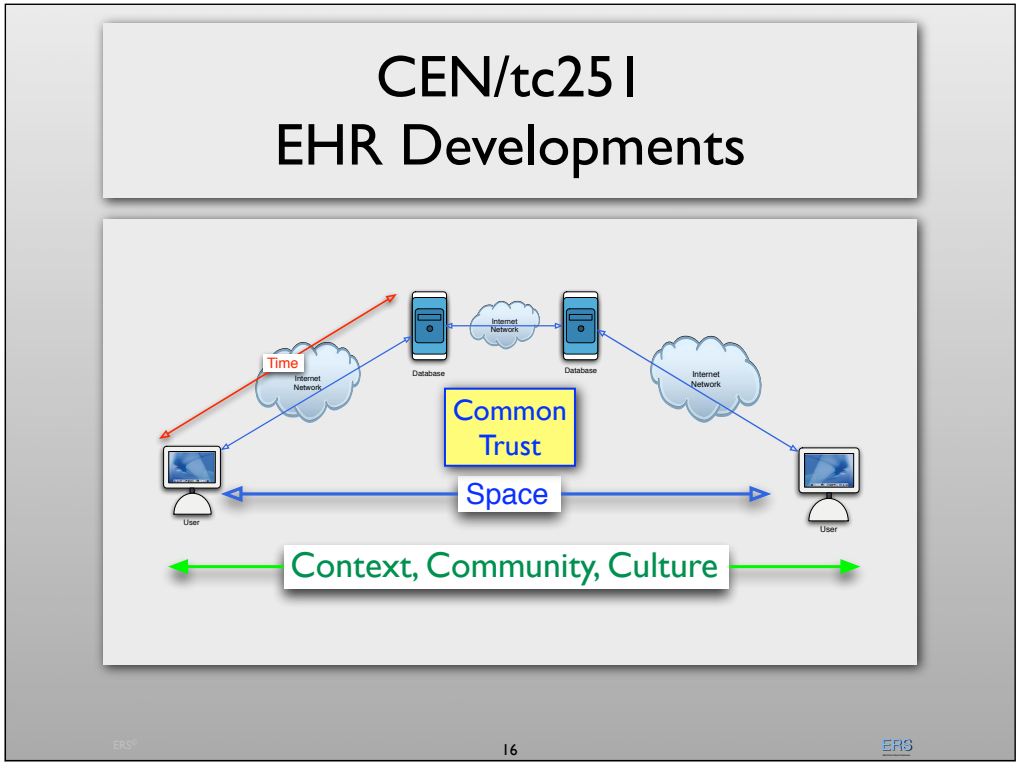
- Uniform standardised EHR data/information (objects) in and between EHR-systems
- Flexibility (Two level modeling)
  Separation between healthcare knowledge domain and IT-technical domain
- Harmonisation with other CEN/tc251 standards
- Multi-language
- Diverse privacy regulation in European Member States



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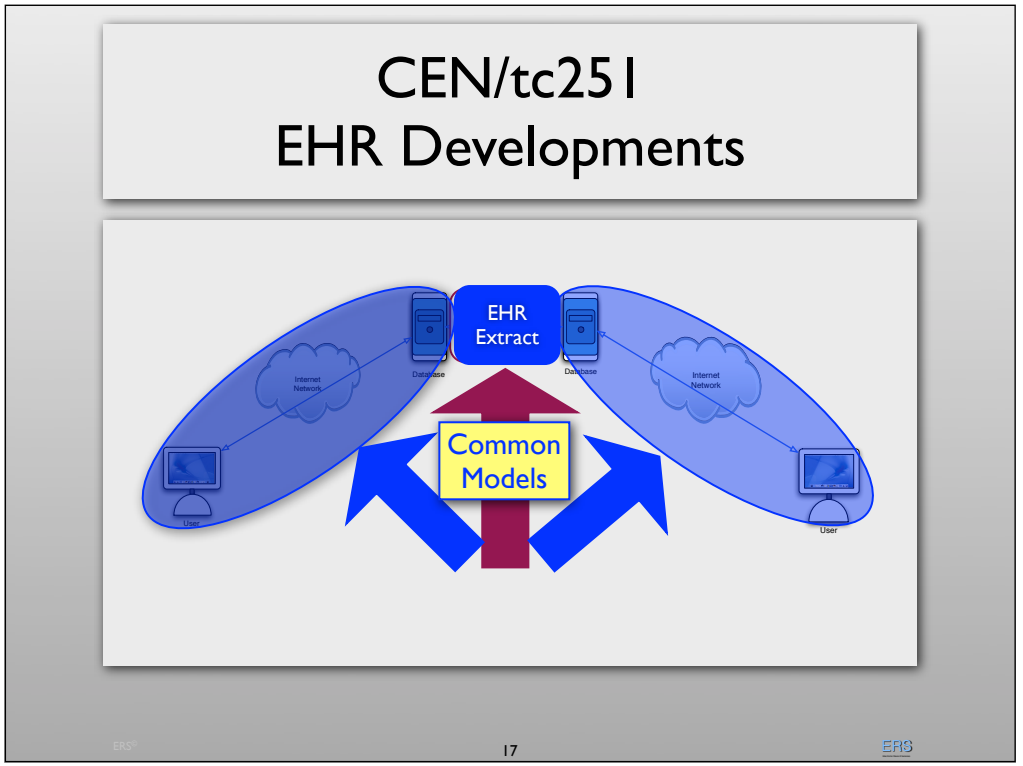
EHR's have two functions: transport of time (Documentation, Archiving), and transport over distance.
This is possible, only, when we have many stable standards and instituted trust in the middle.

We need a national/European eHealth Infrastructure based on open International standards and legislation.



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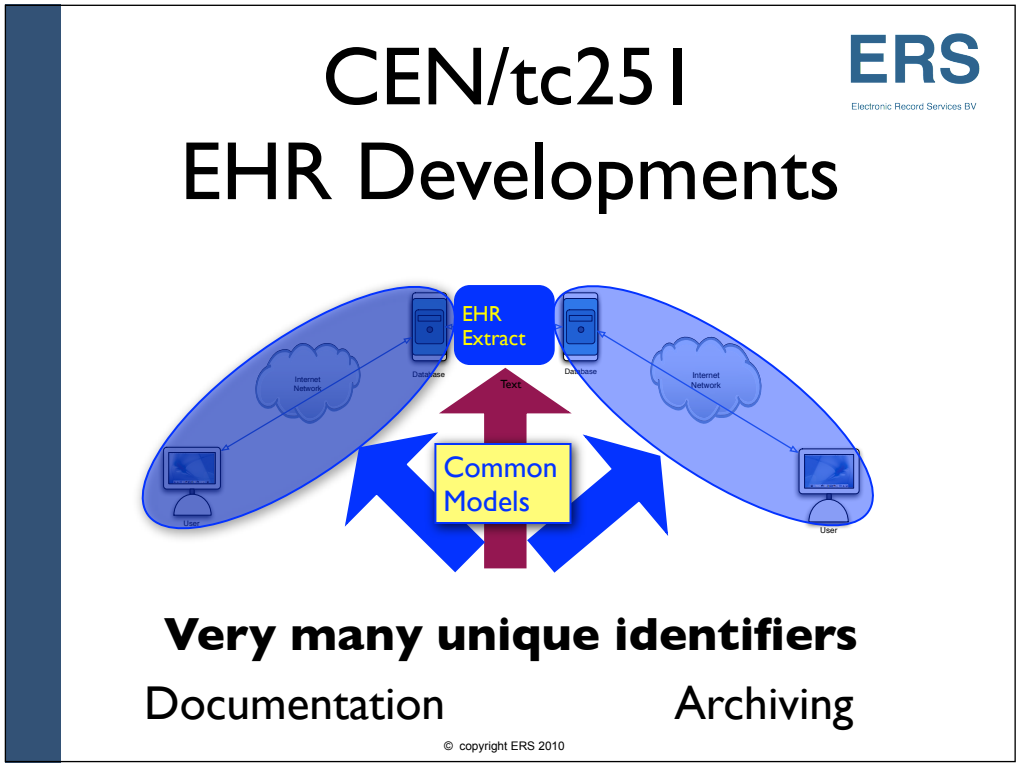
Creating the EHR (eHealth) Infrastructure there two points of departure.
1-
For many years CEN/tc251 (like HL7) has started in the middle.
Message standards we produced to update proprietary databases.
2-
This century CEN/ISO started to think about standards at the EHR-system.
It standardised how Data or Information is stored, retrieved, archived AND exchanged.

It must be clear that therefor Message standards and EHR-standard have one thing in common.
But for many other aspects they have NOTHING in common.
There is only a partial overlap.

All this reflects different point of departure in CEN: Multiple languages.



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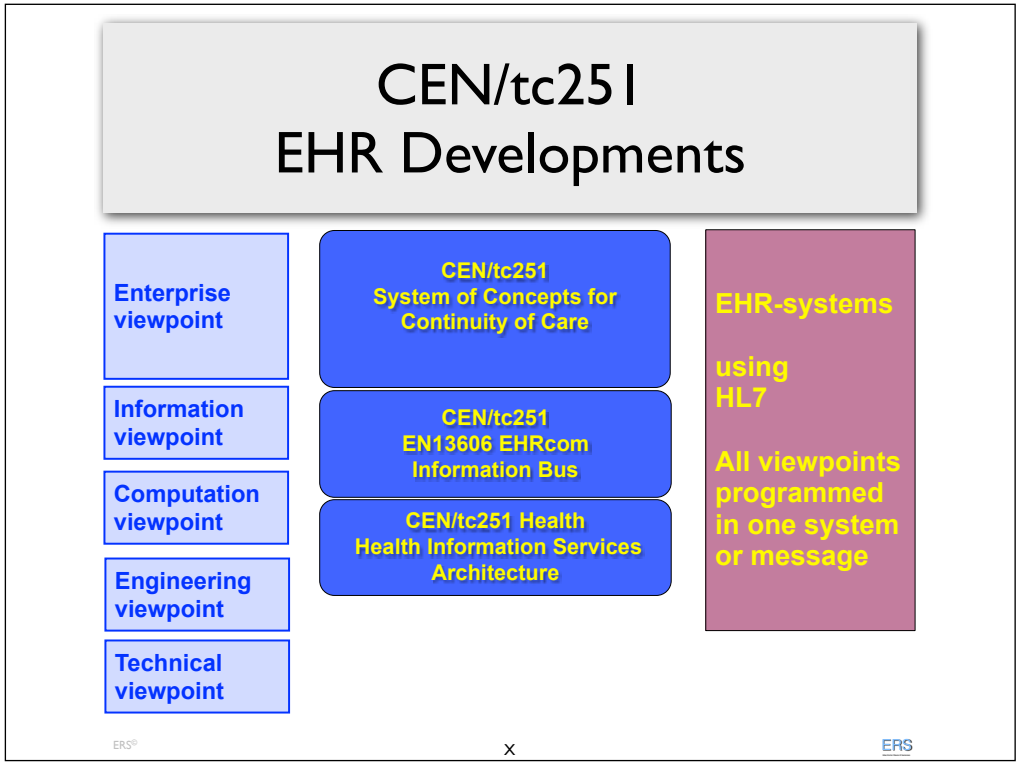

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Depicted here is that in the case of messages
- work processes are standardised,
- translated in an Information Model
- the exchange between databases is choreographed
- and implemented in IT-systems, by programming and
- that have to rolled out.

State-of-the-Art EHR-systems that are based on EN13606/openEHR behave differently.
They only define what has to be Documented, Exchanged, Archived and Re-Used.

They do NOT standardise Workflow or the way information is exchanged.
They define define Engineering and Technology choices.

They ceate EHR-systems that facilitate healthcare maximally.

Why a European EHR standard

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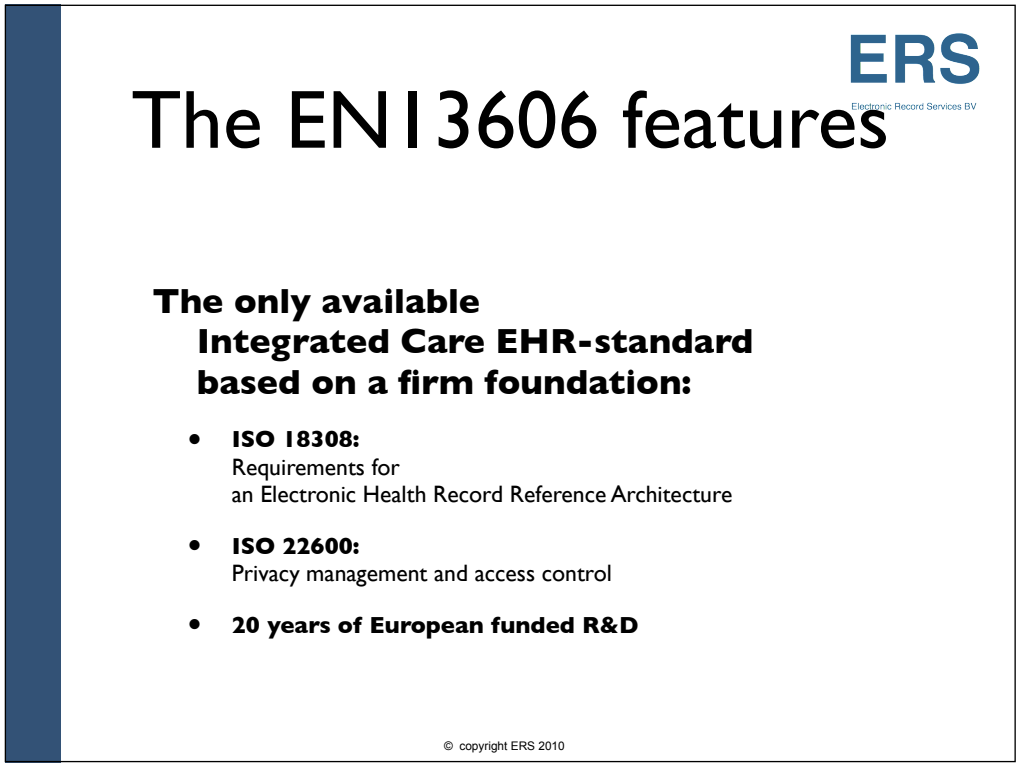
27 European countries

Many cultures, many languages

One united European Community

Free movement of goods, people, money and services

One big competitive European economic space



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This European standard does not come out of the blue.

It has firm foundation in an ISO standard that defines quality criteria for EHR-systems.

It is linked with an important ISO standard for Privilege Management and Access Control thereby implementing European Privacy laws.

And it is based on the results of many European projects.

CEN/tc251
EN13606 EHRcom

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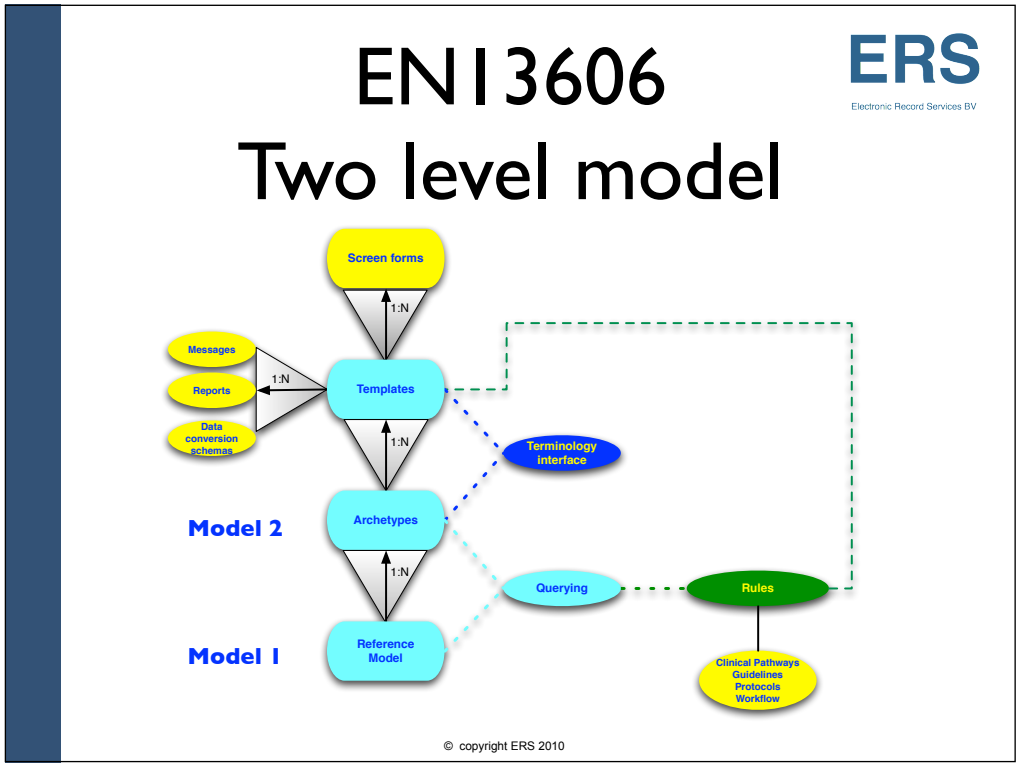
- Academic research based
- 2 pre-standards
- Full ISO/tc215 EHRcom standard as of 2010



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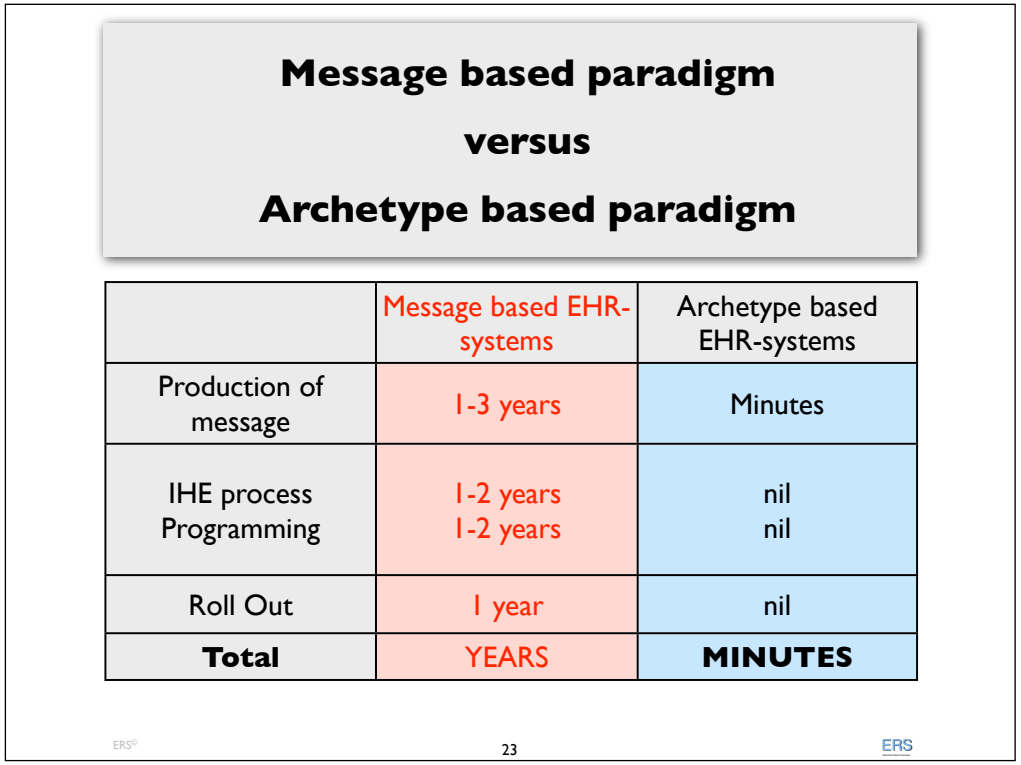
EN13606 innovated the EHR architecture with the TWO LEVEL MODEL approach.
It encompasses several models but two models are essential.

1- one technical model that defines how any data is documented, archived. It has features for to define among others: the structure of records, digital signatures, the patient mandate (access control list) and semantic links.
2- a model that defines the expression of archetypes as constraints on the first model.

This has outstanding consequences for health IT-systems.
Whatever archetypes produced, what ever template produced by the healthcare domain the conformant system can accommodate it without reprogramming, without the need for database conversions any more.



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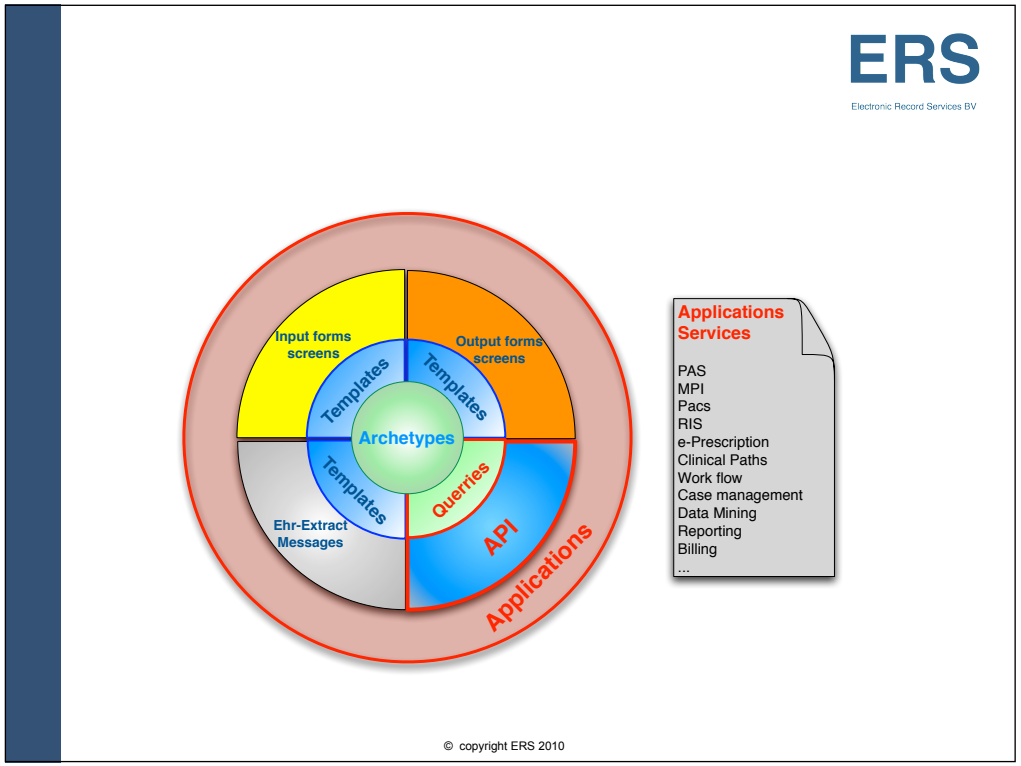
In comparison.
When the EN13606 is used for the exchange function only. There are already striking differences that will influence the discussions on eHealth Infrastructure and the EHR-architecture.

The time it takes to produce and implement new Message specifications or make changes to the database in RED

And the same in State-of-the-Art EHR-systems based on the Information Bus (EN13606/openEHR)

The differences are exciting and staggering.



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IT-systems based on EN13606 use Archetypes in Templates and use it for querying.
Templates are constructs with a structure in which pre-defined and shared archetypes are used to generate input/output screens, forms, documents, messages, etc.

Templates are defined in a local context and can be changed any time, any place.

What is needed is one centrally owned and maintained library of standard archetypes.
Each healthcare speciality will be responsible for its library of archetypes.
Their Archetype LIbrary with all its bindings to codes from coding systems will express the INFORMATION needs of their domain.
The eHealth Infrastructure must have this organised.

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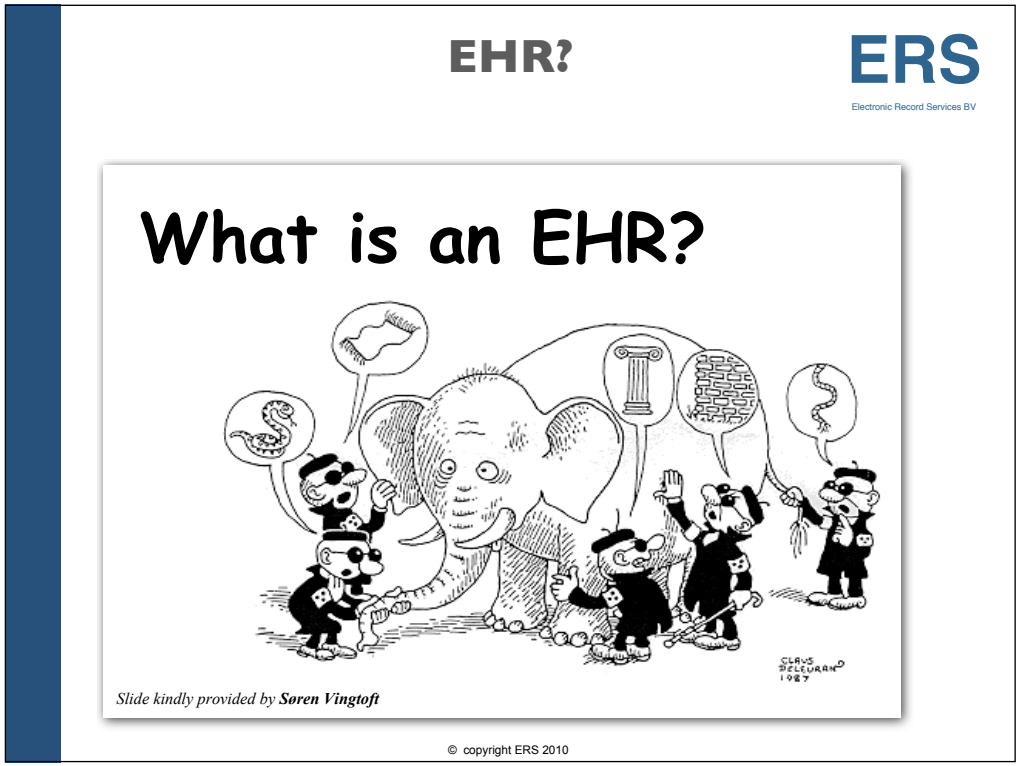

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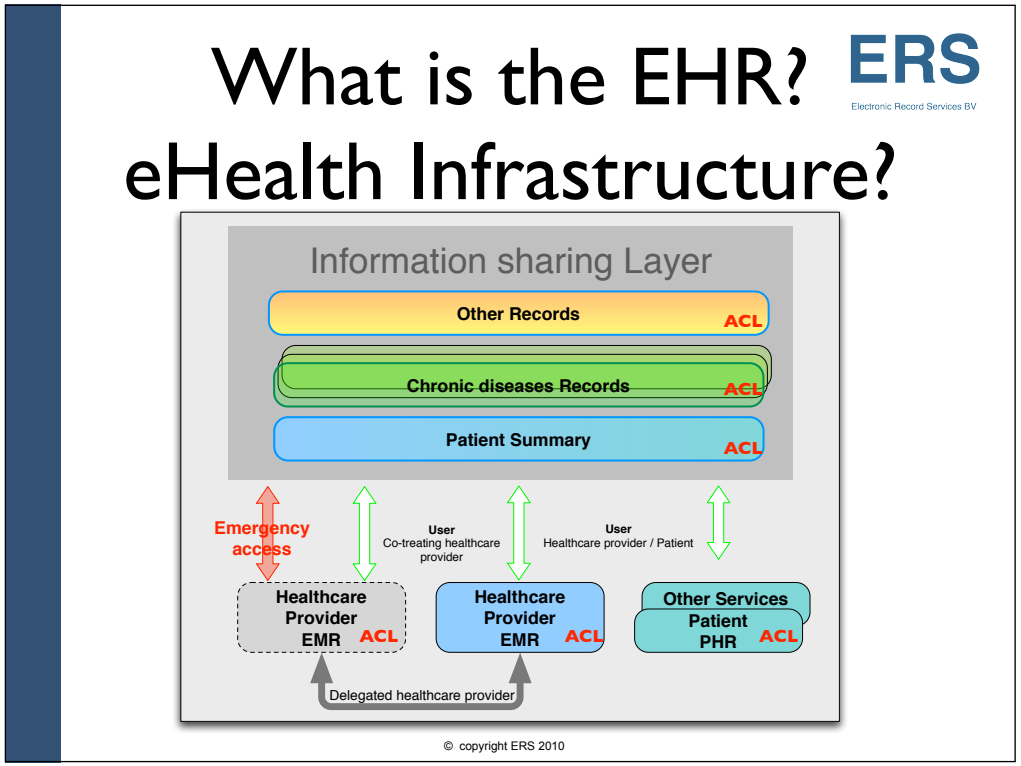
There are many ideas of what an EHR is.
I will not discuss reasons why an EHR is essential in this day and age.

I will discuss what to my mind IS the EHR.



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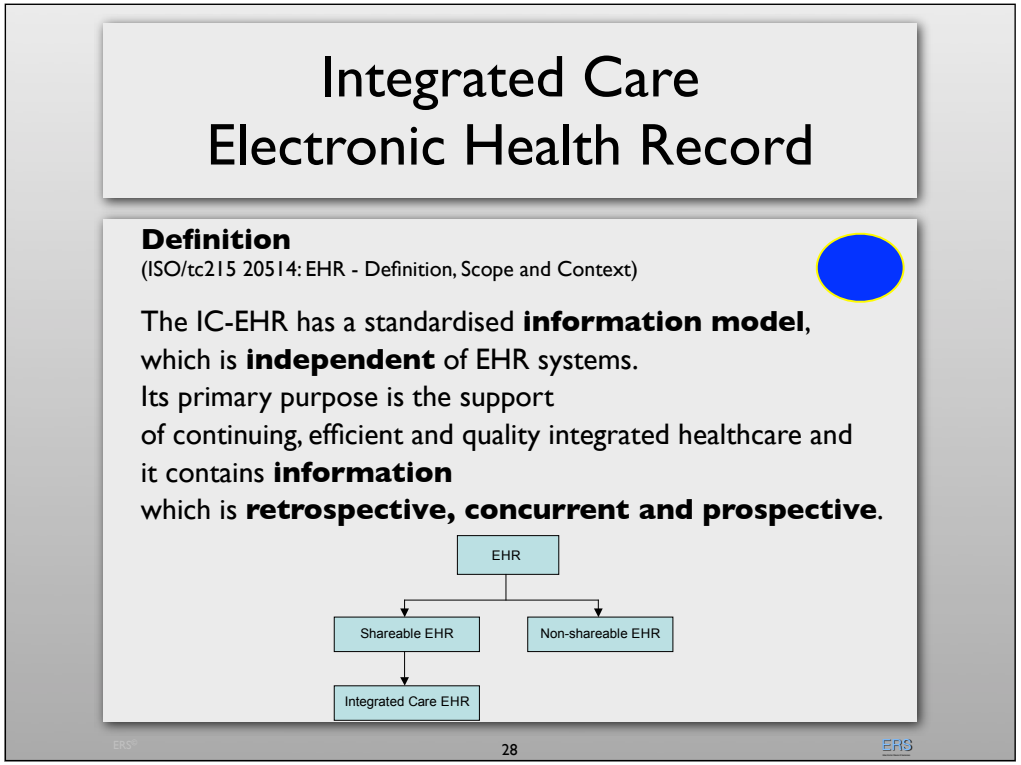
In Essence the EHR is all what you see.
It is a high level model I use to think about an eHealth Infrastructure and the EHR.

Some experiences indicate that any solution that does not fit this picture leads to avoidable discussions and problems in the acceptance.

1- the eHealth Infrastructure (and EHR) is about DOCUMENTATION of the care delivered. The author is central. IT must facilitate the provision of healthcare.
It is NOT the patient that is central!
2- Not only the HCP is author. The patient and its surrounding carers have a need to document.
3- Each author is responsible for what he documents.
4- It is the author (Together with the patient) that decide what will be published in an Information Sharing Layer. They control the Access Control LIst.
5 -E.g. discharger letters will be published for short period of time. The patient summary and the chronic care record will be there permanently. Each artifact needs an accountable person as
5- They can add any other to the ACL as a conscious decision they need to take accountability for.
6- Delegation must not be confused with data in the Information sharing Layer.
7- Seldom-ly one will need immediate access and has to invoke the Red Button procedure, leading to immediate alerting all authors AND the patient.



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In order to be able to have seamless exchange between all systems ISO has produced some definitions.
Key is in the most elaborate state-of-the-art EHR IT-system Information will be defined independently (by a standard).

And documentation, archiving, adaptability will be requirements for those systems

Integrated Care
Electronic Health Record

State-of-the-art IT-systems means

- IT should not dictate, but really facilitate users
- The customer needs extremely flexible and agile systems development
- The customer needs model driven, high quality, highly performant and highly scalable, IT-systems
- The customer needs plug-and-play IT-functionality, managed storage and archiving as a service

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Back to the basics.
This section is about what we all expect from IT
And are disappointed about

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A Metaphor will be used
: Components needed to produce Pastries

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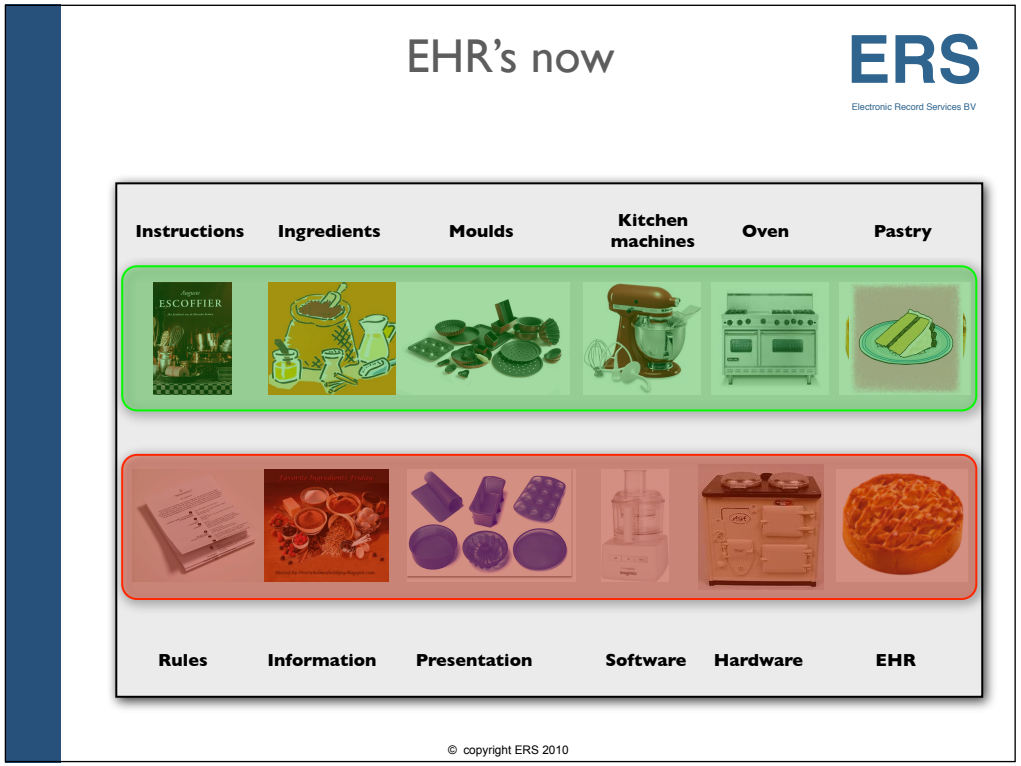
Different Instructions and ingredients make an other type of pastry

The same Instructions used in a different setting produce the same pastry

Metaphor
- Instructions = Business Rules
- Ingredients = Information
- Moulds = Presentation
- Kitchen machinery = Software
- Oven = Hardware



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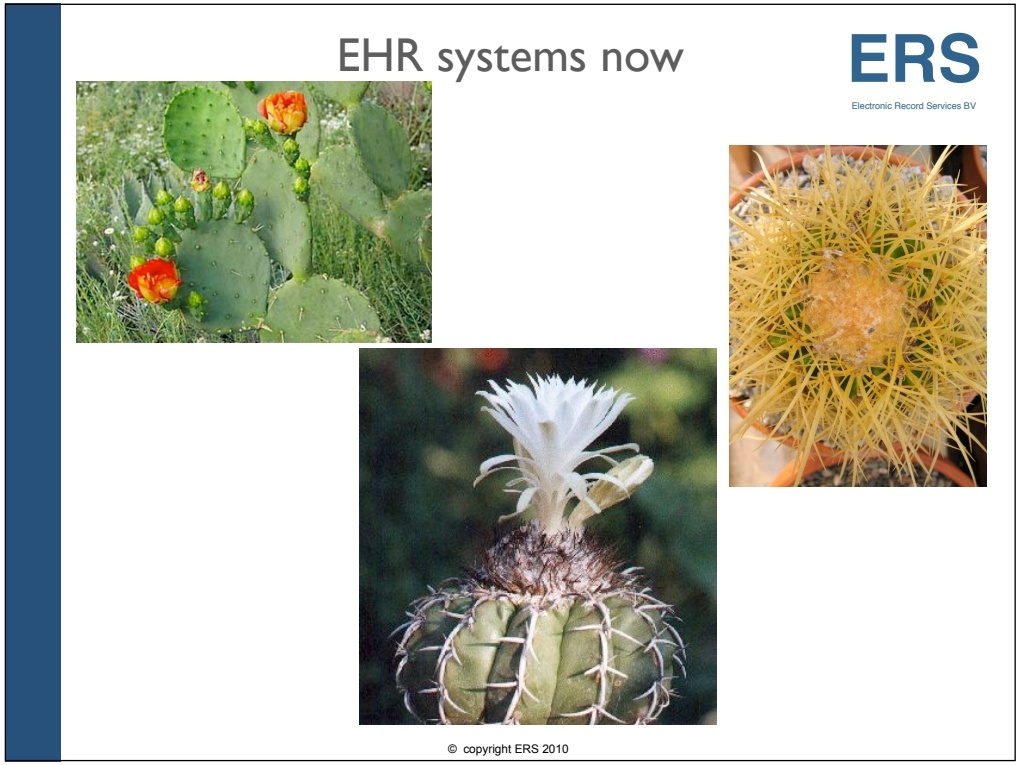
Each IT-vendor delivers a unique (proprietary) system with limited possibilities to adapt to local needs

Rules, Information, Moulds, Machines, and the Oven can not be exchanged.

Each IT-system has proprietary solutions that can not be exchanged



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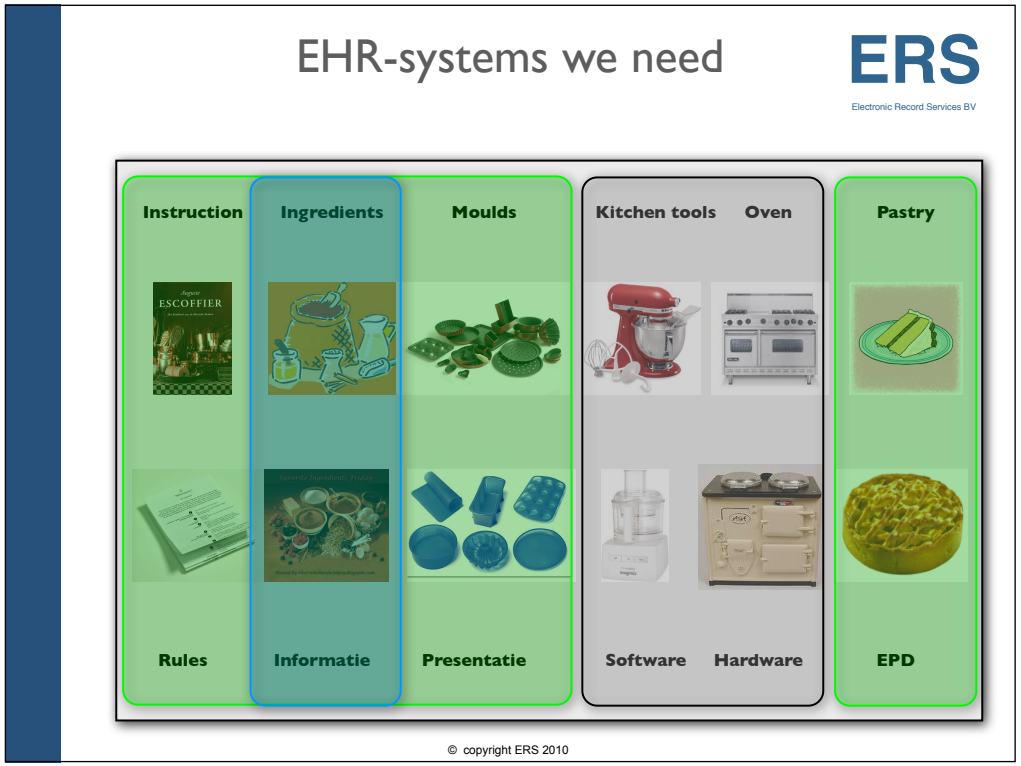
Consequence:

Each selects a nice flower and has to live with the not so nice consequences.



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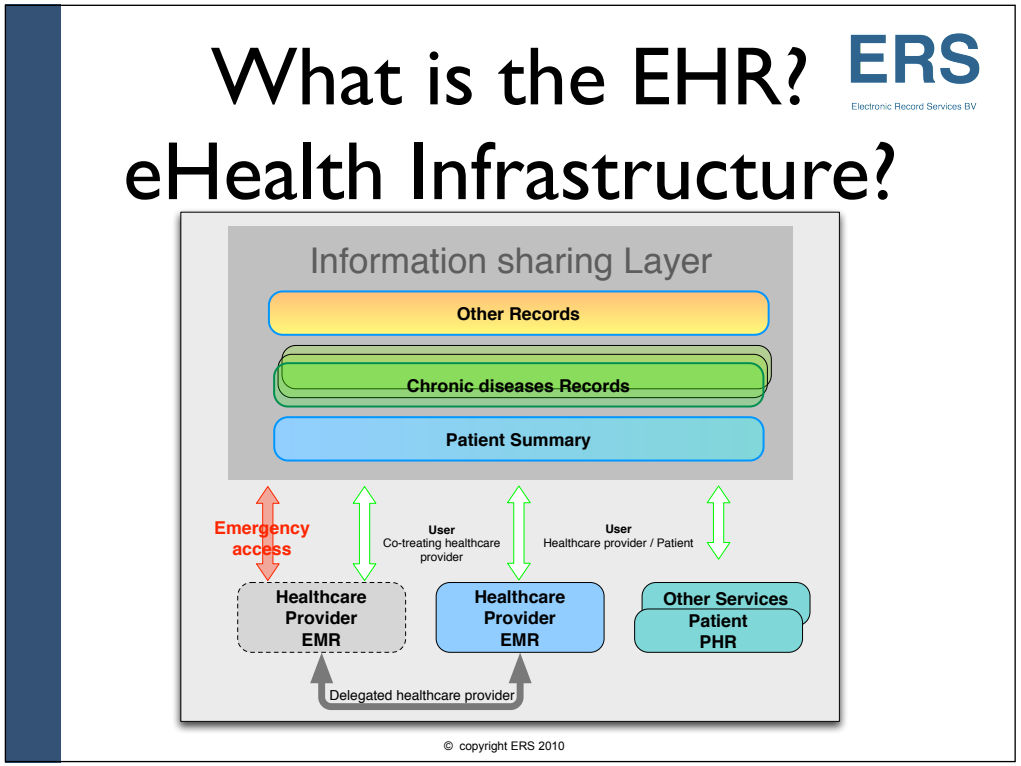
The baker in his bakery is able to exchange all component.

What we need in healthcare is that healthcare providers and organisations can select the components freely.

No more proprietary solutions.
And an absolute separation between Healthcare and the IT-world.
What ever healthcare defines in terms of Instructions (Rules), Ingredients (information), and Moulds (Presentation) the IT-world can deal with it without reprogramming and database conversions.

Any set of Rules, any set of Information, any presnetation spec, can be executed by all IT-systems.



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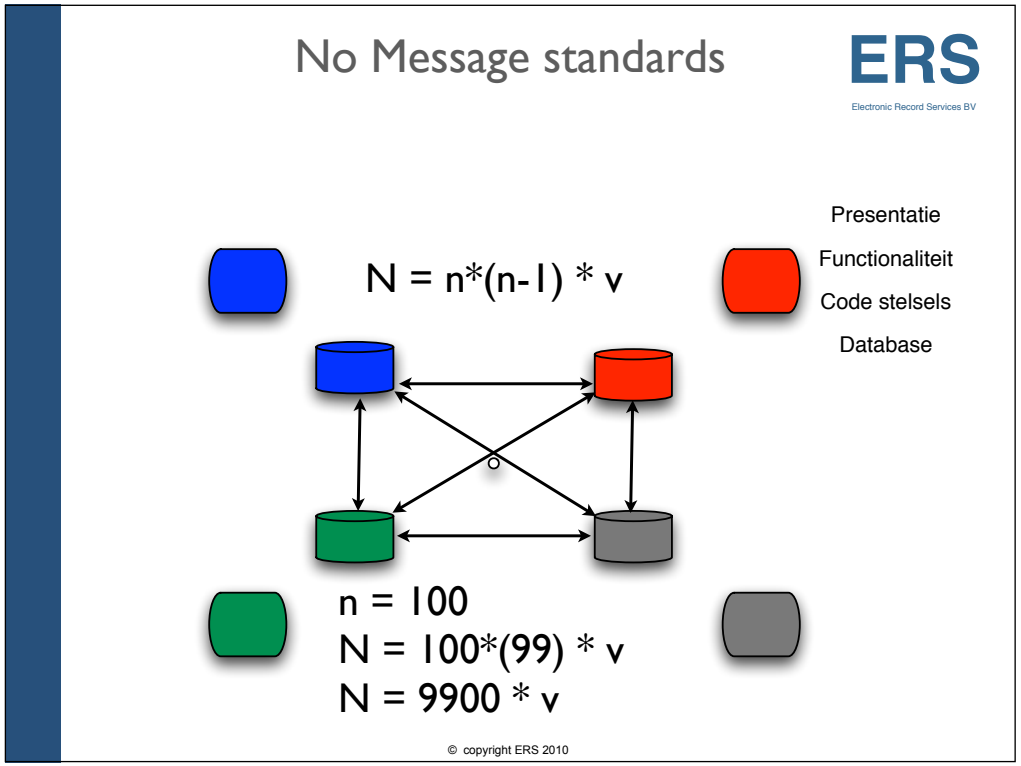
When we go back to the eHealth Infrastructure High Level mental model
It is clear that systems must exchange data and information.

We all know that all systems at present have proprietary ways to store data and information.
How can we make these systems exchange?

All possibilities will be discussed.



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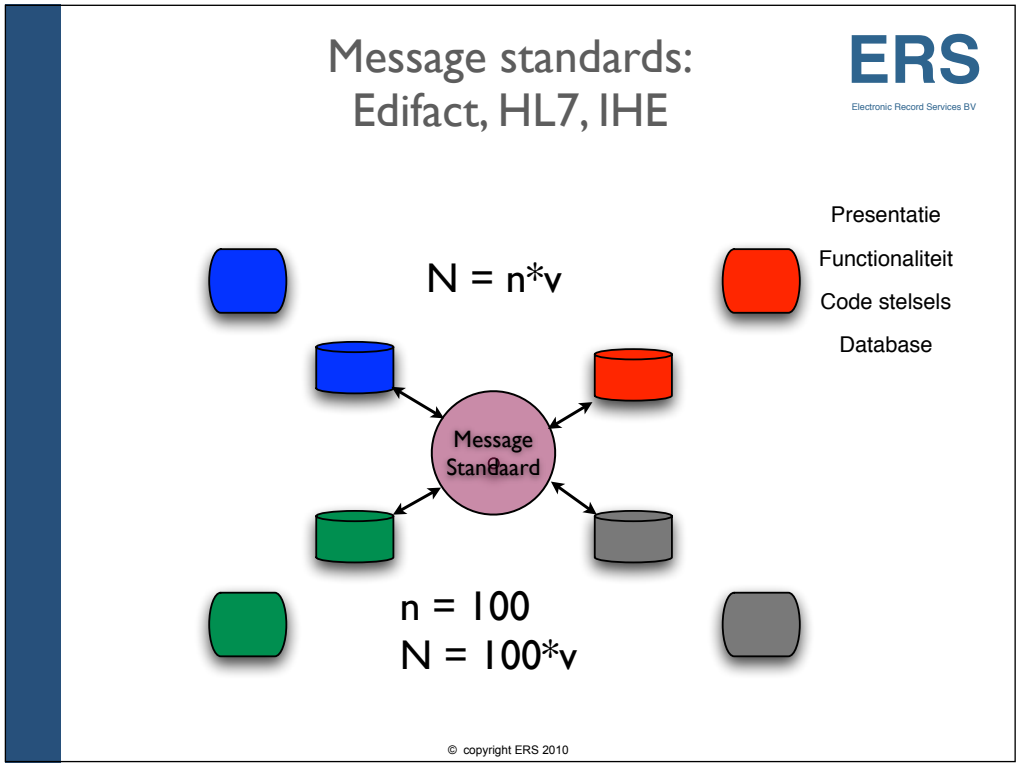
Proprietary systems can exchange ad-hoc.

Conclusion; Not maintanable



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Message standards provide a huge improvement.

Observe that only data is exchanged between proprietary databases.

Some think that this will provide THE solution for healthcare.

Message standards: Edifact, HL7, IHE

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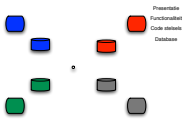
Message implementation process

- Message standard production - 3 years
- IHE profil production and validation of an implementation specification > 1.5 years
- Deployment -0,5 - 1 year



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The major drawback of Message standards is:
- they need a lot of resources (time and money) to realise and maintain.

Message standards: Edifact, HL7, IHE

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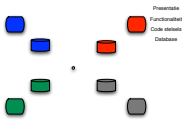
Message standard:

- Implementation needing years
- high cost
- inflexible
- no real support of innovation in healthcare delivery



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No only do they need a lot of resources but ...

Stops effectively INNOVATION

Message standards: Edifact, HL7, IHE

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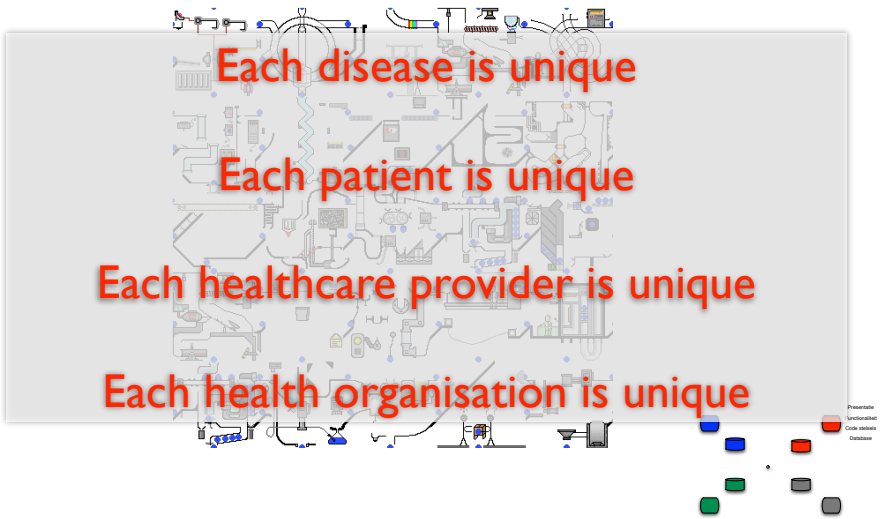

Each disease is unique

Each patient is unique

Each healthcare provider is unique

Each health organisation is unique

Message standards: Edifact, HL7, IHE

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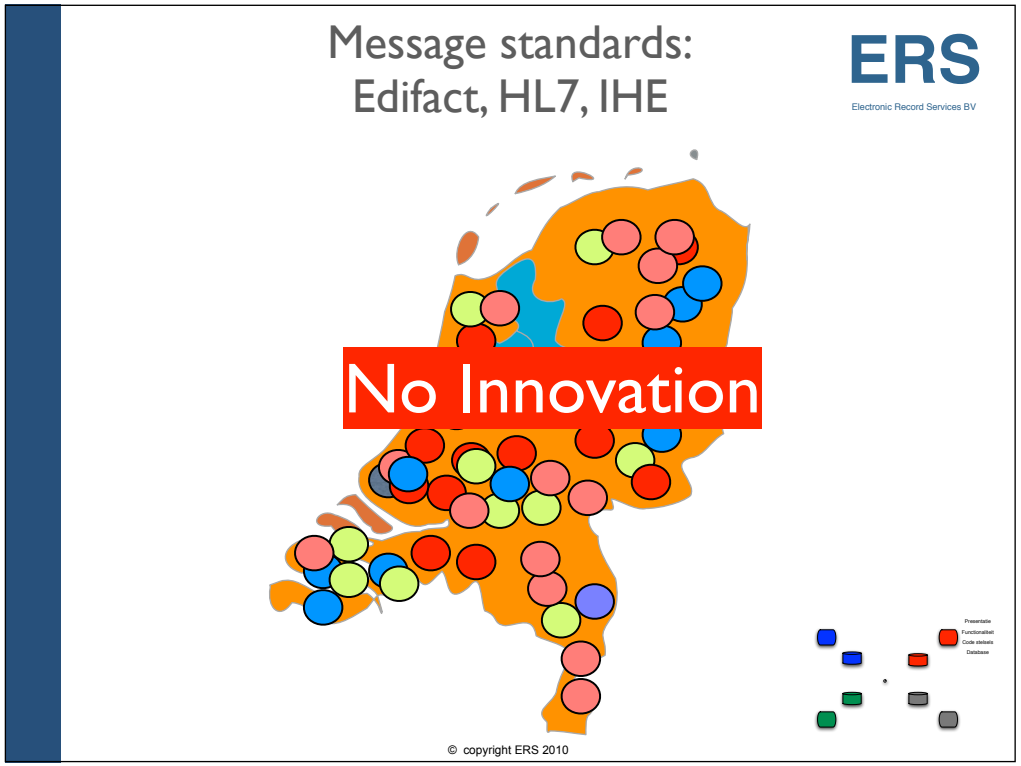
When in a country a set of messages is implemented by the IT-industry this set is based on one use case.
All IT-systems, Healthcare organisations and healthcare providers will treat the diabetic patient is exactly the same way.



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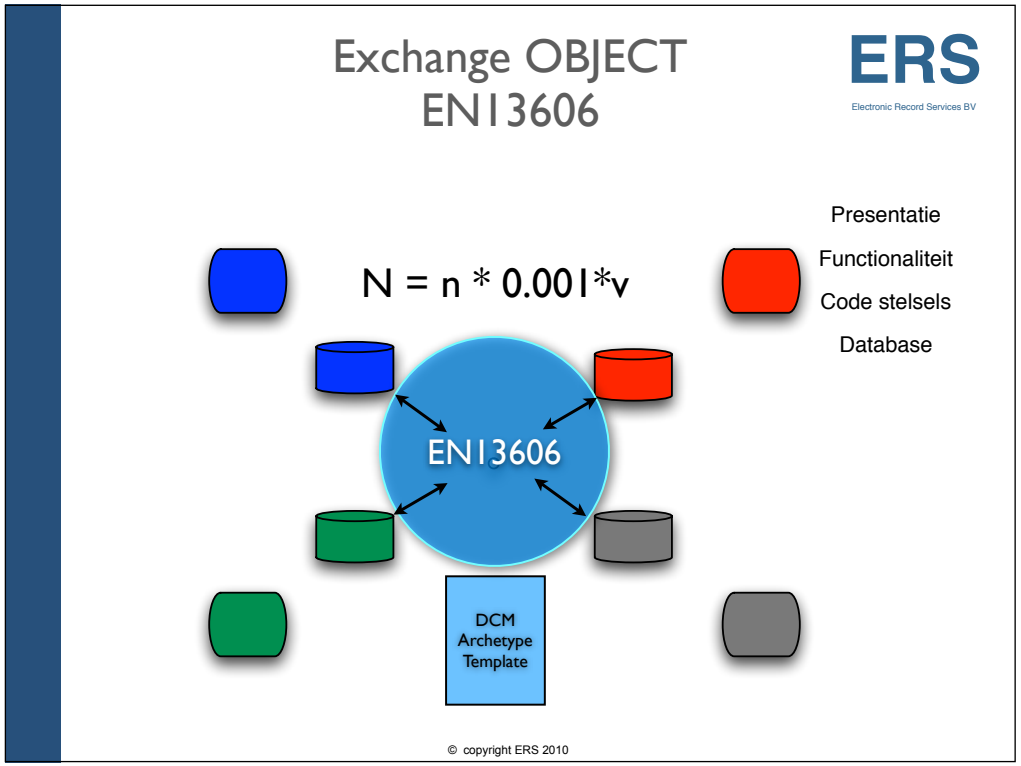
When we declare that healthcare innovation as an important aspect to reduce cost and improve healthcare delivery then message create problems.

Message stop innovation because after the first implementation new changes at local scale will not be provided by the IT-industry.
For each local experiment needing new information to be stored and exchanged, needing new business rules, needing new ways of display, all vendors must implement in their proprietary software all this.
Because of the large resources needed (time and money) experiments on a small scale will not be supported.

Even more so when many want all kinds of local experiments in many place in the country.

The same arguments holds for new items that need reporting to insurers of authorities.

The same arguments holds for the re-use of data in clinical research.



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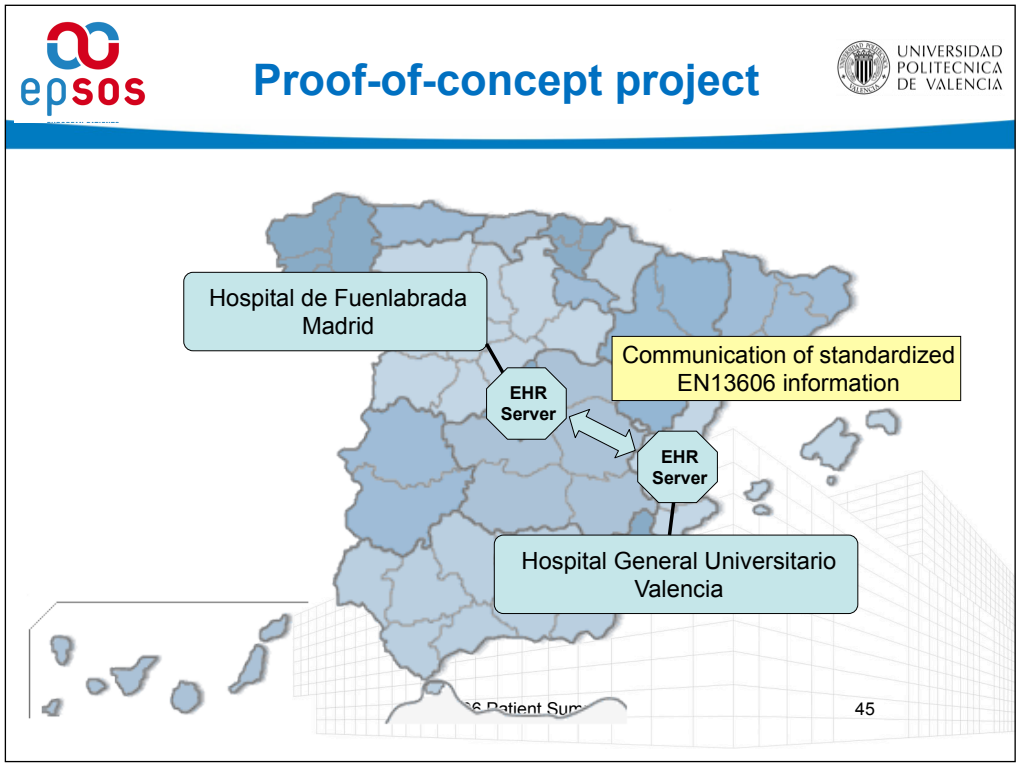
With the use of the EN13606 for exchange between proprietary databases a huge improvement is possible of the classical message stanards



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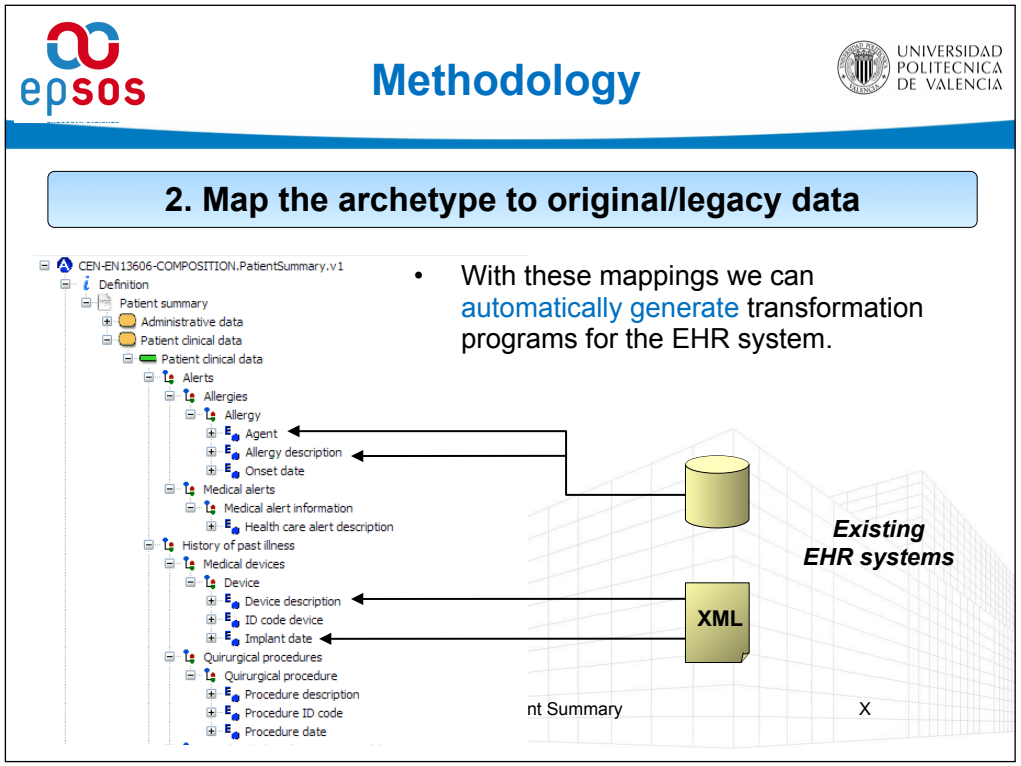
Two University Clinics

Methodology

1. Agree a concept definition and define the archetype

- We have used two different definitions
  - Spanish National Patient Summary
  - epSOS Patient Summary final dataset
- They can be easily edited or modified with open source archetype editors like LinkEHR-Ed

  http://www.linkehr.com



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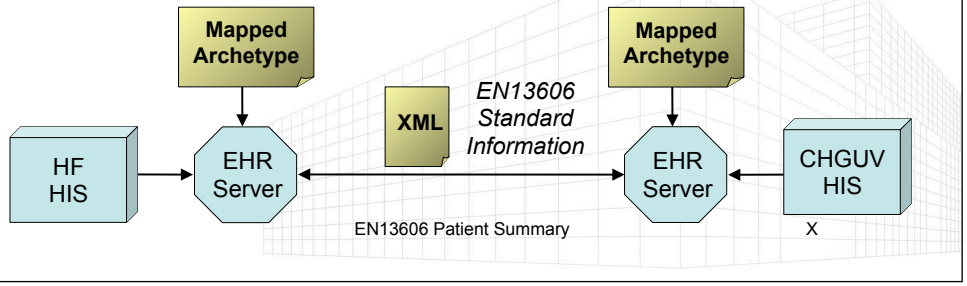
Because of the nature of the EN13606 it is possible to generate software that does the exchange between the systems.

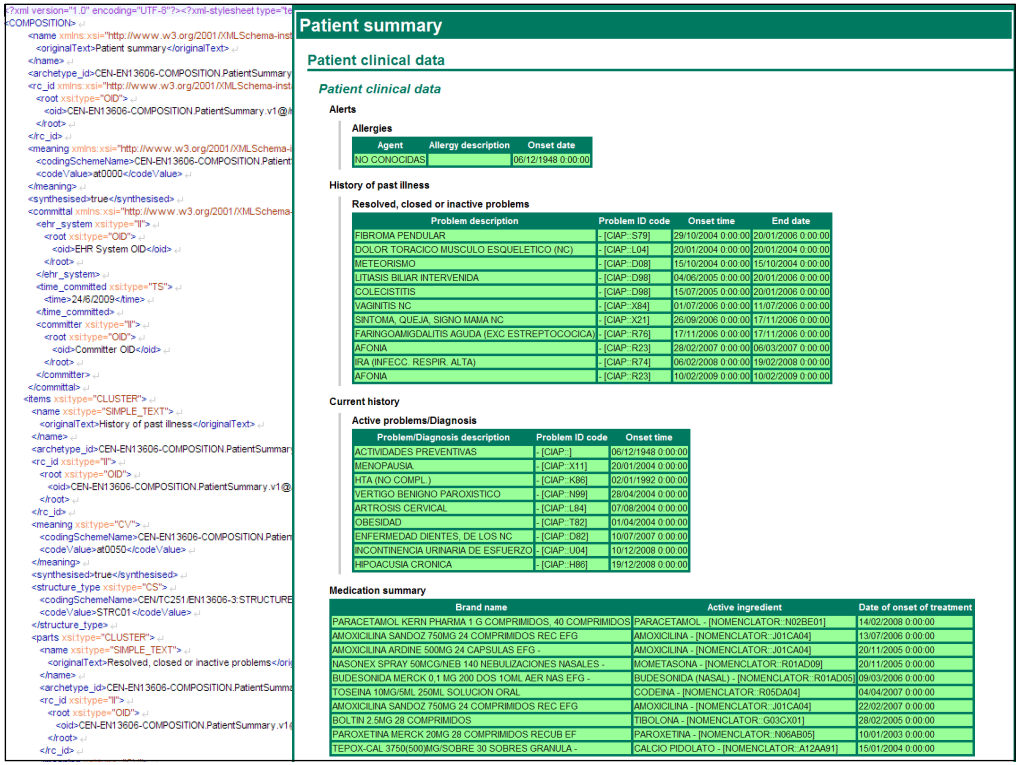
This has many advantages

Methodology

3. Deploy the transformation program in the EHR server

- Set up a standard EN13606 extract server in both hospitals to generate and communicate the standardized information
  - Transformation is applied on demand
  - Web-service based
  - Includes a standard EN13606 web viewer





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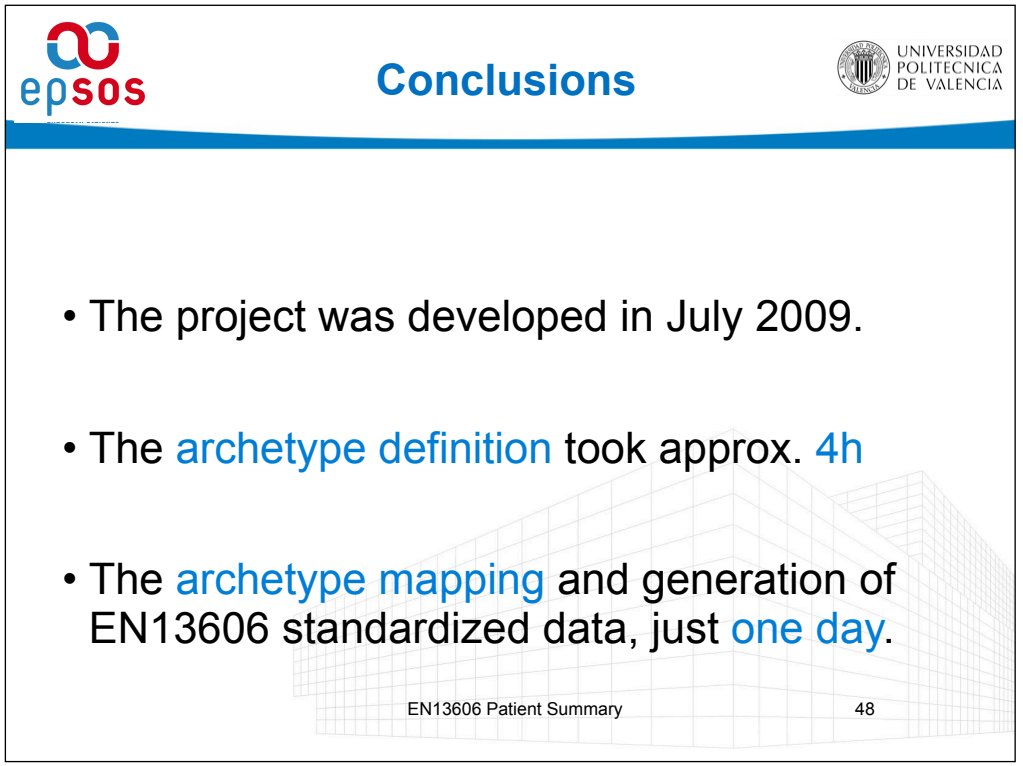

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Remarable results.

Agile development of the Patient summary, easy to produce and change to new or other local needs.

Message standards: Edifact, HL7, IHE

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What is the situation in epSOS today?

Resent-From: wg-semantic@epsos.eu
From: Ana Estelrich <ana_estelrich@yahoo.ca>
Subject: **[epSOS-IT-WP3.5] schematrons**
Date: 17 juni 2010 22:06:57 GMT+02:00
To: epSOS syntax <epsos-syntax-implementation@googlegroups.com>
Cc: Marcello Melgara <MARCELLO.MELGARA@CNT.LISPA.IT> , WG-Semantic@epsos.eu
Reply-To: epsos-industry-team-work-package-35@googlegroups.com

Hello all,

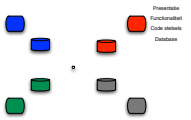
The schemas were due in theory on June 15th. Since this was a woman and two men show (Giorgio and Vassil), it was delivered in time. I will not point fingers; I know Oskar, Tobias and Milada are engaged otherwise, allegedly.

As a side remark, people should either commit or not, as not to give false impression on the resources we can count on or on what they are willing or capable to do. I think this should be reflected in the work effort for each MS (etc).

So far we have two proposals for the medication extension in CDA in the whole three documents concerning epSOS. This endeavor - namely to extend the CDA schema - is hot subject of discussion and a real need in HL7, where CDA R3 is under discussion.

The schemas are all ready for the schematron - they have been since the 15th.

The only point of divergence is the inclusion of the full CMET vs. an-epSOS specific modification, which amounts to a difference in a couple of XML element names.



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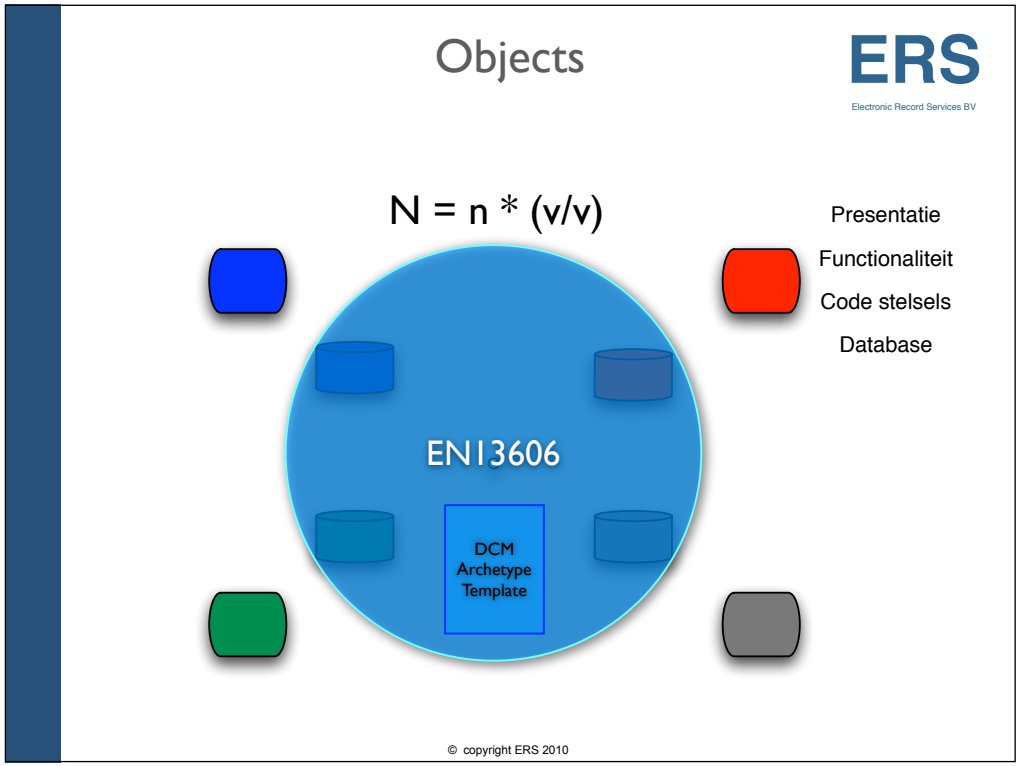
The major drawback of Message standards is:
- they need a lot of resources (time and money) to realise and maintain.



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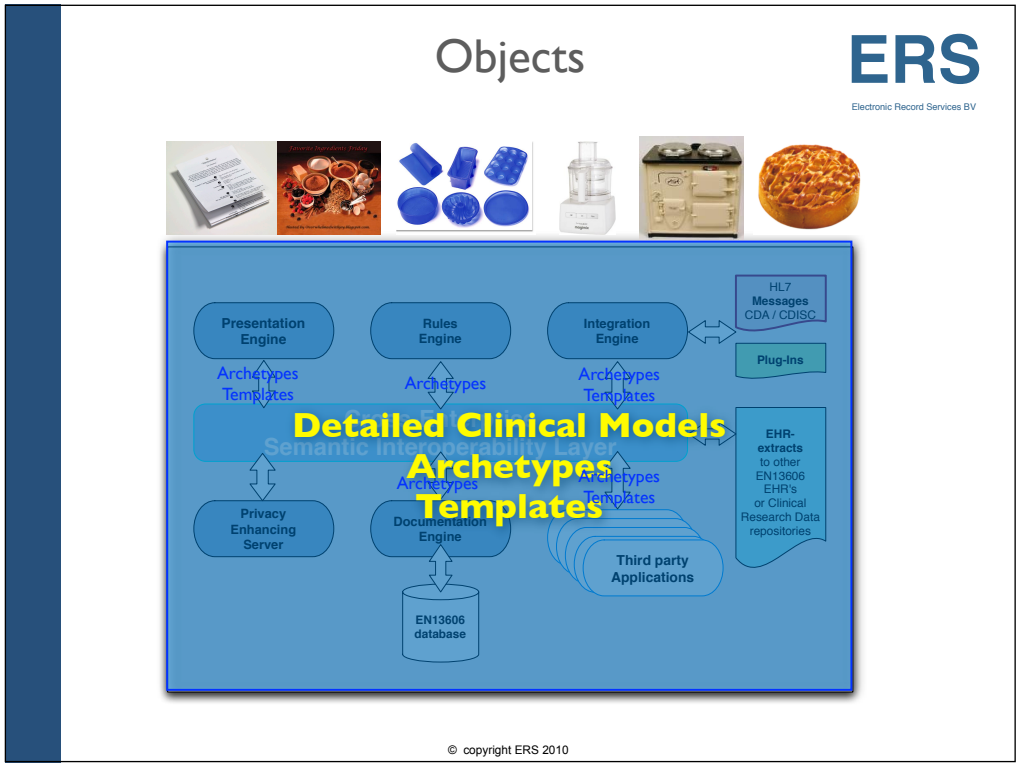
In the proper use of the EN13606 it is foreseen that it will be the basis of a middle ware solution inside EHR-systems.

All systems with this EN13606 based middleware do not longer have a proprietary database.
Archetypes/Templates define what gets stored, retrieved, and archived in the EHR.



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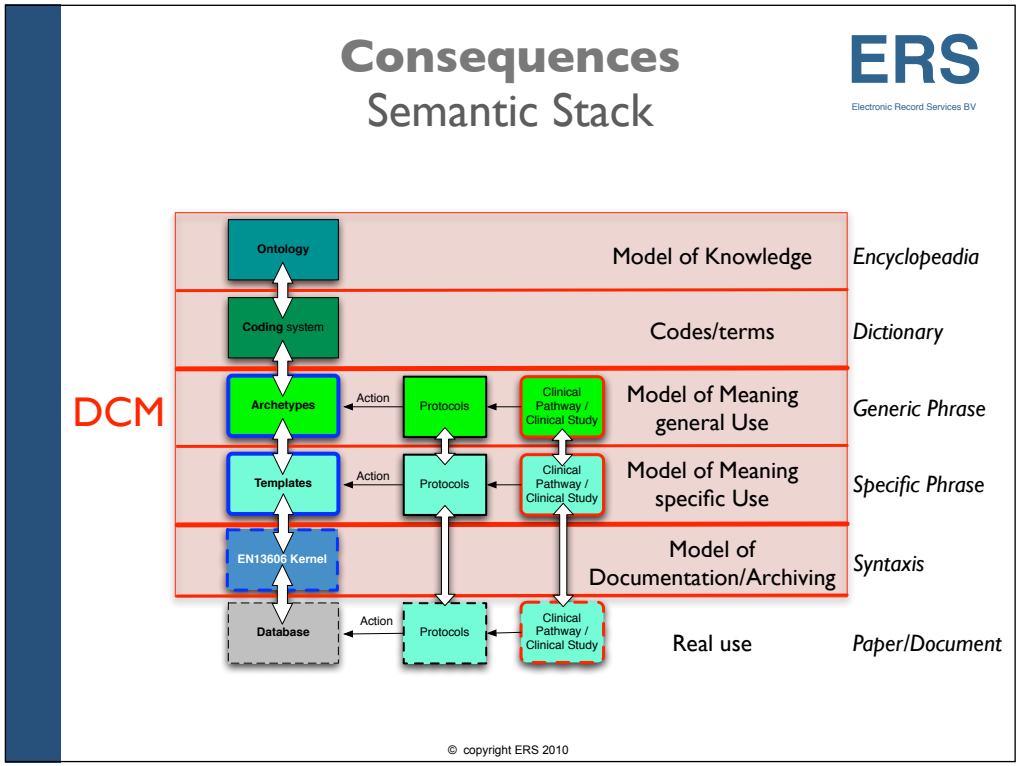
The Integrated Care EHR will enable:
- unified storage of information using Archetypes/Templates
- Screen/report generation using Archetypes/Templates
- A Rules Engine that always finds the information using Archetypes/Templates and helps to create intelligent screens, do case management and clinical decision support

OBSERVE: that Archetypes and Templates (and Rules) define the functionality of the EHR-system and become very dominant and important.
This consitutes the INFOSTRUCTURE (semantic stack)



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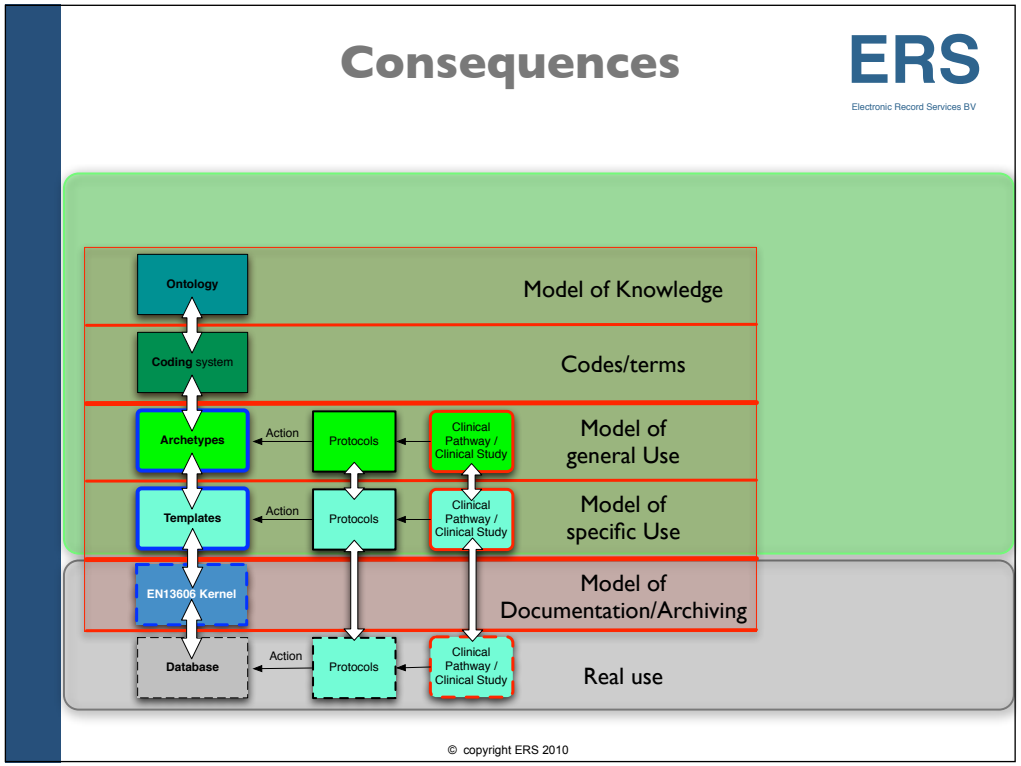
Semantic stack.
This is an idealised picture of what is needed for real semantic interoperability.

We have to deal with:
a- Model of Documentation/Archiving (Syntaxis)
b- Codes/terms (Dictionary)
c- Model of Knowledge (Encyclopedia) to allow systems to reason about the data and information in the future and build correct coding systems.
d- Models of Meaning in general and in specific local contexts.

Archetypes/templates are needed because without it is is possible to construct correct but meaning less sentences:
- the Moon drank the mountain
Or express the opposite of what it states literally
- Once upon a time ...



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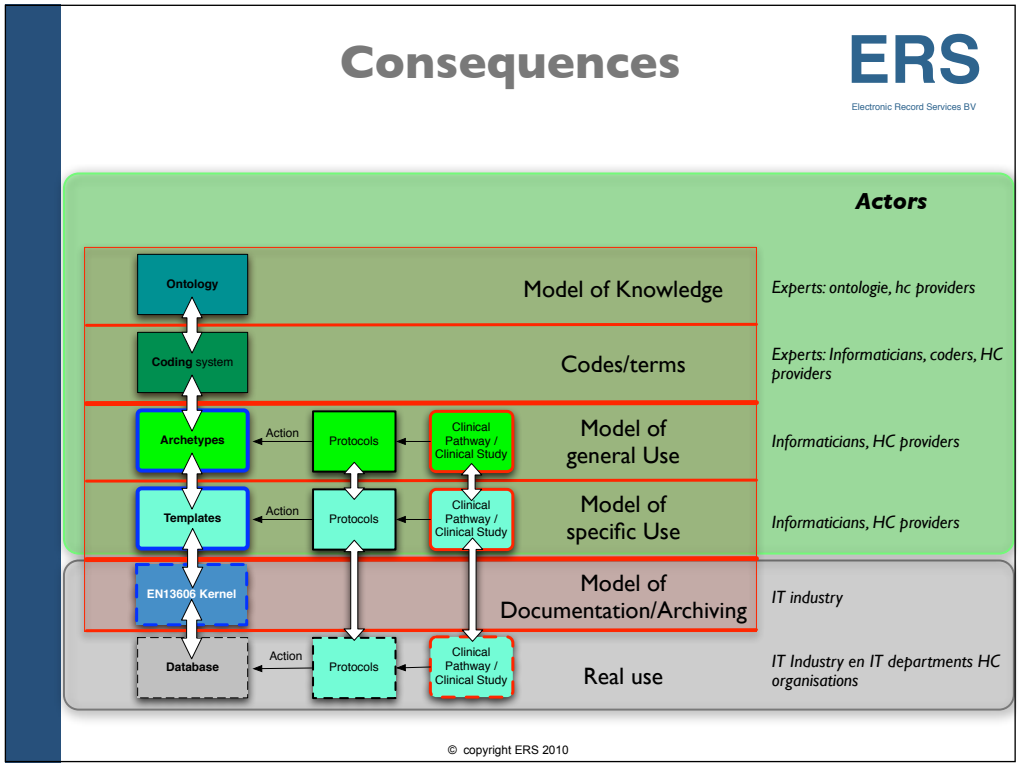
Er zal een absolute scheiding gaan ontstaan tussen de verantwoordelijkheden van de zorg en die van de ICT bedrijven

Nu spelen ICT-bedrijven en ICT-afdelingen van zorginstellingen een centrale rol.
Ook andere actoren: Codeurs, Archivarisen, zorgverleners en Informatiekundigen zullen belangrijk gaan worden.



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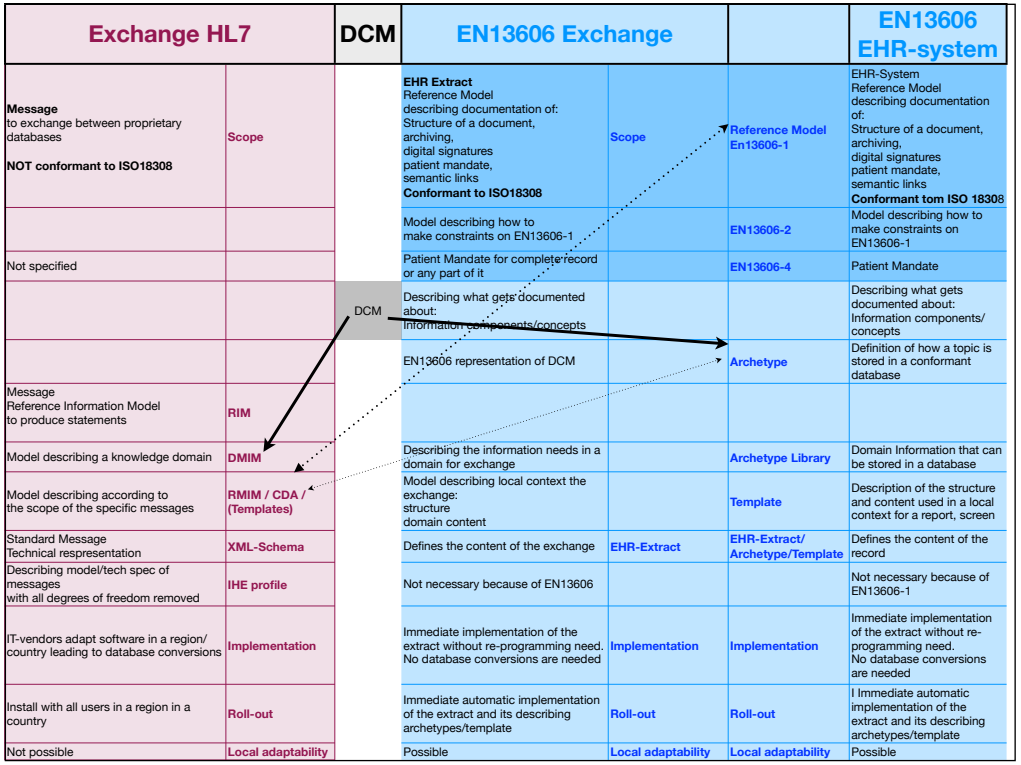
The Healthcare domain will be responsible for the GREEN parts.
The IT-industry will be responsible and active in the GREY domain.

IT-systems will be able to deal with all archetypes/templates the Healthcare Domain produces.
IT-vendors no linger are responsible for the data/information content.



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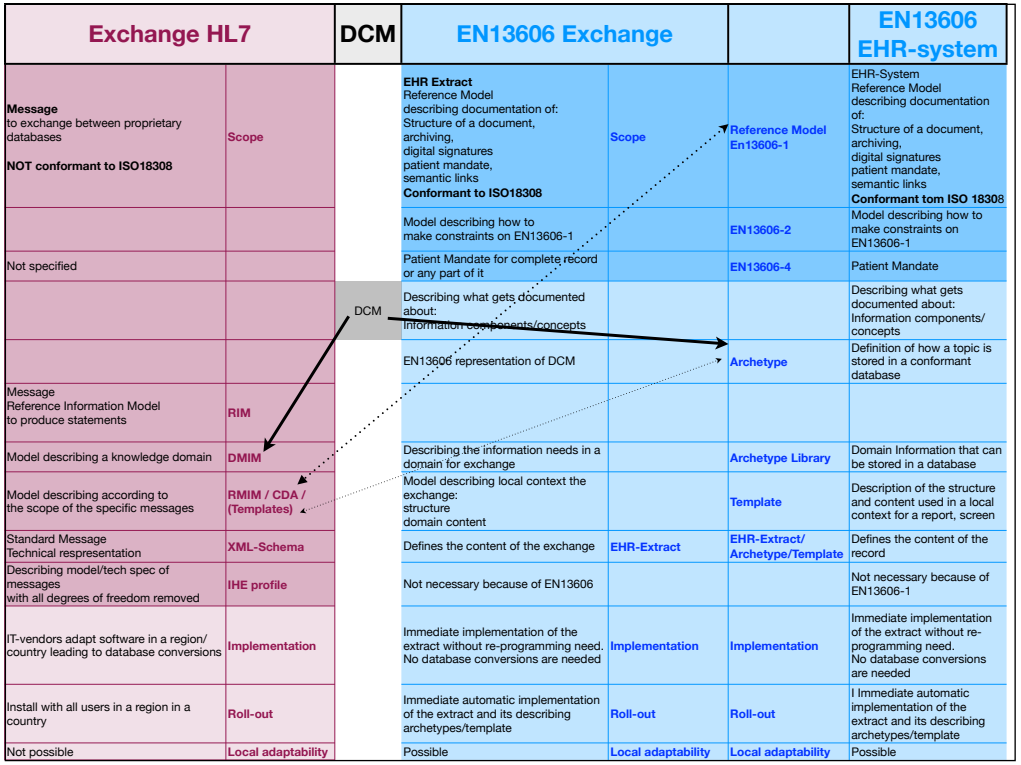
I tried to reflect the similarities and differences between HL7 artifacts and those of CEN/ISO EN13606



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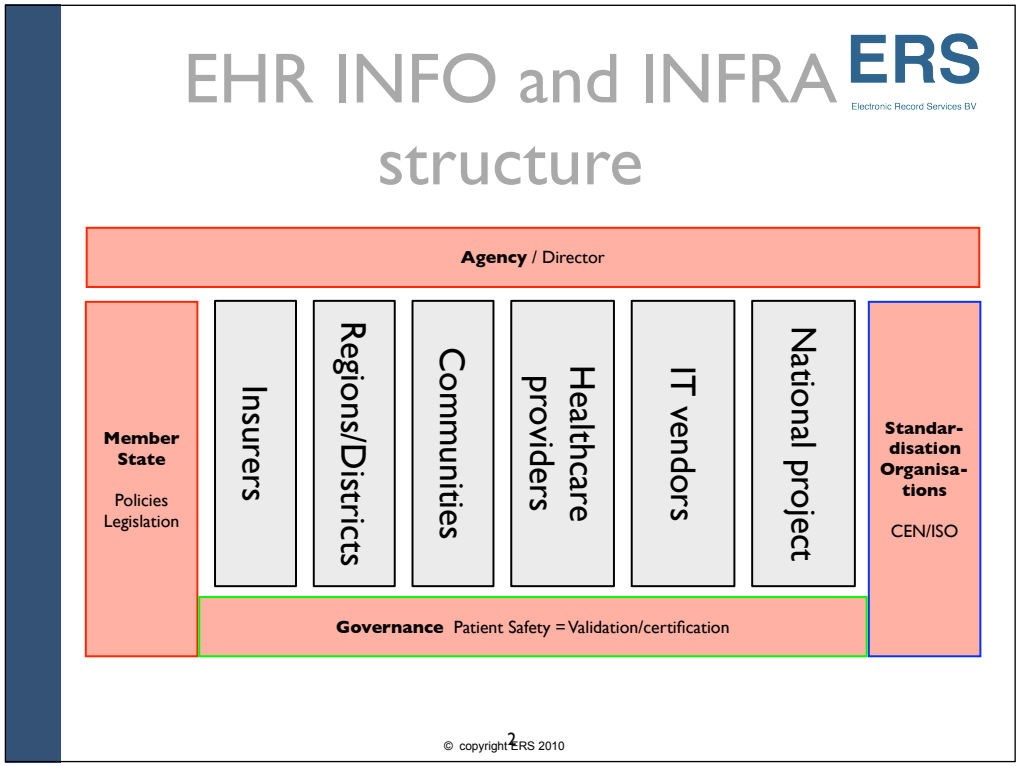
I tried to reflect the similarities and differences between HL7 artifacts and those of CEN/ISO EN13606.
The solid lines depict full equivalence.
The dotted lines depict a limited equivalence.

Observe that left and right there are different shades of collors.
WIth HL7 for a long trajectory both IT and Healthcare have to co-operate to produce an implementable specification using the HL7 and IHE methodology.
With EN13606 most of the stages are fully the responsibility of the healthcare domain. Resulting in specification that get implemented without the need for an IHE process and IT experts.



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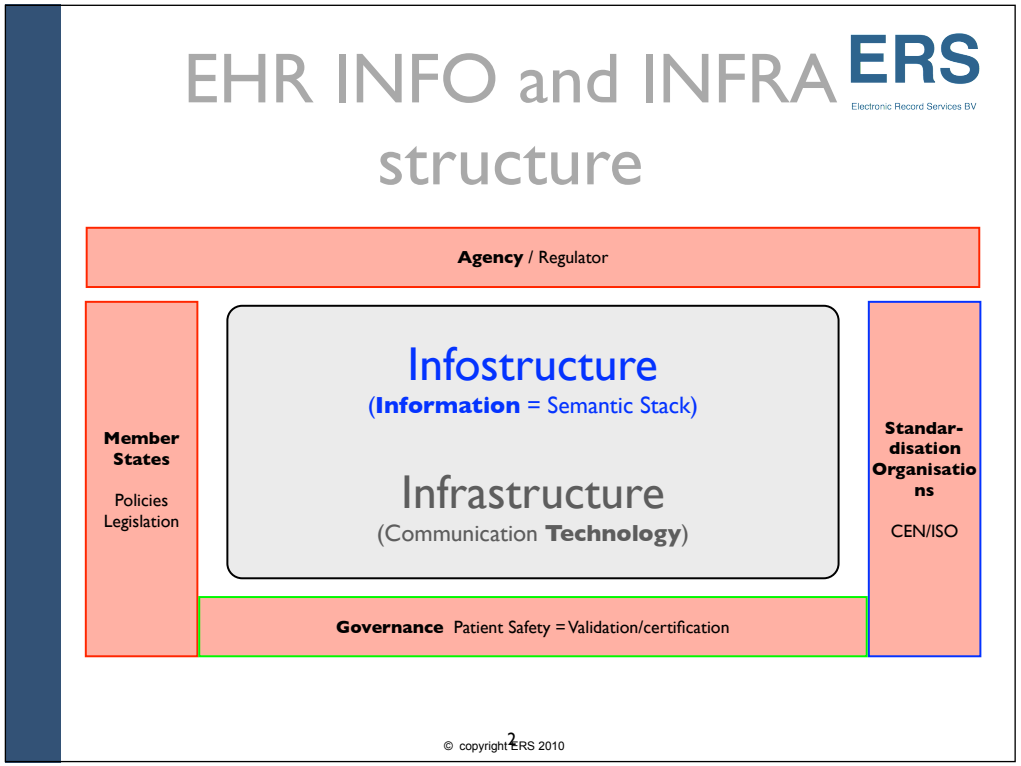
GOAL: one INFRASTRUCTURE for CROSS-BORDER SEMANTIC INTEROPERABILITY

Each INFRASTRUCTURE including the INFOSTRUCTURE needs a supporting FRAMEWORK.
Without such a framework there will not be any infrastructure.
1- **Government**: Policies, Rules and Regulations, proper long term funding.
2- **Standardisation organisations**: with **PUBLIC, OPEN, SPECIFICATIONS**.
It is impossible to create an infra-/info-structure with proprietary specifications
3- **Governance**: Validation of claims to conformance with standards, certification using standardised transparent procedures
4- **Agency/Regulator**: A neutral organisation with experts that help co-ordinate harmonise the complex process.



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Topics

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1. Introduction
2. EHR. What is it?
3. Standards/norms
4. HL7 messages and EN13606 Objects
5. **Conclusions**

Summary

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- **All things need unique identifiers** (persons, organisation, drugs, clinical terms, documents, units of measurement, etc, etc)
- **Messages are static, resource intensive**
- **Messages do NOT support healthcare delivery innovation**

Summary

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- **Messages are about exchange between proprietary databases**
- **EHR is about documentation/archiving health data and not about exchange**

Summary

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- **EN13606 EHR standard is the only European / International standard for an IC-EHR**
- **EN13606 supports healthcare delivery innovation**
- **EN13606 supports re-use of data and information stored**

Summary

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- **EN13606 (Dual Modeling)**
  provides healthcare
  with IT-systems with functionality
  they need and expect
  but never recieved

Summary

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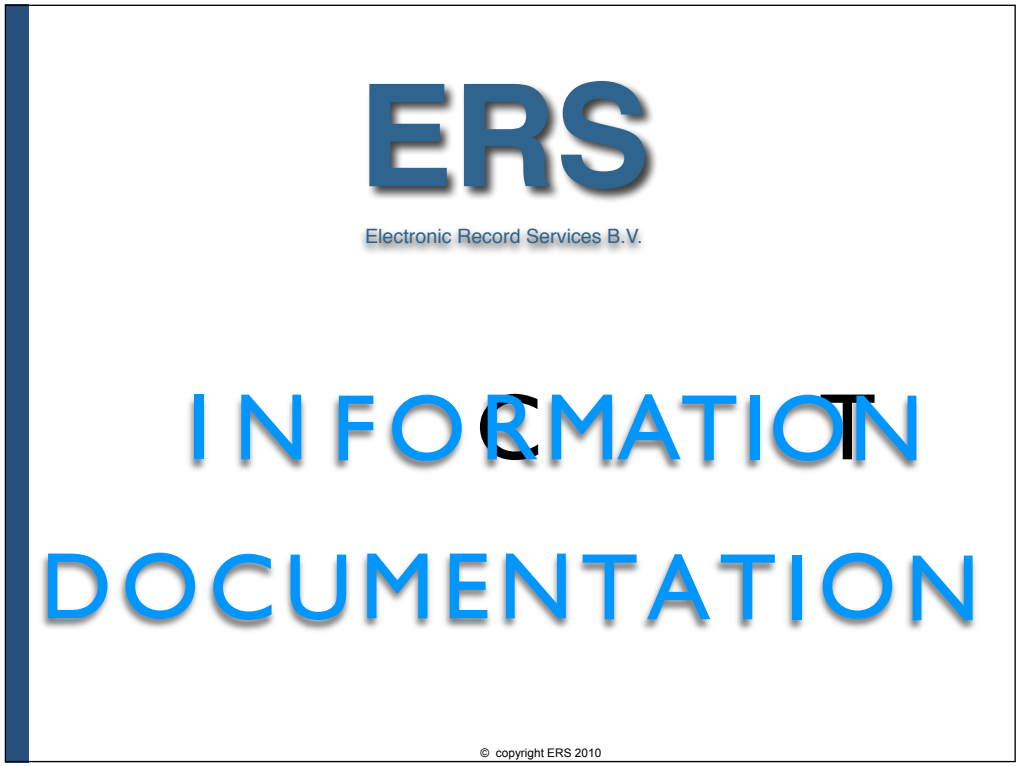
En13606 makes it possible

to start your future today

by dealing with your past



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The EHR is NOT about ICT
It is about Information and Documentation

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