The ERS IC-EHR as Local, Regional and National eHealth Infrastructure

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Present situation

Present Electronic Medical Record systems (EMR-systems) are almost always organisation and healthcare provider focused and like smoke pipes: each pipe is working but not well connected to others. Each healthcare provider or health organisation has its own EMR-system, own set of operating rules, own input and output screens and information that it is able to store and reproduce. Messages update the proprietary databases of EMR-systems. Organisations like hospitals have hundreds of systems, each holding a part of the patient information. Each change to one system will have consequences in other parts in the complex set IT of systems.

Healthcare is very diverse and ranges from tertiary care to the aides and relatives of the patient at home and from healthcare supporting services like preventive medicine, diets, transport, planning and billing. Each user expects a supporting EMR-system that is easy to use and intuitive. Each user has the need for screens that can be adapted to the personal needs (layman to highly trained technician) and at the same time the EMR-system has to deal with the needs of the specific task at hand (simple to complex), from healthcare documentation to business related. Many will have the need to access EMR-systems and interact with it, thereby creating privacy issues.

This brochure describes how the ERS Integrated Care Electronic Health Record (IC-EHR) helps to migrate gradually from the present situation to a state-of-the art eHealth Infrastructure comprising EMR-systems with patient, healthcare provider and organisation focus that together act as an Integrated Care EHR and/or feed a Centralised Clinical Data Repository (CCDR) as an Integrated Care EHR that supports all kinds of eHealth services.

ERS defines the Integrated Care EHR according to the ISO/tc 20514 definition as:

"a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. It has a standardised or commonly agreed logical information model which is independent of EHR systems. Its primary purpose is
the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent, and prospective.”

What healthcare wants

“Several organisations are looking for ways to deliver improved health outcomes ... by delivering integrated and coordinated services within their hospitals, districts and across regions.”

This translates into a set of generic functional requirements for individual Electronic Medical Record (EMR) systems and common eHealth Infrastructures:

- Systems that are patient centric and healthcare provider focused at the point of care;
- Systems for different user types and beneficiaries such as: patients and their relatives, healthcare providers and healthcare organisations;
- Systems that are easy to use and that flexibly combine an integrated view on information, with data-entry, that is adaptive to user needs and unambiguous in presentation;
- Systems that support documentation, archiving, exchange and re-use of information now and in the future any place, any time;
- Systems that flexibly support healthcare delivery processes with decision support, clinical pathways, workflow in co-operating communities and re-use for (clinical) research plus reporting;
- Systems that interact with present existing (working) solutions to aggregate and integrate information to create one single standards based virtual Electronic Health Record;
- Systems that make migration possible from existing (old) systems to a new type of health care IT-system;
- Systems that conform to European and ISO standards for high quality EMR’s including the standards for the protection of privacy;
- Systems that scale well in hospitals, districts, regions and countries;
- Systems that are of high quality, manageable and affordable;
- Systems that can flexibly facilitate reporting and clinical research, because it conforms to the requirements specified by the FDA

1 FDA: 21 CFR Part 11 and 45 CFR 46
the use cases developed by the ANSI-convened Clinical Research Value Case Workgroup.

The ERS IC-EHR has implemented the ISO/CEN EN13606 EHRcom standard and other standards to create an eHealth Infrastructure that makes the above stated list of functional requirements a reality for healthcare.

2 Use of Electronic Health Records in Clinical Research: Core Research Data Element Exchange Detailed Use Case April 23rd, 2009

3 http://publicaa.ansi.org/sites/apdl/EHR%20Clinical%20Research/Forms/AllItems.aspx
ERS IC-EHR: Introduction

The ERS Integrated Care EHR (IC-EHR) is based on the EN13606 and brings to life the potential advantages of this standard. The EN13606 presents a new paradigm for the EHR architecture: the Two Level Model approach. Firstly a Reference Model implemented in an EMR-system or eHealth Infrastructure by technical IT experts and secondly an Archetype Model that allows healthcare experts to define what they need to store, retrieve and archive. Consequently the EN13606 provides a complete separation between the responsibilities for on one hand the IT providers and on the other hand the healthcare knowledge domain.

This Two Level Model approach secures extreme rapid flexibility, adaptability now and in the future and is generically implemented in the IC-EHR.

Using the new paradigm (the Two Level Model approach) the ERS IC-EHR creates an EN13606 Enterprise Information Bus that provides all internal and external applications with a uniform access to the patient information.
Figure 1: The Enterprise Information Bus

The IC-EHR Enterprise Information Bus allows present stand-alone local Electronic Medical Records (EMR’s) to work seamlessly together to form one ‘logical’ EHR. The IC-EHR supports both a centralised and federated architecture for storage of patient health information. An additional advantage is that the new paradigm based on EN13606 makes long term archiving possible, since the meaning of the information is stored via defined archetypes instead of programmed in source codes.
ERS IC-EHR: Integrating and Migrating present EMR-systems

In most jurisdictions many existing EMR-systems are present. The users have selected these EMR-systems because of the functionality these systems provide. Healthcare providers often have emotional bonds with the EMR-systems and functionalities they use. ERS IC-EHR facilitates that this relationship can stay in place in many circumstances.

In a very controlled way the ERS IC-EHR makes it possible to integrate and migrate these ‘old’ systems to modern ones over time. ERS cooperates with existing software vendors to make these transitions possible. ERS provides software vendors with the tools and training to enable the software vendors to connect their EMR-systems to the IC-EHR. Using the IC-EHR EHRcom exchange connector and plug-in structures is a typical first step. As a second step software vendors can migrate their EMR-systems to the ERS EN13606 Information Bus and use the Documentation Engine directly, thereby creating the highest form of semantic integration between systems.

If a jurisdiction decides that all patient health information must be documented, archived, exchanged and re-used following the EN13606 standard, how could an implementation scenario look like when the ERS IC-EHR is used as an eHealth Infrastructure and what results can be expected?

An implementation Scenario

The first step is to decide to use EN13606 for exchange of information as a (National) standard.

As a result of the first step current EN13606 non-conformant EMR-systems will have to use the LinkEHR EN13606 EHRcom exchange connector to integrate with the eHealth Infrastructure. Through the use of the EN13606 Enterprise Information Bus and the Documentation Engine all information stored in the EMR-systems can also be stored in the ERS IC-EHR repositories of the eHealth Infrastructure.

4 LinkEHR™
The ERS IC-EHR repositories can be deployed centrally or dispersed or anything in between in the eHealth Infrastructure. At this stage a EMR-system vendor can decide to migrate from the use of their proprietary database to a situation in which they use the ERS IC-EHR repository (Enterprise Information Bus and Documentation Engine) of the eHealth Infrastructure and make the EMR-systems Archetype\(^5\) / Template\(^6\) driven. Or the EMR-system vendor decides to build their own EN13606 conformant repository. In both cases this will create semantic interoperability at the highest level possible and save the EMR-system vendors money sooner or later.

The EN13606 conformant repositories of the EMR-systems can be deployed centrally or dispersed or anything in between in conjunction with the ERS IC-EHR.

**Benefits for healthcare delivery**

When EMR’s, that healthcare providers use, and Personal Health Records (PHR’s), that patients use, are connected using the EN13606 EHRcom standard the ideal organisation of the delivery of care based on an EHR-Infrastructure becomes possible.

Each healthcare provider has its own Electronic Medical Record (EMR) that supports his work with patients. The healthcare provider can easily adapt the EMR to his wishes and needs at any point in time. The patient uses its Personal Health Record (PHR) for documentation. In the course of this care process the Patient, advised by a Healthcare Provider, decides what information is published via the Patient Summary Record (PSR) and how the information can be consulted by which healthcare providers or a national standard (Template) for the PSR is applied.

(see figure 2)

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\(^5\) Archetypes are the result of consensus between healthcare providers what maximally can be documented about a health topic (like blood pressure, diagnosis, lab-test, etc). In an EN13606 conformant EHR system archetypes can be implemented immediately as constraints on the Reference Model defined by EN13606 part one.

\(^6\) Templates are the result of adaptations to (several) archetypes to reflect the need in a local context. Templates are used to configure Screens and Forms in the EMR-system. In an EN13606 conformant EHR system templates can be implemented immediately as constraints on the Reference Model defined by EN13606 part one.
In case a chronic condition arises more healthcare providers have to be involved in the treatment. The Chronic Care Record defines the agreed information to document and shared cross-enterprise for the joint care provision by each involved individual healthcare provider. Information is entered only once in the EMR of the Healthcare Provider and the PHR of the patient.

The LinkEHR EHRcom exchange connector makes it possible that a proprietary EMR, that is not using an EN13606 Enterprise Information Bus, can connect with an EN13606 based Chronic Care Record.

Both the EMR and PHR are records on their own, containing non-health and health related data. The users of both the EMR and PHR stay fully responsible for documentation of their own care processes. Some of the information in the EMR and PHR becomes part of the Summary Record and Chronic Care Record, including medication, etc.

All information stored in the EMR, the PHR, the Patient Summary or the Chronical Care Record can be re-used for various eHealth Services and Clinical Research. For this purpose the IC-EHR can be used in
prospective-, retrospective correlative studies and inclusion for studies as an Electronic Data Capturing (EDC) system or supporting it.

The Results for the EMR-system vendors
When all patient information is handled in a standard EN13606 conformant way vendors no longer have to build and maintain proprietary databases and complex messages. This saves a lot of money.

The kind of interaction with end-users also changes and becomes less complex due to an absolute separation of concerns between on one hand health care and on the other hand the IT-domain. Healthcare is responsible for the production and maintenance of Archetypes and Templates plus the mappings to all relevant coding systems.

The IC-EHR facilitates an incremental development of sophisticated functionalities, business intelligence and personalised user support by configuration work onsite. All systems functions for intelligent processing, storage, retrieval, exchange and archiving of health information is taken care by the IC-EHR generic Engines.

For Small and Medium Enterprises (SME’s) it becomes more easy to enter the health IT-market with new innovative functionalities when a SME decide to use the existing repositories in the eHealth Infrastructure. The investment for product development will be lower and the time to market will be shorter.

The general commercial approach of ERS is that it works by supporting the IC-EHR for the End User leaving intact the existing EMR vendor or Systems Integrator relationships with that End User.

The ERS IC-EHR can integrate EMR-systems to re-use all medical information for Clinical Research which creates new added value for these EMR-systems.
ERS IC-EHR: Components

The ERS IC-EHR components consists of four Engines plus a Master Indexing Service. (see figure 3)

![Diagram of IC-EHR and the Four Generic Engines with the Enterprise Information Bus and Master Indexing Service](image)

Figure 3: IC-EHR and the Four Generic Engines with the Enterprise Information Bus and Master Indexing Service

Together those components produce extremely flexible and scalable support for documentation, clinical and organisational workflow, migration, integration, reporting, research and presentation. All components use web-services and work together through the EN13606 Enterprise Information Bus. The four Engines can be used by third party vendor EMR-systems. With ERS modeling and configuration tools, national, regional, organisational, departmental and personal needs can very flexibly be defined, changed and configured on the fly without physical reprogramming the IC-EHR system.

Documentation Engine

The Documentation Engine uses the EN13606 Enterprise Information Bus to store, retrieve and archive health information for all connected EMR-systems.
When the Documentation Engine and EN13606 Enterprise Information Bus are introduced in an eHealth architecture it provides to all EMR-systems the same uniform application interface. The ERS IC-EHR Documentation Engine and EN13606 Enterprise Information Bus are designed to support Reference Models that work with Archetypes. The ERS IC-EHR is not designed for one specific database system (like Oracle, SQL Server, Sybase, etc).

**Presentation Engine**
The Presentation Engine dynamically generates screens and electronic forms via defined Templates using Archetypes. The Microsoft/NHS Common User Interface standard is used in order to optimise patient safety by reducing reading errors. The Rules Engine is used to dynamically generate screens or electronic forms. (see figure 4)

![Presentation Engine screenshot](image)

**Figure 4: Presentation Engine screenshot**

**Rules Engine**
The Rules Engine provides several functions:
- rules based intelligent screens and electronic forms,
- rules based clinical workflow, case management,
- rules based clinical decision support,
- rules based organisational workflow.

The formal language Prolog, as used in artificial intelligence, and PROforma, as a formal knowledge representation method, are used for
the development and execution of clinical guidelines. PROforma is the result of several European R&D projects. Archetypes provide Rules Engines with one unified way to get patient information from the EMR. This means that only once the ERS Rules Engine need to be configured for all EMR systems that conform to the EN13606 for the application interface.

**Integration Engine**
The Integration Engine uses the EN13606 Enterprise Information Bus to integrate seamlessly the information from existing EMR-systems. Many existing EMR-systems have possibilities to send and receive messages (Edifact, HL7v2, HL7v3, CDA, ...). The IC-EHR is able to interface using these technologies. In addition to integration through messages the IC-EHR has the capability to integrate seamlessly with existing EMR-systems that are EN13606 conformant or use the ERS IC-EHR EHRcom exchange connector. (see figure 1)

**Master Indexing Service**
With the Master Indexing Service (MIXS) safe and secure relations can be maintained between any kind of database and/or tables. In combination with the EN13606 Enterprise Information Bus the MIXS ensures the privacy and security of Electronic Health Records. (see figure 5)

In an IC-EHR system the patient identifying information and patient health data are stored in two separate databases. The relation between the patient identifying and medical file records is stored in a safe and secure way inside MIXS. In this way, even if the medical records are exposed to unauthorized people, it is not possible to relate this medical information to specific patient identifying information.
MIXS brings the privacy and security of database relations and Electronic Health Records to a higher level. The MIXS server connects a Demographic server with the patient record in the EHR. It plays a central role in access control to the EHR plus it logs who asks and obtains access to the EHR.

Additional important functions of MIXS are:
- Providing scalability of the IC-EHR system by supporting federation of Documentation Engines and Integration with EMR-systems having an LinkEHR ERS exchange connector. It allows almost unlimited numbers of users and numbers of records the IC-EHR can deal with.
- Controlled digital archiving with active patient records stored in fast servers and legacy information stored in slow or off-line storage.
ERS IC-EHR: Information security and privacy features

IC-EHR has several important information security and privacy features. In the IC-EHR all patient identifying demographic data is stored in a Demographics server outside of the EHR itself. The MIXS-server is responsible for granting access to the patient record by persons and external applications like Lab-systems. It generates a complete access-log in the patient record. The EN13606 Enterprise Information Bus enables to sign digitally by the user and attach the patient mandate to all or any part of the patient information. With the Patient Mandate the patient is able to specify who has access to what particular information. In addition it is impossible to change and overwrite any data or information. Only additions to the record are allowed thereby creating a faithful log of what happened and what was documented over time.
ERS IC-EHR: Conformance to high quality standards

European R&D projects have lead to European and ISO standards related to the EMR and EHR. The conformance of the ERS IC-EHR to these standards is one of its unique features.

A few important standards are listed below.
- The CEN/ISO EN13606 the EHRcom standard that defines a Reference Model and Archetype Model.
- The ISO 18308 standard that define the Requirements for EHR architectures. All relevant requirements have been mapped to the EN13606 classes and attributes. This fact makes the EN13606 a very well researched and validated standard.
- The ISO 22600 standard that define the Privilege Management and Access Control. Part 4 of the EN13606 is based on this standard. It enables the patient to control access to any part of his medical record according to European legislation.
- The ISO New Work Item proposal # 13972 on Quality Requirements and Methodology for Detailed Clinical Models has just started its work. Detailed Clinical Models will define in a technology neutral way what clinicians need to document, archive, exchange and reuse. These will become the basis for Archetypes and Templates.
- The work on the Common User Interface (CUI) for the presentation of clinical objects on screens by the NHS England and Wales. In collaboration with Microsoft the specifications for the unambiguous presentation of medical information to the user of an EMR are produced.
ERS IC-EHR: International developments

The European Institute for Health Records (EuroRec) has from the year 2000 developed the organisational and technical infrastructure for ongoing stimulation of the improvement of quality of IT in healthcare.

EuroRec has built a database and web-portal to publish a large collection of functional quality criteria for EMR-systems. These criteria can be queried and grouped on certain aspects and used for certification, procurement and product description of EMR-systems. EuroRec launched a special Quality Seal for EMR-systems complying with a set of the criteria. ERS IC-EHR is in the process of applying for the Seal.

The EuroRec repository on functional quality criteria will be extended with quality criteria for Detailed Clinical Models (non technical expression of Archetypes) and Archetypes plus the methodology for quality assurance and publication of those. ERS is executing this process on behalf of EuroRec.

Quality criteria are needed to secure semantic interoperability between EMR-systems and across Nations. The ERS IC-EHR uses quality assured archetype libraries based on the EuroRec quality criteria to assure patient safe documentation and exchange of information.

Coding systems play an important role in achieving semantic interoperability in conjunction with Archetypes. SNOMED-CT and ICD 11 are expected Reference Terminologies to be used worldwide. The ERS IC-EHR has facilities to support the Healthcare Provider to deal with all local and international codes. At design time of archetypes the appropriate codes will be added by terminology experts. For use at runtime the healthcare providers can make context dependent sub-sets of any coding system.
In June 2010 EN13606 implementers from more than ten countries attended an invitational conference. An EN13606 consortium will be established to co-operate with CEN/ISO, HL7, WHO, ITHSDO and EuroRec.

7 www.EN13606.org
ERS IC-EHR: Product overview

The ERS IC-EHR consists of:
- Integration Engine with a LinkEHR EN13606 EHRcom exchange connector for integration of EN13606 conformant and non-conformant EMR-systems;
- Presentation Engine;
- Rules Engine (Decision support, work flow, Presentation Engine logic);
- Documentation Engine;
- EN13606 Enterprise Information Bus;
- Supporting tools to configure user specific EMR’s, such as a nursing EMR, chronic care records, PHR and patient summary record.

IC-EHR Portal with the capability to integrate all kinds of third party:
- services like ePrescriptions, eMedication, eBooking, eReferrals, eWaiting lists;
- EMR-systems like Radiology System, Laboratory Systems;
- administrative functionalities for the EMR and Hospital Information System: Agenda, Billing, PAS (Patient Administration System), ...

The ERS IC-EHR and tools for modeling are Reference Model independent and can be adapted to changes in and extensions to the EN13606 Reference Model and derived proprietary Reference Models (e.g. openEHR).
This implicates that the IC-EHR and the tools can deal with changes in the way archetypes are modeled and codes from Coding Systems are integrated, making technical innovation and improvements in semantic interoperability possible.
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