KITH

The use of eHealth standards in Norway

A brief history

Torbjørn Nystadnes, KITH

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Introduction

In 1990 KITH[1] was established in order to contribute to coordinated and cost-efficient application of secure information technology in the health sector. According to its statutes, KITH should establish the standards necessary for safe communication within the Norwegian health sector and between the health sector and actors outside this sector.

The European Health Informatics Committee CEN/TC251 was established in the same year as KITH and Norwegian delegates have participated actively from the start both in the committee, the working groups and in a number of the projects and Task Forces that has drafted the standards.

One of the main challenges for CEN/TC251 in the early years was that there hardly were any existing solutions that could form the basis for health informatics communication standards. In order to gain experience, CEN/TC251 therefore produced pre-standards which were to be tried out in the CEN member states. Using the feed-back from the national implementations the pre-standards could then be revised into full European Standards.

Among the CEN/TC251 pre-standards which have been particular important for Norway, are:

- ENV 1613:1995 Medical Informatics - Messages for exchange of laboratory information.
- ENV 12538:1997 Medical Informatics - Messages for patient referral and discharge.
- ENV 12539: 1997 Request and report messages for diagnostic service Departments
- ENV 13606:1999 Health Informatics - Electronic healthcare record communication.
- ENV 13940: 2001 Health Informatics – System of concepts to support continuity of care.

In addition to standards and pre-standards from CEN, Norway uses a number of international classification systems.

- ICD 10 - International Classification of Diseases - 10th Revision.
- ICF - International Classification of Functioning, Disability and Health.
- ATC - Anatomical, Therapeutic, Chemical classification system for therapeutic drugs.
- ICPC-2 International Classification of Primary Care – 2nd revision.
- The Systematized Nomenclature of Medicine (SNOMED) 1984 ed. - (A national profile covering pathology is used.)

[1] KITH, the *Norwegian Centre for Informatics in Health and Social Care*, is a limited, not for profit, company owned by the Ministry of Health, the Ministry of Social Affairs and the Norwegian Association of Local and Regional Authorities (KS)

Standards such as DICOM (Digital Imaging and COmmunication in Medicine) and HL7 version 2.x messages are to some extend used for communication between the different systems used within a hospital while standards from IEEE and others are used for communication with medical devices. In 2009 a couple of services based on HL7 v3 RIM have been developed and implemented in a few hospitals. Some more such services are expected to be developed in the near future.

The policy has been, and still is, to adapt European or international standards whenever possible. National standards are developed from scratch only in situations where existing European or international standards doesn't cover the requirements.

Furthermore, when a standard has been disseminated and is actively used by the health sector, the policy is to keep the standard as stable as possible for several years. Only minor amendments are allowed in that period. Since the costs of implementing eHealth standards are considerable, this policy has been imperative in order to get the standards accepted. Both the health care organisations and their vendors have to be confident that they get a reasonable return of investment when they decide to implement a standard.

To replace an already implemented standard with a new European or international standard is a great challenge and will normally have to take considerable time. Whether the standard to be replaced is a nationally developed standard or e.g. a CEN pre-standard, is of minor importance. If the new standard doesn't provide sufficient benefits for the users compared to the already implemented standard, the willingness to invest in the new standard will be negligible.

In order to ease that problem, a long period of overlapping is required when replacing one generation of standards with a new.

First generation of eHealth standards

EDIFACT messages

The eHealth message standards which CEN/TC251 develops include syntax independent information models. In order to meet the requirements from the different CEN member states, these models encompass a large number of optional elements. Such optional elements may be omitted when a creating profiles of the standard to be used for a specific purpose within a specific domain.

In the early years of European health informatics standardisation, EDIFACT was the preferred syntax for messages and the permanent expert group EEG9 of the CEN workshop eBES (European Board for EDI/EC Standardization), defined a number of EDIFACT messages standards suitable for use together with the CEN/TC251 standards.

Starting in the mid 90'-ties, a number of national profiles on those EDIFACT message standards was specified by KITH in cooperation with the concerned parties in the health sector. Some of these messages, especially the laboratory service reports, was implemented by several vendors and put into widespread use.

Second generation of eHealth standards

XML messages

EDIFACT messages were not highly esteemed by ICT professional. EDIFACT was considered to lack flexibility and the process of defining new EDIFACT elements was very time-consuming. When the Extensible Markup Language (XML) emerged as a simple, flexible text format derived from the ISO Standard SGML, it rapidly became very popular.

Using XML, the message syntax could be defined in an XML schema without any dependencies to EEG9 or others. But by skipping the co-ordinating expert group that defined message syntax, a new problem was introduced. Whilst the CEN/TC251 eHealth message standards were intended to provide cross-border semantic interoperability, the EEG9 EDIFACT messages provided syntactic interoperability. Since no-one took an active lead and defined European or international XML standards as replacements of the EDIFACT messages, the result was that the XML syntax was defined on national, regional or local level. In order to get rid of the limitations opposed by EDIFACT, the coordinating factor that provided the possibility for cross-border syntactic interoperability was lost. It was much like throwing out the baby with the bath water.

In Norway, the transition from EDIFACT to XML started around year 2000. Since no European or international standards for XML eHealth message syntax were available or expected in the foreseeable future, a national methodology was developed. Whilst the information models still should be based on European (pre-) standards whenever available, the guidelines for developing XML schemas was inspired by the early work of HL7 regarding the use of XML, using a subset of the data types defined in CEN TS 14796.

Even if a considerable number of national XML eHealth message standards were developed the first few years, the dissemination took more time than expected. To help solve this problem, KITH established a test server for eHealth messages in 2005. For the time being, this server handles about thirty eHealth message standards and may be used by vendors for testing their implementations of eHealth message standards, both sending and receiving. After having completed the necessary tests successfully, the vendor may apply for a certification for sending and/or receiving that particular message. KITH's test and certification service has been a success and as a result the dissemination has gained speed.

Both the use of the test server and the KITH certification is free of charges for the vendors.

Electronic Health Records

EHR in Norway

In Norway, health record is an all-embracing, logical concept. It follows by law that each health institution (e.g. hospital) should keep one, and only one, health record for each patient that has received health care. A patient's health record should be used for all episodes of care from birth to death, and the record should encompass all kinds of information related to the health care of that patient. This also includes digital images, sound- and video-recordings, information given to the patient, and very sensitive information like decisions regarding committal to a psychiatric hospital.

All categories of authorised health care professionals are obliged to record relevant and necessary information about the patient and the health care in this record. The law specifies

28 categories of authorised health care professionals, e.g. physicians, psychologists, pharmacists, nurses, care workers, medical secretaries etc.

In short, this means that within a hospital, nearly all existing information related to health care provided to a particular patient, is a part of that patient's health record. Regardless of whether the information is on paper or in digital form, and regardless of which file or database the information may be stored in. Health information not considered necessary neither as documentation of health car provided nor for providing safe health care in the future, shall as a general rule be deleted.

The electronic health record (EHR) is the part of that record that exists in digital form. An EHR system is an ICT system that may be used to process the whole or parts of electronic health records.

The health record, including the EHR, should be kept by the health institution until ten years after the patient's death. Thereafter it should be transferred to the National Archives.

When it comes to accessing the EHR, the general rule that follows by law is that a health care professional participating in a specific episode of care should be given the information needed to provide safe health care to the patient in relationship with that particular episode. Nothing more, and nothing less. It is indeed challenging to comply with that rule. A traditional role-based access control isn't sufficient. It has to be supplemented with a component that dynamically can modify the access rights according to the decisions taken regarding the treatment of the individual patient.

Furthermore, the patient has a general right to refuse any health care professional, except the one responsible for the patients health record, access to the whole or a part of the health record. Such blockings may however be overruled in situations where the information is deemed to be essential for the health care to be provided.

This and other provisions related e.g. to the editing, correction or deletion of information in the EHR, makes it very challenging to develop EHR systems. Therefore, requirements that may be deduced from legislation have been given high priority when it comes to national EHR standardisation.

EHR standards

The first version of the national EHR standard was published in 2001. It is based upon the European pre-standard ENV13606-1, Electronic Healthcare Record communication: Extended Architecture, but the scope is much wider. The standard has been revised and version 2 was published in 2007.

In addition to an EHR information architecture compatible with ENV13606-1, the standard covers the following areas:

- Access control
- Patient consent
- Editing, correcting and deleting EHR information, including audit trails
- Archiving

These are all areas where detailed national legislation exists, and the standard shows the preferred way to comply with the provision of law.

The EHR information architecture is slightly more generalised than the ENV13606-1 architecture. Among others, the attribute "component name structure" that is mandatory for each instance of record component in ENV13606-1, is replaced by a reference to a formalised specification of the content of that component. A similar change was done when ENV13606 was revised to a full European Standard. In EN13606-1 the corresponding attribute is named "archetype_id".

This standard does not include any specifications of clinical content, but it specifies how standards for such content should be defined. Based on these specifications, a considerable number of separate national standards specifying clinical content have been developed. These standards correspond to "Archetypes" as later specified in EN13606-2: 2007, and may be transformed to such if needed.

The clinical content specified by these EHR content standards, are also referenced from the eHealth message standards developed the last couple of years. This provides a flexible way of communicating EHR content, providing both semantic and syntactic interoperability on the national level.

Next generation: European or international standards

Nearly all Norwegian hospitals and GPs and a rapidly increasing numbers of nursing homes and other health care providers have the possibility to send and/or receive a selection of electronic messages based on the second generation of national XML eHealth message standards. Some still use the first generation EDIFACT messages but the intention is that the use of these messages should cease by the end of 2010.

Implementation and dissemination of eHealth messages following the already developed national standards have high priority and will go on for the next few years. A number of new eHealth message standards are also expected to be developed on the grounds of the existing national methodology and these will also have to be implemented and disseminated.

All in all, one must expect that the total numbers of second generation national eHealth message standards will be closer to 100 than to 50 before the transition to a new generation of communication standards, starts.

The methodology used for developing national eHealth message standards involves both users of EHR systems and the vendors of such systems. Most vendors are quite satisfied with this situation. Since they are involved in the standard developing process and all standards are based on the same methodology, re-using whatever could be reused form other standards, they find the standards easy to understand and to implement. The test server helps the vendors in their implementation and the KITH certification has a reassuring effect on those who are going to use their systems. However, some vendors with international ambitions advocate a transition to international standards and so does ICT architects from the major hospitals.

Cross-border semantic and syntactic interoperability has from the early 90-ties been a long-term national goal, but it presupposes European or international standards on a more detailed level than those available for the time beeing.

Currently there seem to be two partly overlapping alternatives, ISO EN 13606 Health Informatics - Electronic Health Record Communication, or HL7 v3 RIM (Reference Information Model) and CDA (Clinical Document Architecture). Whilst both standards underpin syntactic interoperability, semantic interoperability presupposes additional work to specify the information to be communicated. Before any of those standards can be used for cross-border exchange of clinical information on regular bases, a set of European, or even better, International Standards for clinical content has to be developed.

European countries have chosen different approaches when it comes to EHR and eHealth communication. Whilst some have decided to use archetypes as specified in ISO EN 13606, others have chosen HL7 CDA. Obviously, European cross-border interoperability cannot be achieved unless a common (EU) decision is taken on which standards to use. Thereafter the necessary new standards may be developed utilising the work done in different European countries and by openEHR. This will have to take several years.

Acknowledging that national standards only solve parts of the problems, adptability has been an explicit goal for the national eHealth standardisation. Since the Norwegian EHR architecture and methods for eHealth communication are very flexible and based upon European pre-standards, it can be assumed that Norway will be able to adapt to a European decision on the use of standards, regardless of what the decision will be.

For Norway, there doesn't seem to be much to gain by starting the transition to the next generation of eHealth standards *before* such a decision has been taken on the European level.

When a decision have been taken on which standards to use for eHealth communication in Europe, a plan for the transition from national to European or international standards can be made. Taken into consideration the time it takes to develop and disseminate new functionality in complex EHR systems, it will take at least two years before cross-border communication can take place on a regular basis.

To replace the existing national eHealth message standards with a new generation based on international standards, will anyhow represent quite a challenge. Most users of EHR systems have experienced that with every new version of the system, new problems are introduced. Therefore it is likely that considerable added value have to be demonstrated, before the health care organisations will accept to replace existing, well-functioning implementation of eHealth messages with new implementations following new standards.

In the transition from the first to the second generation of eHealth messages, this problem was partly solved by starting with the development of new eHealth messages meeting new requirements. Then, in a second phase, XML versions of the existing EDIFACT messages were developed. But nearly ten years after the transition to XML started, EDIFACT messages are still in use. The transition from national eHealth standards to European or international standards is also likely to drag on, and for many years parallel solutions will have to exist.

Conclusions

EHR systems are used by most health care providers in Norway. The systems used by hospitals, GPs, nursing homes and in community home-based care include the possibility of sending and receiving eHealth messages based on national standards. The number of message standards implemented in the different systems, varies but the number is steadily increasing.

XML syntax is used in national eHealth message standards, and the structure is compatible with EN13606.

In the transition from EDIFACT to XML based messages that started world-wide around year 2000, the possibility of cross-border syntactic interoperability was in reality lost. But new standards approved by CEN, ISO and HL7 the last few years, gives a hope for the future when it comes to cross-border semantic and syntactic interoperability.

There are two partly overlapping alternative standards that both may be used to help achieve such a goal:

- ISO EN 13606 Health Informatics - Electronic Health Record Communication
- HL7 v3 RIM and CDA (Clinical Document Architecture).

In order to achieve cross-border interoperability, a European decision should be taken on which of those standards to use. Furthermore, a set of European or International Standards for clinical content have to be developed.

A transition from the current generation of national eHealth messages to a new generation utilising one of the above mentioned standards will be possible. The experiences from the previous generation-shift form EDIFACT to XML indicates that such a transition will take several years to complete.

The implementation and dissemination of the first new eHealth message (a message that isn't intended to replace any existing message) utilising one of the mentioned standards, should be expected to take about two years.