Quality assurance and certification of Health IT-systems communicating data in primary and secondary health sector

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Abstract

Each year more than 70 % (25 mill) of all electronic health documents between secondary and primary health sector in Denmark are exchanged electronically using European EDI standards. Despite this widely use there have been several problems in showing the transferred data in correct and full context. These problems are solved in the 3 years MedCom certification and consolidation project.

The project financed by Ministry of Health, Danish County Association and others through MedCom, involved all relevant health professional groups, organisations, all SW suppliers and all local governments. A new detailed and exact documentation with recommendations and obligatory needs published in “The Good EDI letters” was made, followed by training courses for programmers, test and certification of IT systems by MedCom and finally implementation of certified systems by all users in the country. The certification and implementation process are followed on www.medcom.dk

The results are now a high quality of information and the state of art: One and only way of exchanging documents which are accepted by health professionals and implemented by all SW companies at all users. To day only MedCom certified IT systems are used[2] and the certification is a must for SW companies to be in the market.

Keywords: Certification; Electronic communication; EPR; Implementation process; Health professionals advisory group; Good EDI –Letters; National recommendations;

1. Introduction

Each year more than 25 mill documents are exchanged electronically in primary health sector and between primary and secondary health sector in Denmark. It means that more than 70 % of all prescriptions, lab results, discharge letters, specialists notes, x-ray reports, referrals, labrequests and reimbursement claims and many more are transferred electronically using European EDIFACT standards.

86 % of all GP clinics, all hospitals, labs and pharmacies are interconnected and using electronic documents. The communication is based on a Danish version of UN-EDIFACT standards and have been I use for the last 6 years. But despite this widely use several problems in displaying the transferred data in correct and full context have been seen. Information send was often not displayed or it was misinterpreted. The reason for this was

1. Lack of complete and detailed data definition of each single data element and
2. A national acceptance by health professionals and description of what must be send, what can be send and
3. The specific information placed in the EDI standard.
To solve these problems a 3 year project was launched by the Danish Health data Network: MedCom as: The Consolidation Project.

2. Consolidation (QA) process

The scope of the MedCom Consolidation Project was to improve the quality of the electronic communication of documents and minimize misinterpretation of information. The Consolidation process should include a certification as known from other sectors and countries [2,3].

The current use of electronic health documents in Danish Health sector are covered by 6 European EDI standards for: Discharge letters, Referrals, Lab results, Lab requests, Prescriptions and Reimbursements. The use of the standards was documented in Message Implementation Guides (MIG). The MIG’s are very general and can be used for all types of information and therefore doesn’t show how it must be used in specific documents.

The Consolidation project should solve these problems in 3 steps:

- Making a complete new set of documentation: “The Good EDI-Letters”
  To streamline and point out every single data element and its detailed nationwide use in all types of health documents. Up till now 38 “Good EDI-letters” are published.
- Testing and certification of IT systems:
  All systems must pass a test procedure for each document to show the correct use and presentation of information as documented in “The Good EDI-Letters”.
- Nationwide implementation:
  All users of EDI must implement a one and only certified “The Good EDI-Letters” version of the IT system within a specific deadline.

Step one, “Making the Good EDI-Letters”

Contracts:
MedCom, The Danish Health Data Network, issues written contracts or agreements to participate in the project. The contracts are offered to and accepted by all partners i.e. All SW companies offering systems to the health sector, all 15 counties (hospitals and reimbursement), all laboratories and others.

Draft documents: The Good EDI-Letters:
MedCom makes a draft document for each type of message, i.e. The Good Biochemistry lab results, The Good Microbiology lab results, in total 36 documents. The draft documents are based on current use of the standards, but specify in details the recommended use for each datafield and the presentation of the data at the receiver.

Health Professionals Advisory Groups (HPG):
HPG was established within each specialists area and consisting of representatives from the Medical Societies i.e. Danish Society of Biochemists, Danish Society of Micobiologists, Danish Radiologists Society, GP’s organisations, some IT vendors and MedCom.
In total 6 HPG’s was formed:

- Hospital/GP’s Discharge Letters/X-Ray reports / referrals group,
- Physiotherapists report/referral group
- Biochemists report/request group
- Microbiology report/ request group
- Histopathology and Cytology report/request group
- Reimbursement group.

The HPG went through the draft documentation and made consensus about the recommended use of what must be send, what may be send and how should the information be presented at the receiver. A special topic was how should preliminary results and information be presented and how should corrected results and information be presented at the receiver so the no information was lost or presented in the wrong contest.

Another example is: Just one national way of presenting antibiotic sensitivity schemes in Microbiology.

The HPG made consensus about the content during just two meetings.

A new set of secondary draft documents was made including the HPG’s advise and these documents was presented for a Technician Group.

**Technician Group**

The revised Good EDI-Letters was presented for a Technician Group. Consisting of programmers from leading IT companies and programmers with great insight in EDIFACT. The group went through all the documents to validate if the proposed recommendations were all possible to implement. A series of technical changes was agreed as well as agreement of the definition of each dataset, its use, and exact place in the respective EDIFACT messages so the HPG’s recommendations was fulfilled.

A final version of The Good EDI-Letters was then issued.

**The Good EDI-Letters**

The final version of “The Good EDI-Letters” consists to day of 36 separate documents each covering a specific area. Each document has the following content:

- Health Professional Groups recommendations with paper based examples showing data from a complete document of the specific type. It has also a general description of how the document is used and for what type of information it is used. This description is in non-clinical terms so it can be interpreted by programmers and other non-health professionals.
- Key for the one and only use of the standard within this specific field. Stating what is obligatory to send and what may be send and where is each data placed.
- Data list with the detailed definition of each dataset, its current use and with limitations in length of data-field and type of data-field.
- Qualifiers list with all accepted qualifiers and their definition.
- EDIFACT examples of messages with maximum content of data and information.
- Eventually other relevant information i.e. codes / barcode definition etc.
Step 2
Implementing "The Good EDI-Letters"

All documents ready
At a specified date all documents was ready and could be used without any fee and free to use for everybody. They could be found as a) Printed paper versions, b) Electronic documents on MedComs website [www.medcom.dk](http://www.medcom.dk) De gode EDI-breve and c) On a CD - ROM.

Training course for programmers
MedCom arranged 2 intensive training courses for programmers from all participating SW companies. Each document was presented in detail, and there was possibility for programmers to start programming and to share experience amongst each other. The overall costs for the training courses were covered by MedCom and followed our so-called NICE-concept, where programmers are taken abroad so they can concentrate about this task.

Testing and Certification
After fulfilling the training courses and making programme adjustments the SW companies must pass a test and certification procedure. The test and certification is followed on MedComs website where all certified SW products are listed (green coloured) as well as the non certified (red coloured). The testing is documented in a test protocol [4], where it is detailed described which steps a sender must pass and which steps a receiver must pass to be certified.

MedCom has developed a software product: EDI-CHECK, where each type of document can be tested according to “The Good EDI-Letters”.

For a sender it is obligatory to make a series of documents covering all information stated as maximum examples, send it to MedCom and have it tested in the EDI-checking SW. A check report without any remarks must be passed before a certificate can be issued.

For a receiver, MedCom sends several test documents by EDI and it is obligatory to show how different types of documents are received and presented according to the test protocol. The presentation of data in right context is an important part of the test. A test report without any remarks must be passed before a certificate can be issued.

Implementation

In the MedCom contracts with the SW suppliers it is stated that a certified version is distributed to all customers within a specific deadline and no old versions are allowed to be distributed after this deadline.

For the hospital owners, counties and laboratories the MedCom contract requires, that all must buy and implement updated and certified versions of the software within a specific deadline. The cost of the updated software is covered by the user. All counties and laboratories are also obliged only to communicate with partners using Certified systems. MedCom follow the implementation by a monthly statistical overview presented on the web.
3. Results
36 documents “The Good EDI-Letters” covering all relevant types of EDI –messages in use in the Danish health sector are issued. The documents describe the recommended content and use of all messages as well as the detailed description of how the messages are implemented.

53 SW suppliers are tested and have passed the certification process during a 1 ½ year period. In total 611 applications have been tested and passed the certification process. Only certified document types and SW versions are now in use at the end of year 2002 and more than 25 mill messages (70 % of all documents), are transferred each year using this new versions.

Number of inaccurate or faulty EDI-messages are measured by “negative-controls”. The number of negative controls has reduced from 7491 to 2253 during the 3 month period from October 2002 to December 2002, after implementation of DGE.

4. Conclusion
The consolidation and certification process for all users of EDI communication in the Danish Health sector results in the one and only way of exchanging electronic documents in the health sector. It has greatly improved the quality of the information [5] and for the first time there is no discussion of what must and what may be send. Everybody knows the content of each type of document and many discussions about a specific document is omitted. It is easy to find the documentation and it is written in a clear language so programmers without health background can understand it.

Setting up a national strategy for establishing a common understanding and agreement of the content of electronic health documents is a must. It is supposed that the way it has been organised in Denmark can be transferred with minor changes to other countries. There are great benefits for making it as a national project, and the only disadvantage seems to be that it is a huge project which need to have an organisation to follow up and maintain the standards and handle new rules and reglations which need to be implemented.

5. References
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