Term paper

„Beschreibung und Analyse ausgewählter E-Business-Aktivitäten
im Gesundheitswesen (eHealth)“

The ePrescription System in Finland.

A Case Study

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1   Introduction

During the recent 20 years, information technologies significantly changed the daily life. Modern computer systems, in combination with communication systems, offer a variability of new services, in business as well in private households and environment.

The Health Care sector, as a combination of private and public sector, also experienced various changes with the introduction of information systems. In 1999, the term eHealth showed up in academic literature, and has been introduced for a variety of related services. Eysenbach defines eHealth as *"an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies"* (Eysenbach 2001)

A more specific definition for eHealth mentions the usage of information and communication technology (ICT) by the health care stakeholders (Iakovidis et al. 2004). We will follow this definition and extend it slightly:

- On the patient's side: seeking health related information online, the usage of self-management tools or the request of second opinions from health care professionals,

- For primary care: ICT for patient management, medical records and electronic prescription

- In home care: medical services delivered electronically by medical professionals to the patient's home. This includes automatic data transfer of patient data from electronic medical devices for personal usage or support of continuous long term treatments, e.g. coronary heart diseases or diabetes by electronic supervision of current conditions

- In hospitals: ICT for scheduling logistics, patient administration, inner-organizational information exchange of clinical and administrative data (including laboratory, pharmacy, nursing) and telemedicine

- For insurers and governmental organizations: ICT for invoicing between the participants and collecting statistical data

1.1   ePrescription as one application in eHealth Systems

Electronic prescribing, as the electronic handling of prescriptions by health care professionals, is clearly a part of current eHealth approaches as seen above.

Kilbridge and Dladysheva define e-Prescribing as *"entering a prescription for a medication into an automated data entry system (handheld, PC, or other), and thereby generating a prescription electronically, instead of handwriting the prescription on paper"* (Kilbridge & Dladysheva 2001). As this definition has no specification, how the prescription actually will

be processed to the dispensing organizations (e.g. a local pharmacy), electronic prescribing in their sense is a way to use information systems and database to create a prescription, while any further processing can be handled without any information system.

In addition to the action of e-Prescribing as the creation of a prescription, we define an electronic prescription, also called ePrescription, to be

"the processing of a drug prescription in an electronic form, starting from the medical professional prescribing the drug and ending with the actual dispensing to the patient", including the process of drug selection and invoicing, with the data always stored electronically"

ePrescription under this definition is the main research topic our case study is focusing on. An electronic prescription is, seen in context of our extended definition for eHealth systems, a mayor communication link between the stakeholders in eHealth systems.

For this reason, our research will focus not only on technical aspects, but the relations between the stakeholders and their experience and influence in implementing this inter-organizational information system.

1.2 Motivation – Why a case study, and why in Finland?

Electronic health care systems are running in several countries and in different stages. Also, ePrescription is running in variant flavors, e.g. in the United States, Sweden or Denmark. In our case study we will describe the situation of ePrescription deployment in Finland, as the systems just started in a productive environment in the period this case study was prepared and conducted.

Next to the close temporal link, the local concentration of involved parties in Finland gives the possibility to get a complete view on the system with all its participants in deployment as well as in daily usage.

Literature of the current running system is not available in an accurate quality, and with the focus on interactions between the participants and not only on the technical process, the research method of a case study is an appropriate way to get a view on deployment of the system and the way electronic prescriptions are handled.

1.3 The health care market in Finland

We will provide a brief introduction to health care in Finland in general, and the stakeholders involved in eHealth and ePrescription solutions in general. All information was available from public sources, and is independent from our case study research.

1.3.1   The public and private health care system

Three main health care systems receive public funding: municipal health care is fully covered by local taxes, while private health care and health care offered by employers are partly funded by the National Health Insurance. The National Health Insurance (NHI) also covers expenses for outpatient drugs. NHI is run by KELA, the Finnish social insurance institution. It is compulsory and funded by insurance fees collected with taxation (Vuorenkoski, Mladovsky & Mossialos 2008).

Expenses on prescribed medicines were 1,890.3 million euro in the year 2008, which is 84.7 percent of the total expenditure for pharmaceuticals and other medical non-durables (Matveinen 2010).

Outpatient healthcare is mainly provided by the public health care system. The municipalities are responsible to offer primary health care to any of their residents by a local health center or in a federation with other communities. 237 health centers were counted in 2007 to serve the residents of 415 municipalities.

1.3.2   Pharmacies in Finland

The pharmacies in Finland are privately owned. Regulations require that a pharmacist may obtain one license to hold a pharmacy and up to three licenses for a subsidiary. An exception is the university pharmacy Yliopiston Apteeki, which holds several branches in different parts of Finland.

The Association of Finnish Pharmacies (AFP) reports that 2009, 617 community pharmacies with 194 subsidiaries were open to customers. 594 pharmacy owners are responsible for a total staff of 7,717 employees by 31st of December 2009. 79 percent of the pharmacies dispense less than 100,000 prescriptions per year, 26 percent even less than 40,000.

In total, 48.6 million prescriptions have been dispensed in 2009 (Kostiainen et al. 2009).

1.3.3   Electronic systems used in the Finnish health care sector

Pharmacy systems

Two players cover the whole Finnish pharmacy market with their software products, sharing the market equally approx. fifty-fifty. A privately run company is Receptum Oy with LIN-NEA and MAXX, where LINNEA is the mature system and widely spread. Receptum has about 40 employees in total. The AFP runs its own software company called Pharmadata Oy with 12 employees. Pharmadata sells the mature SALIX system and the newly developed pd3 system. pd3 is based on Microsoft Navision and should gradually replace SALIX (Kostiainen

et al. 2009). Both systems include invoicing mechanisms for drug reimbursement with KELA as the paying institution for the National Health Insurance (NHI).

Information systems for medical professionals

The market for software in medical environment is covered by 80% by two software products. LOGICA offers its product PEGASOS, which is actively supported by several municipalities to be adopted for Finnish requirements. TIETO's product for health sector applications is EFFICA, available in several flavors for primary care, hospitals and dental care.

Both companies are global IT service providers, TIETO with 16,500 and LOGICA with 36,000 employees in total. TIETO is based in Helsinki and has approximately 6,000 employees in Finland (Tieto Corporation 2010). LOGICA is based in the U.K. and serves Finland with 3,100 employees in 18 Finnish offices (Logica plc 2010).

2 Literature review

Part of our preparations to conduct this case study was an accurate literature review and research. Both academic literature and information material and presentations such as slide shows and posters of the participants were in our focus. Using this material, we began built up our case study database as proposed by Yin (2003) and to draw a time line about historical evolution of the system and also a sketch of the implemented system.

The material we reviewed can be classified in three main categories: academic reviews of the situation in health care, academic publications concerning electronic prescription, and eHealth and information material by different stakeholders in the project. Using this classification, one can get a first impression about validity and accuracy of the information obtained from the literature collection.

2.1 Academic reviews of the health care system and eHealth strategy

Vuorenkoski, Mladovsky & Mossialos (2008) describe the Finnish health system as well as the planned perspectives for future development. Their report gives a complete view to the health system, mentioning eHealth and electronic prescription as one of the future challenges. The role of eHealth in the Finnish health strategy is pointed out and put in the overall-context.

The eHealth in 2007 situation is stated by Doupi, Hämäläinen & Ruotsalainen (2007). The overall road map and the deployment achieved at this time are presented. The ePrescription system and implementation itself plays only a minor role in their disquisition.

The report "eHealth of Finland - Check point 2008" by Hämäläinen, Reponen & Winblad (2008) presents results and conclusions from a 2007 survey. All areas of eHealth in Finland

are covered; they also mention data security and economic issues and their influence on the electronic prescription system.

2.2　Academic publications on electronic prescription

The electronic prescription has been evaluated from different point of views in Finnish academic circles. The first publication concerning electronic prescription in Finland that we found during our research was published in 1997 by Niinimäki & Forsstöm. It mentions a first pilot in 1989-1992, but focuses on a pilot project called TROPPI which took place in Turku in 1997. The paper gives a first idea about the Finnish model of a centralized prescription database managed by one authorized institution.

Suomi & Salmivalli (2002) investigate the idea and advantages of electronic prescriptions and factors of a successful implementation. Their publication is summarizing a case study conducted in November 2001 and thus a snapshot at the very early state of the whole project. It points out the expectations of various stakeholders and can be used for a comparison of goals set in the beginning and actual achievements at the current time.

Hyppönen et al. (2005) are focusing on the evaluation of a pilot project during 2004. They describe the methods and background of their evolution and give a short overview of their results. This publication can be seen as a hint to the main problems which may have been appeared in the current implementation of the productive environment. In a conference proceeding, Hyppönen, Salmivalli & Suomi (2005) describe problems and implications of the implementation as it is a "national infrastructure project". They mainly aim on the organizational point of view and compare the Finnish experience with those in other countries.

In a third publication by Hyppönen, Salmivalli & Tellinger (2006), a rough comparison between the evolution of ePrescription in Finland and Sweden is made, characterizing the Finnish approach as a "top-down [...] path"

Salmivalli published an article (2006) and his PhD thesis (2008) "Governing the implementation of complex inter-organizational information system network - The case of Finnish prescription". He gives an overview about the pilot project running 2006-2008 and, as the title implies, is illuminating on challenges in governing such a project. With these publications, the reader is able to get a complete overview about the preliminary organization before starting the 2010 production system. Also, the main cruxes which appeared and, most likely, should also re-appear in the 2010 system are analyzed here.

2.3 Information material by different stakeholders

We obtained any further information about technical details and important events by presentations held by representatives of the involved parties, some key material were, amongst others, (Virtanen 2008) and (Horelli 2009). Additionally, KELA offers information at the KanTa project website (KELA / The Social Insurance Institution of Finland 2010)

3 Methodology

Researcher Robert K. Yin defines the case study research method as "an empirical inquiry that investigates a contemporary phenomenon within its real-life context; when the boundaries between phenomenon and context are not clearly evident; and in which multiple sources of evidence are used" (Yin 1994, p. 23).

3.1 Single-case descriptive design

In order to understand and examine the processes of introducing ePrescription in Finland, case study method was chosen. This method enabled us to exploit the real-life context of introducing a new electronic healthcare system in Finland and to understand "how" and "why" the process evolved.

In identifying the three main case study designs (exploratory, explanatory and descriptive), Yin characterized the descriptive study through the following attributes:

- The collected information constitutes mainly describes processes and events, as well as the contexts in which they occurred (qualitative data).
- The main emphasis is on the construction of verbal descriptions of experience but quantitative data may also be collected.
- Provided Data is highly detailed. (Yin 1994, p. 22)

The amount of literature, interviews ant the closeness to the information sources enabled us to gather a deep view of the process and a good understanding of it. Therefore we argue that are able to bring out the details of the system-introduction process from the viewpoint of the participants by using multiple sources of data.

According to Yin, there can be different rationales for choosing a single-case design: critical state, revelatory status, longitudinal design or representativity of a whole industry/society. (Yin 2003, p. 39)

We consider our case to be unique, given the novelty of the system and of the Finnish approach to it. Nevertheless, the Finnish ePrescription system is to some extent representative for inter-organizational processes with a large number of actors.

3.2   Definition of the research questions

According to Stakes and Yin, the first step in case study research is to establish a research focus to which the investigator can refer over the course of his study. The focus of the case study can be stated by proposing questions about the situation to be studied and determining a purpose for the research. In general questions which begin with "how" or "why" are particularly suited to establish the purpose of a case study. (Yin 2003, p. 21; Stakes 1995, p. 15)

In this case, our focus was the accurate description of the introduction process and the functioning scheme of ePrescription system, as part of eHealth approaches in Finland. Based on literature review, our study questions have initially been:

- Why should this system be implemented in Finland?
- How does the system work?
- Which development steps can be identified?
- Which stakeholders can be identified?
- Which challenges have arisen in the development and how have they been dealt with?

During our investigation, we were able to gather a solid grasp of the facts and discover new areas of interest for our research. We refined our study questions list and added:

- How is the project being financed?
- How does the specification process function?
- How is the security of the system being assured?

3.3   Case Study Protocol Design

The second stage in conducting a case is the development of the case study protocol. This stage is composed of two main chapters: Determining the Required Skills and Developing and Reviewing the Protocol.

3.3.1   Determining the Required Skills

According to Yin (2003, p.58), the skills that are to be expected of the investigator in order to conduct a quality study are: Good knowledge of the phenomenon, ability to ask good questions, ability to be a good listener, lack of bias and flexibility throughout interviews.

In our investigation we started with a through preparation of the literature, being able to assure that each member of the team had a sound knowledge of the system we were investigating. The design of flexible question-guide and the group discussions preceding each interview, provided each member with the necessary knowledge of "good questions" needed to conduct a quality interview. Through discussions with our professor, as external advisor,

we managed to assure our unbiased view of the study subject and remain flexible throughout the investigation.

3.4   Developing and Reviewing the Protocol

"The case study protocol is a major way of increasing the reliability of the research and is intended to guide the investigator in carrying out the data collection from a single-case study." (Yin 2003, p. 67)

A draft of the protocol has been developed by the team in the early stages of the research. This followed extensive relevant readings on the topic which helped in developing the study questions and in identifying the appropriate interview partners.

The protocol included the following sections:

- Overview of the case study project – objectives, case study issues, theoretical framework
- Data collection procedures – literature sources, data collection plan, interview schedules
- Case study questions – as listed above
- A guide for the case study report - outline and format for the final report.

3.5   Conduct of the Case Study

The next stage of the methodology recommended by Yin (2003, p. 83) and which were used in the current study, is the Conduct of the case study. There are three tasks in this stage that must be carried out for a successful project: Preparing for Data Collection, Distribution of the Questionnaire, and Conducting Interviews.

3.5.1   Preparing for Data Collection

In case studies, data collection should be treated as a design issue that will enhance the construct and internal validity of the study, as well as the external validity and reliability. (Tellis 1997)

According to Yin (2003, p. 83), there are three principles of data collection:

a) Use multiple sources of evidence

The rationale for using multiple sources of data is the triangulation of evidence. Triangulation increases the reliability of the data and the process of gathering it. In the context of data collection, triangulation serves to corroborate the data gathered from other sources.

Out of the six primary sources of evidence identified by Yin (2003, p. 86), our research has been based on three of them therefore fulfilling the data triangulation requirement:

- Documentation (formal studies and papers, press articles, administrative documents)
- Interviews (open-ended interviews in order to expand the depth of data gathering and to increase the number of sources of information)
- Direct observation (field visit to the pharmacy running the ePrescription pilot)

b) Create a case study database

The data collected during the investigation need to be organized and documented in order to be available for later use.

To serve this scope, we have developed in our investigation apart from the final report:

- Interview recordings and transcriptions database
- Interview partners database
- Case study documents database
- Case study notes database

c) Maintain a chain of evidence

In recommending that a chain of evidence be maintained, Yin "was providing an avenue for the researcher to increase the reliability of the study. Reliability refers to the stability, accuracy, and precision of measurement. " (Tellis 1997)

In order to assure this, we have made the following arrangements:

- The link between our initial study questions and the chosen case study procedure has been pointed out in the Methodology Section of the final report.
- The data collection has been deployed as described in the case protocol so that procedure can be repeated at a later point with the same results.
- All actual evidence has been stored in the databases for later checks.
- The final report contains extensive citing of the case study database and of the literature used.

Also as part of our data collection preparation we tried to anticipate key problems and events (such as unavailability of interview partners, lack of new information provided in the interviews), we identified key players in the Finnish eHealth system, prepared letters of introduction and requests for interview appointments, established rules for confidentiality, and actively seek opportunities to revise the research design in order to add to the original set of research questions.

3.5.2   Distribution of the Questionnaire and Conducting Interviews.

As our case questions were almost entirely of qualitative nature, we based the data collection procedure on open-ended interviews and have made no use of questionnaires.

We decided to conduct open-ended interviews with members of each key organization using a check-list to guide interviewers during the process so that consistency can be assured in the data.

In order to achieve a broad view of the ePrescription process, we have identified all major stakeholder organizations and conducted interviews with the following representatives:

- Organization of the ePrescription project:
    - Representative of the Social Assurance Company Finland (KELA)
    - Representative of the Ministry of Social Affairs and Health (STM)
    - Representative of the Pharmacies Association Finland
    - Software Development:
    - Representative of PharmaData Oy (PharmaData)
    - Representative of Receptum Oy (Receptum)
    - Representative of Tieto Oy (Tieto)
- Further Stakeholders
    - Pilot Program Coordinator (Turku PC)
    - Medical Doctor taking part in the pilot project (Kirkkotie)
    - Pharmacy taking part in the pilot project (Nummenmän)
    - External Observer, now employed with the National Institute for Health and Welfare (Observer)

Through the choice of interview partners and through the amount of information we were able to get different views of the process (from competing stakeholders), obtain appropriate and unbiased information about key issues (through large amount of triangulated data) and get a complete functional and organizational view of the process (through coverage of all participants).

4   Results and Evaluation

With our collected material, and with respect to our case study concept, we evaluated our data sources to get an overview about previous systems and their possible influence to the current implementation. The current implementation is investigated regarding the participating stakeholders and the status and functionality. Furthermore, we review the idea and approach of the system and give a short idea about appearing problems, summarized and classified in some major critical aspects.

4.1   Previous Systems

In the beginning of the Finnish ePrescription development the experiments and pilots have mostly been on the initiative of private companies and have not been guided by an official party. For example MediWeb Ltd. has tried three times to pilot an ePrescription system in Finland. The first pilot was in 1996, followed by projects up to the year 2000 (Suomi & Salmivalli 2002, p. 8).

4.1.1   TROPPI project in 1997

Niinimäki and Forsstöm (1997) describe an electronic prescription system called 'TROPPI', which was started in 1997. It was planned to "build a regional shared care system for electronic prescribing and management of patients" medication' (Niinimäki, Savolainen & Forsström 1998). The main idea of TROPPI was to use a smart card for identification and should be owed by the patients themselves, the physicians and the pharmacists, participating the project. The usage of the smart card differed from the first mentioned smart card project between 1989 and 1993 (Salmivalli 2008, p. 19). That time it was planned to use the storage function of a smart card to transfer the prescriptions between physician and pharmacist.

The central element of TROPPI's architecture was the prescription database. It stored the prescriptions itself as well as the users' data. To ensure the reliability of the prescriptions, it was cared about a security and a logging layer. The prescriptions were fed into the database by the "drug prescription client", which was mainly used by physicians. After that the pharmacists, which were using the "drug delivery client", could see the prescription and dispense the medicine. Additionally a third party was considered to have access to the prescription database: the reimbursement authorities, which could use the so called "reimbursement client". As an auxiliary to the prescription database, other databases should have been added to check the drug interactions and to provide a list of the latest medicines, which are available in Finland.

In 1998 the project was in its implementation phase and should have been tested in the beginning of 1999 in an area with "50,000 inhabitants, 10 pharmacies and 5 clinical units" (Niinimäki & Forsstöm 1997, p. 3). However the result of the TROPPI-project is not described by the authors.

4.1.2   Web based system in 2000

A totally different system for electronic prescription has been presented in 1999/2000 by a software company called 'Atoline', later 'Novo Group'. The development of the system was a private initiative, not supervised by an official body of the country. The company developed a

web based system, like a web portal, which could have been used by every doctor and pharmacist, who had access to the internet and a computer with a browser.

The authentication was similar to the one used at online banking. Also the whole organization of the system was in the style of a bank account. The prescriptions were not stored in a centralized and public database, but on the servers of the company. It was planned, that the prescriptions were stored to the patients file so that the prescription was the patient's own. In December 2000 one prescription was made in a hospital in Turku. (Interview Observer 2010)

However the Social Insurance Institution (KELA) and the Finnish Ministry of Social Affairs and Health were not satisfied with those previous pilot projects. They criticized the local approach of most pilots and the fact that, especially in the web based system, the authenticity could not be guaranteed sufficiently. Therefore a reimbursement problem manifested, because KELA was not willing to pay for irretraceable prescriptions. So the law was changed in such way that KELA became the only national authority to run a prescription database. Furthermore it was instructed to use a smart card for authentication. (Interview Observer 2010, Interview STM 2010, Interview KELA 2010)

4.1.3   Earlier pilots 2001-2006

Shortly after the law regarding electronic prescription was changed, KELA was instructed by the Finnish Ministry of Social Affairs and Health to develop specifications for ePrescription. After the release of those new specifications in December 2001, KELA and some other companies have been asked by the ministry to realize and to test them in first pilots. So the following efforts can be summarized as pilots under the leadership of KELA.

The development of a new pilot system started in 2003. The basic ideas of this system have been nearly the same as described above in the TROPPI project. The prescriptions should have been stored in a central database and they had to be signed with a strong digital signature. But the big difference to TROPPI was that it should be a nationwide project, not only local.

Altogether four different areas in Finland participated in this pilot project. "Two specialized hospitals, one health care centre and one occupational health unit" (Hyppönen, Salmivalli & Suomi 2005, p. 5) and some pharmacies took part. "The pilot project was regulated by the Decree of the Ministry for Social Affairs and Health on Experiments with Electronic Prescription (771/2003). It entered into force on 1 September 2003." (Hyppönen et al. 2005, p. 6)

However the project was not very successful. Already the first tests showed that a stand-alone software for electronic prescription is not suitable for daily practice, because it was too slow to deal with the prescription in the ePrescription software as well as in the basic pharmaceutical software. This knowledge made the development process more difficult. At the end of the year 2004 only two of the four test sides had implemented an ePrescription system. Only one of them could already develop an integrated system, all the other test sides had still been dealing with stand-alone software (Hyppönen et al. 2005, p. 4).

Due to different technical and software problems the pilot project was stopped in 2006. However, most of our interviewees agreed that they learned a lot from this project.

After these early pilots have been terminated, a new approach has been started in 2007. The specifications have been improved and software companies were found during an open call or tenders. The starting point for the new pilot project was a law on permanent ePrescription, which "came into effect in April 2007" (Hämäläinen, Reponen & Winblad 2008, p. 41).S

4.2 Stakeholders expectation and participation

The main stakeholders can be divided into two groups. The first one could be called the "specification group" with KELA and the ministry, which could mainly influence the specification process. The second group could be termed as the "development group". These stakeholders like the software companies have a subordinated role in the standardization process and implement the specifications of the first group.

4.2.1 The specification group

The national insurance company KELA and the Finnish Ministry of Social Affairs and Health have a leading part in the specification process of ePrescription. Additionally KELA has to meet its' leadership obligations, so that the development process is coordinated and all parties are being heard.

The main expectations of this group are the avoidance of double medication, wrong medication and dangerous interactions between medicines. Also the misinterpretation of the handwritten prescriptions as well as the loss of prescriptions should be eliminated with electronic prescriptions. (Interview KELA 2010, Virtanen 2008, Suomi & Salmivalli 2002)

However the financial savings are also one of the main expectations of KELA and the ministry, because double medication and hospital stays due to wrong medication incur massive costs. During further progress, KELA could also expect some statistical data from their database on which ePrescriptions, but also patient records, could be stored. (Interview STM 2010)

4.2.2   The development group

Probably most of the developing companies have the same expectations regarding electronic prescription system than KELA and the ministry, but for them commercial matters are higher ranking than ideational matters.

Especially the providers of the hospital and pharmacy software (Logica, PharmaData, Tieto, Receptum) would lose their customers, if they do not develop regarding the specifications. (Interview PharmaData 2010)

It looks similar to the other developing companies like Fujitsu, which is providing all servers and the database, and the National Supervisory Authority for Welfare and Health (Valvira), which is producing the smart cards and the related pin codes.

Further stakeholders, which can not directly be sorted into one of these groups, are the Pharmaceutical Association Finland and the end users of the electronic prescription system.

4.3   Current status and functionality

The main improvements expected from the new ePrescription system on the patient side, compared to the old paper-based prescription system would be, according to Vuolasto (2009) the following:

- no lost prescriptions
- less errors in prescription and dispense
- renewal requests can be made through pharmacists or service providers
- information on renewed prescriptions directly to mobile phone via SMS (in later phase)
- easy renewal of prescriptions based on citizen eAccess (in later phase)

At the time of our interview, the project is approaching its successful end, as the involved parties had a running system. Kela, the social insurance institution of Finland, being responsible for the ePrescription database (Interview Kela 2010), offers both a test server, where virtual prescriptions are written, to test proper operation and compatibility of the software involved as well as a real server. Kela looks after basic security for all persons resident in Finland. The terms and conditions of the benefits provided by Kela are defined in legislation. Kela is also responsible for providing public information about its benefits and services, for undertaking research to develop social security further, and for compiling statistics, estimates and projections required for the planning and monitoring of benefit programs and other operations (Kela website www.kela.fi). With the exception of one pharmacy software provider, all

other parties have their ePrescription software ready for mass deployment (Interview Phar-maData 2010) – either as an add-on module to their current software or as a stand-alone pro-gram – and are waiting optimistically for the nationwide distribution to commence.

The project is currently undergoing practical tests in the city of Turku. This pilot project in-volves on the software side two companies: one on the pharmacy side (Receptum Oy with the pharmacy management software Linnea), as well as one on the hospital side (Logica Oy offer-ing the hospital management software Pegasos). Other major parties involved are the KELA, offering the server with the database for the entire ePrescription project as well as the Kitkot-tie Health Center in Turku and the Nummenmäen pharmacy, who prescribe and dispense about 30 prescriptions per day to the patients (Interview Turku PC 2010). At the time of the interviews, the ongoing tests were successful, during the first days supplying over 100 pre-scriptions (Interview Nummenmän 2010). This first test proves the proper operation of the system, operating with a small amount of data. According to all the involved parties, an in-crease in the data amount involved, by adding new clients to the server (either pharmacies or health centers) should not be an issue and would not cause lag or delay in the processing of the prescriptions, keeping the processing time of an electronic prescription less than the time required for a paper-based version, a major improvement in comparison to the old attempt of implementing the project (Interview Kela 2010).

A second pilot project is expected to start in the near future. It involves the other two software providers (PharmaData with the software Salix on the pharmacy side and Tieto with its soft-ware Effica on the hospital side) in the city of Kotka. This start is delayed due to software issues (Interview PharmaData 2010) and is expected to commence, according to our intervie-wee at PharmaData sometimes in early autumn 2010. In order to prepare for the 2nd pilot project, people in the involved pharmacies and health centers are already being trained by personnel who know the software or using training videos (Interview PFA).

4.4   Idea and approach of the system and organization

The Social Insurance Institution of Finland (Kela) has mandate on the information content of both paper-based and electronic prescriptions. Kela is also responsible for building the Na-tional ePrescription Centre and several other services to implement the national eArchive for patient records (Interview Observer 2010). The law sets a transition period until April 1st 2011 when ePrescription is required to have been implemented and deployed nationally (Vuolasto 2009). An initial set of functional and data requirements for the ePrescription system were defined by consultants and Kela through several iterations. HL7 technical specifications were

developed in parallel – multiple iterations and national ballots were required to achieve the version for the first development and deployment phase (Interview Pharmadata and Receptum 2010). A consortium of companies was selected for the implementation of the ePrescription service in May 2007. These include the national Private Key Identification (PKI) solution, the national pharmaceutical database, the code sets and classifications provided by the national code server, patient's browsing system, decision support applications and the certification criteria for the applications related to the ePrescription service (Interview Kela 2010).

4.4.1   System on the pharmacy side

Figure 1 displays the structure of the electronic prescription system implemented and currently undergoing tests in the city of Turku. Orange lines represent information transfer, green the hard- or software suppliers, and gray the involvement of other parties.
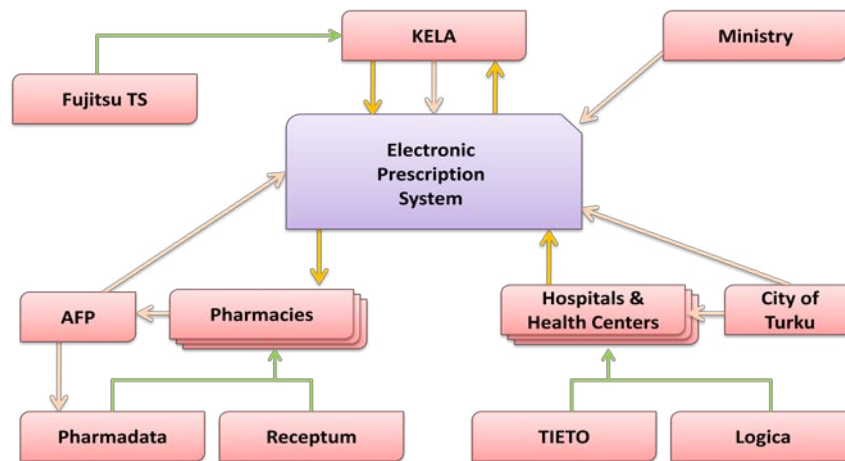

Figure 1 - Structure of the ePrescription System

The pharmacies are supplied with software (green lines) by the two software companies, Pharmadata and Receptum, while most hospitals and health centers (about 80% of the total amount of hospitals and health centers) receive their management software from either Tieto or Logica (Interview Turku PC).

The major difference between the paper based and the electronic prescription is the way information is transmitted from the doctor, prescribing the medicine, to the pharmacy, dispensing it to the patient. In order to improve patient data security, the information regarding the prescription is no longer written on paper and sent to the pharmacy by giving it to the patient, but uploaded by the doctor in the database maintained by KELA (hard- and software related to the database server being supplied by the company Fujitsu TS), where it will be saved for the next 30 months in order to prevent negative side effects because of the prescribed medi-

cine (Interview Kela 2010). After 30 months in the centre e-prescriptions will be moved to an archiving database where the information is archived for 10 years. The eArchive is a system that provides possibilities for the searching and archiving of patient records. Healthcare providers will have their own patient record archive but compared to the current situation, the structure of the archives will be uniform and they will be maintained by the Social Insurance Institution in a single system. A future version of this database should also be used for the eArchive project, currently undergoing tests, but not yet finished as a project. This project should store not only the prescriptions received by any given patient, but also its entire medical history.

4.4.2 System on the KELA database

Once a prescription is uploaded to the KELA database it can no longer be deleted (Interview Kela 2010, Interview PFA 2010), and will be stored for the next 30 months in the ePrescription database and then for another 10 years in the eArchive. When prescribing, the doctor is able to read – with the consent of the patient – the entire patient history, and make sure there will not be any negative side effects of the prescribed medicine. The identification of the doctor is performed by using a unique identification card and PIN code (Interview Kirkkotie and Nummenmän 2010). The prescription is encrypted using the Pubic Key Infrastructure with two way SSL/TLS supplied by Valvira, the National Supervisory Authority for Welfare and Health. If third-party service providers mediate messages, Web Services Security X.509 token profile is required for the authentication of the user organization (Interview Pharmadata and Receptum 2010). It provides the certification authority services for the users of the nationwide healthcare information systems. Organizations providing healthcare services including their employees and data networks are the intended user group of the healthcare computer assisted services (Interview STM 2010).

The healthcare computer assisted services provide the means for identifying the users and the hardware in nationwide healthcare information systems. It is also possible to electronically sign documents and other data transferred in the healthcare information systems. Use of the identification and electronic signature services requires that the user has a healthcare smart card. The healthcare smart card is an ISO 7816 size smart card including healthcare certificates issued by Valvira. Healthcare professionals and other authorized persons that use healthcare information systems have to use the smart card for authenticating to health information systems and to sign documents electronically. Valvira issues the healthcare smart card and the authentication and signature certificates upon application to authorized applicants

(Interview Tieto 2010). Both certificates contain role identifiers and the signature certificate also includes information on the user's role mandate. As the signature certificate is used to electronically sign e-prescriptions, the mandate information is necessary do define the user's role as medical doctor or pharmacist. Distribution of healthcare smart cards takes place in registration facilities that are maintained by the hospital districts (Interview PFA 2010).

The prescriptions are sent to the server using a slightly modified HL7 standard, introduced by the HL7 Finland Association and the Social Insurance Institution of Finland, and based on the HL7 CDA R2 and V3 messages (Interview Pharmadata and Receptum 2010).

The HL7 Finland Association is financed by its members according to the size of the organisation. During the last years the association is co-funded also by the Ministry of Social Affairs and Health (Interview STM and Observer 2010). HL7 specifies a number of flexible standards, guidelines, and methodologies by which various healthcare systems can communicate with each other. Such guidelines or data standards are a set of rules that allow information to be shared and processed in a uniform and consistent manner. These data standards are meant to allow healthcare organizations to easily share clinical information, in our case the data required for the electronic prescription. Theoretically, this ability to exchange information should help to minimize the tendency for medical care to be geographically isolated and highly variable. Version 2 messaging is widely deployed in most hospitals and healthcare centers. CDA R1 is used in sharing patient records on a regional level (HL7 Finland 2010)

4.4.3   System on the pharmacy side

After sending the prescription to the server, it can be read by any pharmacy connected to the system, identifying both the patient by his/her social security number, as well as the pharmacist using an identification card and a PIN code (Interview Nummenmän 2010). The pharmacist then checks the prescription, to make sure it is safe, and to prevent any side effects. Should any objection occur, it is necessary to freeze the prescription and contact the doctor directly by the pharmacist. The information about any dispensed medicine is then sent directly to the KELA server, updating the prescription.

The encryption used is similar to the one used on the connection from the hospital to the Kela database, identifying and logging each pharmacist (Interview Turku PC 2010). It is performed directly on the pharmacy client computer, sent to a local server inside the pharmacy, where all dispensed prescriptions are logged, keeping a local patient record, and finally sent to Kela
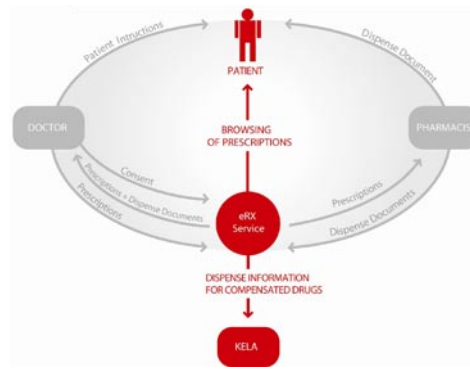
Figure 2 - ePrescription in Finland (Vuolasto 2009)

updating the amount of available medication, thus preventing possible misuse (Interview Pharmadata 2010).

The security of the patient is gained at cost of his privacy, since any pharmacy can see someone's prescriptions just by knowing the respective social security number. This is prevented from happening by allowing the patients to check who has read their electronic prescription history using the eAccess system. The eAccess system allows citizens to view their personal medical information in the archive. A service called Kanta.fi (www.kanta.fi) was opened, allowing citizens to access their information by using online banking identification or an electronic ID card. The information will appear as the organizations start using the e-prescription system. Other information viewable by citizens over 18 include visits to healthcare providers, referrals, treatment summaries, patient consents and any log data which the patients are entitled to access.

4.5   Critical aspects of the project

Several critical aspects appeared during the current project, as we could obtain from our observations and our interviews with the different stakeholders. We will point out six specific issues which we regard as the most significant.

4.5.1   Financial aspects

One critical aspect which has arisen throughout interviews with several stakeholders was the financing of the ePrescription system. The coordination of the pilot project in Turku had been initially financed by a community of health care providers using the Pegasus system together with Logica. Their aim was to gain practical experience in using ePrescriptions as well as to gather feedback from the users (Interview Turku PC 2010).

As stated by their representatives (Interview Receptum, PharmaData, Tieto 2010), software companies had to use own financial means for the development of products that enable physi-

cians and pharmacists to issue and dispense ePrescriptions. Corresponding revenues are expected from selling these products to health care providers and pharmacies, thus software companies are waiting for the introduction of ePrescription on large scale.

Health care providers who are expected to acquire licenses for the new software products are founded by the municipalities. According to the coordinator of the pilot project in Turku, the cities of Turku and Kotka were receiving financial support (about 50% of the budget) for using ePrescription from the Ministry of Social Affairs and Health at the time this case study had been conducted. Financial aid for shifting to the new software was though not granted to pharmacies.

The development of the database center as a core component of the ePrescription system was being financed by the Ministry of Social Affairs and Health at the moment of the presented case study. Nevertheless long term financial aspects regarding the ePrescription system and the database center were unclear. In the opinion of the ministry, after reaching maturity, the system should be self sustaining by means of a fee collected from the users. KELA, on the other side, suggests not charging the patients, at least directly.

Taking into account the financial uncertainty related to the project and the dependence on the willingness of private companies to invest own resources for the success of a project initiated by the government, financing can be pointed out as a major draw-back to the timely development and introduction of the ePrescription system.

4.5.2   Interaction between stakeholders

The main issue regarding interaction between stakeholders reported by many of our interviewees was that no entity was in the position to assume leadership over the others within the project. In order to understand the reasoning behind this statement it is necessary to review the roles of every stakeholder. Responsibilities, assumed by the Ministry of Social Affairs (STM) and Health as the project manager for the national ePrescription project, were developing the strategy, preparing the legislation, defining the system architecture as well as the necessary data structures, and handling international relationships (Interview STM 2010).

The National Institute for Health and Welfare (THL) subordinate to STM was involved as observer and consultant for health care issues. KELA as the national insurance institution having already a broad experience in handling large amount of data related to prescriptions, was designated as the technical producer and administrator of the system (Interviews KELA, STM 2010). It was the responsibility of software companies like Logica, Tieto, Receptum and

PharmaData to deliver software to health care providers and pharmacies according to the given technical specifications. Finally, according to legislation, it is the health care providers and the pharmacies obligation to issue and dispense ePrescriptions.

The critical aspect which should be indicated at this point is that hat even though STM as the project manager delegated KELA the central role of making ePrescription services available and maintaining them, KELA is not an institution subordinate to the ministry, thus has theoretically no obligation towards it. A similar relationship exists between software companies and KELA. As KELA was coordinating the technical development by organizing several meetings with the software companies, health care providers and pharmacies (Interviews Receptum, Pharmadata 2010) but was not financing their product development, it could not impose a timeline following which the software products had to become available for health care providers and pharmacies.

STM, KELA, software companies, health care providers and pharmacies had found themselves in a vicious circle that caused considerable delay for the nationwide deployment of ePrescription. STM could not advance with the introduction of ePrescription as the software solutions for pharmacies and health care providers were not in place. Software companies had waited for message specifications from KELA and for the database center to be in place. Pharmacy software companies blamed the inadequate documentation supplied by KELA and the hospital software providers for not inserting test-ePrescriptions in the database on time or for not keeping the technical specifications (Interviews PharmaData, Receptum 2010).

After the pilot project in Turku had started with software from Logica and Receptum on hospital and pharmacy side, respectively, Tieto whose software was also mature enough for a pilot project in the city of Kotka was still waiting for the pharmacies in Kotka – using PharmaData software - to be able to dispense ePrescriptions (Interview Tieto 2010). As confirmed by most interviewees the reason why ePrescription could not be spread away was that PharmaDatas solution supporting ePrescription hadn't been ready for deployment. According to PharmaData, their solution would be ready in August 2010 (Interview PharmaData 2010).

It is worth mentioning that the Finish Pharmacy Association (FPA) comprising most of the Finish pharmacies is owner of PharmaData. Thus the FPA is biased by the responsibility to defend the interest of pharmacies as well as the interest of PharmaData. According to its representative, the FPA is "sad" about the situation caused by PharmaData but the FPA cannot force PharmaData to have the needed software ready (Interview FPA 2010).

In conclusion, the interaction between the few stakeholders is based mainly on voluntary co-operation rather than admitted responsibility. While no entity was in the position to impose deadlines and sanctions a timeline for the project could not be set but only be estimated roughly.

4.5.3   Conflict of interest regarding KELA

A critical point identified during this study is also the role of KELA both as the national in-surer – directly interested in the data contained - and the administrator of the ePrescription database. As explained by STM there was no other option as to put KELA in charge of the database center, as the large amount of sensitive data could not be trusted to a private compa-ny. Moreover KELA had the necessary experience in dealing with prescriptions (Interview STM 2010). However the ministry is aware of the possible conflict of interests. It is regulated that KELA does not access all information in the database for own purposes directly but to ask for the needed data. THL is the authority which determines which data is really needed and supervises the access to the database.

4.5.4   Privacy

When analyzing a national ePrescription system based on which different actors gain access to patients medical information such as their medication, a deeper look into privacy issues becomes indispensable. How does introducing an ePrescription system as the one planed for Finland influence patient's privacy? The answer to this question lies in the comparison be-tween privacy before and after ePrescription.

Before using ePrescription medical doctors could not obtain a complete image of the medica-tion previously prescribed to the patient by other doctors unless the patients told them about that medication. (Interview KELA 2010) Thus patients could decide for themselves which information they are willing to expose. Same applies within the patient - pharmacist relation-ship. Patients have to reveal only that information about their medication to the pharmacist which is written on the paper prescription.

In order to permit refunding by KELA, dispensed medication is inserted into the pharmacy's database as a record containing also the patient's social insurance number. This database is owned by the pharmacy, thus each pharmacy possesses pieces of their customers medical in-formation. For example, supposing a person gets all its medication dispensed at one and the same pharmacy, then that pharmacy literally owns that persons medication history, which is

definitely interfering within the person's privacy. Similarly, health care providers own patient information stored in their systems.

With the introduction of the ePrescription system, the data stored in the national database is propriety of the patient (Interview STM 2010). It may be privacy concern that every physician and pharmacist having a smart card and PIN can view one's prescriptions only by entering one's social insurance number. In order to prevent misuse of this private data, patients can check online using eAccess which institution has been accessing their prescriptions. Moreover it is the patients who are responsible of reporting when noticing that their data has been accessed without their consent.

4.5.5   Acceptance among citizens

Factors that influence acceptance of ePrescription among citizens are next to privacy concerns also the local availability of the service and the citizens' understanding for the benefits provided by the system.

To raise awareness of the benefits provided by ePrescription information materials such as leaflets and posters have been displayed in the institutions participating in the pilot project. An information website had also been created.

An online survey initiated by the project management has shown that 80% of the participants would use ePrescription if it were available. However it is assumed that the degree of acceptance only among the "eCitizens" who participated in the survey may exceed the overall acceptance in Finland (Interview Turku PC 2010). Nevertheless during the first week of the pilot project no patient whom had been suggested an ePrescription had refused this in favor of the paper prescription.

The way to bypass the database is to ask for a paper prescription. For strong medicine as diapams this will not be possible in the future (two years) regardless the acceptance from the patient (Interview Turku PC 2010).

4.5.6   Interoperability with other countries

One of the reasons in choosing HL7 to be used within the ePrescription system was to assure a future interoperability with other countries. Unfortunately, as the standard suffered modifications, integrating the finish system with a future European or worldwide ePrescription system is expected to be a great challenge (Interviews KELA, Observer 2010)

5   Conclusion and perspectives

Bearing in mind that Finland has a wide surface which is sparsely populated the authors consider the introduction of a national electronic prescription system to be very a suitable.

By analyzing the process of standardization, specification, development and the results of the pilot projects initiated in Finland over the last years, other countries can learn from the finish experience with ePrescription. The critical aspects pointed out within this study such as financing, interaction between stakeholders, privacy, acceptance by citizens or interoperability with systems in other countries should be considered when building up ePrescription systems in other countries.

Note, however, that the finish model cannot be applied directly in countries with multiple health insurers. Also differences to health care systems of countries may require a special approach to ePrescription. Not less important are the cultural differences. For example, the German society which is very sensitive to privacy matters would require for a more complex data security policy.

Due to the delay that interfered with the development and deployment, it becomes clear, as also confirmed by our interviewees, that ePrescription will not be available at large scale in Finland by August 2010, as planned.

It is expected that after a gradual expansion starting in Turku, Kotka and finishing in Helsinki, by 2012 every finish citizen will have access to ePrescriptions. As seen in the past, the deployment process is prone to delays. However, as shown by the analysis of the system, as well as by the results of the pilot project in Turku, promising steps towards a sustainable national ePrescription system have been made. Since dealing with an ongoing project future studies could reveal further interesting aspects its lifecycle.

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