ICT STANDARDIZATION STRATEGIES AND SERVICE INNOVATION IN HEALTH CARE.

Completed Research Paper

Ole Hanseth
University of Oslo
Oslo, Norway
Ole.Hanseth@ifi.uio.no

Bendik Bygstad
Norwegian School of IT
Oslo, Norway
bygben@nith.no

Gunnar Ellingsen
University of Tromsø
Tromsø, Norway
Gunnar.Ellingsen@hn-ikt.no

Liv Karen Johannesen
University of Tromsø and DIPS ASA
Tromsø, Norway
lkj@dips.no

Eli Larsen
Norwegian Centre for Integrated Care and Telemedicine
Troms, Norway
Eli.Larsen@telemed.no

Abstract

Standards have played an important, but often unrecognized role in the development of modern organizations. This role is accentuated by today's growth of large business and government infrastructures, in the turbulent processes of globalization. In this article we investigate the relationships - and tensions – between standardization strategies and service innovation in the health care sector.

Our empirical material is nine longitudinal case studies in the Norwegian healthcare sector, collected and analysed over a period of 20 years. We identify three generic standardization strategies; anticipated standardization, integrated solutions and flexible generification. We argue that the two first strategies do not support service innovation, while the strategy of flexible generification does so.

Keywords: information infrastructure, standardization, service innovation, health care

Introduction

Important service innovations are enabled by new ICT solutions (Jong et al. 2003). Such enabling ICT solutions are shared by service providers and customers and they consist of a huge number of technological components. Technical standards are central to such solutions and the development, implementation and diffusion of such standards are central elements of service innovation processes.

Traditionally standards are developed within the framework of a standardization body like the International Standardization Organization (ISO). Such bodies have detailed rules specifying how the activities should be organized, who are allowed to participate, voting rules, criteria a standard's specification must fulfil to be approved, etc. The standards are specified based on anticipation about what the users' future needs will be. The standard is then, hopefully, implemented in solutions which are adopted by the anticipated users. This is the way standards have been settled within, for instance, telecommunication. And this strategy was also adopted by the IT industry when standards emerged as an important issue within this industry. However, the formal approach of most standardization bodies has often been considered too slow and bureaucratic for the IT industry. Accordingly various consortium models have been preferred in many cases. Yet another standardization strategy is the one followed by the Internet community. Here standards are developed and settled in a much more bottom-up approach. A standard is not finally approved as such until, first, the need for it is proved by real use of solutions requiring a standard, and, second, several independent implementations of the standard have proved to interoperate.

In this paper we investigate the interplay between ICT standards and service innovation in the healthcare sector. By service innovation we here mean the improvement of the quality or decreases the costs of existing services or the development of new ones. On the one hand, ICT may support existing ways of working and making these more efficient by automating manual procedures. One the other, ICT is widely held to have the inherent capacity of enabling radically *different* ways of working and organizing than the existing ones. In addition ICT enables ways of working and organizing that are also radically more efficient or the delivery of new services of radically higher quality than existing alternatives. This assumption is also considered valid for health care. The combination of new digital instruments combined with new minimal invasive diagnostic and interventional services (i.e. surgery) are good examples. However, the growing number of digital systems in health care makes standards crucial. Accordingly, continuous ICT enabled service innovation in health care requires standardization strategies that support this. The same is the case for other business sectors. There are great political expectations to the contributions from ICT for service innovation and effectiveness in the health care sector. We therefore consider the health care sector to be an excellent context to study standardization in general. Moreover, it is a sector with a plethora of standards, which presents a number of large cases to learn from and theorize on. In order to focus our investigation, we suggest using the term *standardization strategies* denoting the strategies or approaches chosen for developing new standards, i.e. how the development of new standards are organized and which steps are taken or procedures followed in the definition and implementation of a new standard. But the concept of standardization strategy also includes how actors relate to standards in innovation projects more broadly, i.e. which existing standards they chose, how they implement them, how they are used in inter-organizational integration and how they are changed over time.

Our research question is then: Which standardization strategies support service innovation in the health care sector? I.e. which strategies are most successful in terms of, first, leading to the settlement of new standards which are implemented in ICT solutions which eventually are widely adopted, at the same time as the adoption and use of the solutions based on these standards enables and contributes to service innovation? This means that the success of a standardization strategy is ultimately measured in terms of the benefits the new services, which the standards are a part of and enabling, deliver to their adopters. A standardization strategy is not in this context considered successful even if it leads to a large number of standards which are agreed upon if these standards are not implemented and if their implementations in new services are not delivering significant benefits to their users. The standards we will look at are technical ones: data formats and protocols for exchanging them.

We proceed in the next section by presenting our theoretical approach of information infrastructures, and assessing some key research on ICT standards and service innovation. Then our research approach is described, before we present the main body of the paper, a collection of cases from the Norwegian health

sector, researched over a period of 20 years. Finally, we discuss our findings and provide some conclusions.

Related research

In this section we first present a review on service innovation and the role of ICT within this. Next we present our theoretical approach, the *information infrastructure* perspective. Then we discuss the role of standards which focuses on the tension between standardization and flexibility and the concepts flexible standards and generification.

Service innovation and ICT

The full diversity of services and the complexity of their inner attributes make it difficult to determine a single definition of service providing (Nardelli 2012). Rather than proposing a comprehensive definition, one way to clarify the nature of services can be looking at their distinguishing characteristics as compared to tangible goods (Nardelli 2012). Although the differentiation is much more blurred in the actual practice than in theory, services tend to involve customer participation in the service process and to be: (a) simultaneously produced and consumed; (b) perishable; (c) intangible; and (d) heterogeneous (Fitzsimmons and Fitzsimmons 2000). Each service is characterized by a unique combination of these attributes and relative degrees. According to den Hertog (2000), four main dimensions describe a new service: (1) new service concept; (2) new client interface; (3) new service delivery system; (4) technological options. Any service innovation involves a certain blend of these dimensions.

Research indicates that service innovations are more incremental than product innovations (Johne and Storey 1998). Service innovation processes are less formal than product innovation processes (Kelly and Storey 2000) and it is more difficult to apply a stage-gate process model. Service innovation is often customer driven and customer involvement is important (Alam, 2002). Successful service innovation methodologies may differ from product innovation methodologies (Nysveen and Pedersen, 2007).

Jong et al. (2003) show that technology especially impacts on service innovation in the process of service delivery. Furthermore they demonstrated how correct adoption and use of Information Technologies (IT) not only can increase efficiency, but also have a positive impact on innovation in services by: (a) facilitating idea generation for new and/or improved services; (b) accelerating the development of the time-to-market of new services; and (c) easing interactions within and between stakeholders.

Information Infrastructures

ICT solutions supporting new services are shared by both service providers and service consumers. Often they are shared by most members of a business sector (like health care). This makes the solutions and their development complex because the solutions include a large number of technological components at the same time as a large number of development and user organizations are involved. Much research into the challenges related to the development and use of such ICT solutions is conducted by conceptualizing them as *information infrastructures* (Star and Ruhleder 1996; Hanseth and Lyytinen 2010). An information infrastructure is defined as *"a shared, evolving, open, standardized, and heterogeneous installed base"* (Hanseth 2002).

- Shared: An information infrastructure is shared by the members of a community, including vendors, users and staff
- Evolving: It is not "designed", but evolves continually, as growth and innovation expands it
- Open: In principle, there is no limit on the number of users
- Standardized: Infrastructures rests on standards, which allow for scaling and interoperability
- Heterogeneous: Infrastructures consist of different elements; technology, users, organizations, etc.
- Installed base: Such structures are seldom created from scratch; rather they grow from existing practices and infrastructures

An information infrastructure is a socio-technical system. In the health care sector, for example, such structures may encompass several patient record (EPR) systems, hundreds of medical units and tens of

thousands of users. Standards are core elements of information infrastructures, and a large part of the research on information infrastructure has focused on and disclosed a very dense and complex web of relations between technical and social issues and elements of the standards (Star and Ruhleder 1996; Hanseth and Monteiro 1997).

Research on ICT standards is in its infancy, but its volume as well as assumed importance is growing (for example illustrated by the Special Issue of MIS Quarterly on the topic published in August 2006). This reflects the growth in number of and importance attributed to ICT standards. But it also reflects a change in requirements of standards due to a more complex and rapidly changing world. This again causes changes in the nature of standards and new the requirements to standardization processes and how to organize these.

Standards and flexibility

Research on information infrastructures has identified the tension between standardization and flexibility as a key issue in the evolution of such infrastructures (Hanseth et al. 1996). Standardized systems such as ICTs tend to become accumulatively *change resistant* as they grow and diffuse (Egyedi 2002; Egyedi and Blind 2008; Hanseth et al. 1996). Thus, to endure, these systems have to be prepared for change to avoid becoming obsolete (Tassey 2000). Standards must allow for growth and change through various means of flexibility to avoid this. Flexibility can be obtained by standardized interfaces, decomposition, and modularization and black-boxing, allowing some components to be kept stable while others are changed without implications for the rest of the system. Allowing for peripheral change and innovation can release a significant potential for increasing the size of the system, its market (Tassey 1995) as well as the diversity of services (Lessig 2001).

The location of functions close to the application that uses the function, the so-called end-to-end architecture, is one example of providing flexibility by systems design (Saltzer et al. 1984). The point of this architecture is that functionality in communication networks only can be appropriately implemented if based on knowledge that only exists close to the applications standing at the endpoints of a communication system. Thus, the network should not control how it grows, the applications should. Both Lessig (2001) exemplify this argument by illustrating the Internet as a network where intelligence is in the fringes. Since the network is not optimized for any application but open for and inviting the unexpected and surprising, innovations can flourish without changes in standards. While standards nurture and sometimes are the very preconditions for innovation, the interrelationship between innovation and standards is intricate. Standards may for instance result in future innovations being hampered by previous innovations which now are de facto standards in a market (Dunphy et al. 1996). Because of an increasing installed base, not only does the cost of switching and changing standards become higher but innovations are required to conform to existing standards. Research has also found that there is a subtle and bidirectional relationship between standards and service innovation in networks; standards provide a platform on which services may be innovated on, but the innovation process also drives the need for new standards (Wakke et al. 2012; Tidd and Hull, 2003; European Commission, 2011)

Flexible standards and generification

One possible solution is *flexible standards*, as described by Braa et al. (2007). Building on complexity theory, they show that comprehensive standardization is not effective in heterogeneous contexts, such as the health care sector in developing countries. Instead they suggest a strategy called *"flexible standards",* which includes establishing a few rudimentary standards ("attractors") that supports local practices, but also provides some key interoperability formats. This strategy is sensitive to the local context, allows change to occur through small steps, and provides a mechanism for scaling the information infrastructure (Braa et al. 2007).

Successful commercial software has proved to be effective standards. The past two decades have witnessed a great shift in how organizations acquire software systems; from developing proprietary and tailored solutions to buying standard software packages, such as SAP. Mainstream IS research has emphasized the benefits of this approach; large software packages are relatively cheap and they contribute to "streamline" (i.e. standardize) the processes of the organization. Other researchers have investigated implementation of such solutions and often found that substantial local appropriation is necessary (Avgerou 2002).

Pollock et al (2007) argue that researchers tend to over-emphasize the gap between localized practices and standardized, generic solutions. There is no doubt that there are numerous highly successful (standardized) applications that are used by millions of organizations around the world. Pollock et al. found that over time there is a subtle and complex interplay between suppliers, consultants and users that manages the balance between standards and organizational diversity. This includes for example flexible configuration, the construction of templates, the smoothing of differences and the generalization of requirements. This process is institutionalized and managed by the "software community", and results in the *generification* of software packages, i.e. software that can serve a large number of organizations. This process then, is a standardization process where a specific solution is made more general to serve the needs of a larger user community, i.e. to work as a general standard. Accordingly, we consider generification as described by Pollock et al as a general standardization strategy.

Methodology

The empirical material reported in this study was collected more or less continuously from 1989 to 2011, a period of over 20 years, in the Norwegian health care sector. Our research has been motivated by a strong interest to understand the development of large information infrastructures in health, at different levels, as they evolve. Studying these large socio-technical structures over time is challenging because of the complexity of the domain; the number of actors and initiatives is high, and the projects often last for several years. The significance of standards has been prominent, as they played a crucial role at different levels.

Our research approach has been a multilevel, longitudinal case study (Miles and Huberman 1994; Hitt et al. 2007). Specific projects have been studied in detail over time, and were documented extensively. At higher levels regional and national initiatives (with international links) have been followed, and we have been particularly interested to investigate the dynamics between different levels.

Data collection

The cases were chosen based on a combination of systematic and pragmatic reasons. We have selected some key national initiatives, and in addition researched interesting local and regional projects that were available. The most important source has been interviews with informants in different roles; doctors and nurses, line managers, IT professionals, staff users and high-level bureaucrats. Interviews focused on three topics:

- The interaction between government agencies, ICT specialists and the medical professions in understanding needs and developing standards and solutions
- The actual use of ICT solutions by the different organizations and users
- The overall interplay of technology and innovation; how ICT solutions enable (or hinder) the development of new work processes and innovation of new services

Literally hundreds of reports has been collected and analysed. At many occasions, solutions have been demonstrated, and we have observed systems in use in many situations. An overview of the cases is shown in table 1. The seven projects have been followed over a long period of time, and several informants have been interviewed several times. Results of the projects have also been discussed with informants many years after they were finished, in order to have informants' reflections over the cases.

Table 1. Cases and data collection

Case	Type	Period	Period of data collection
1.CEN TC/251, etc.	Standardization initiatives	1992-96	1989-96
2. ePrescription 1	Pilot project	1993-96	1990-96
3. The Elin project	Regional project	2004-	2004-09
4. ePrescription 2	Large national project	2004-	2008-11
5.Fürst's Med Lab.	Commercial project	1987-	1984-96, 2009-10
6.NNHN	Regional project	1997-2003	2005-10
7. DIPS Interactor	Commercial project	2006-	2006-11

Data analysis

Each case has been analysed separately, focusing on the role of standards in the innovation process. Then the full portfolio of cases has been analysed in two dimensions (Pettigrew 1985):

A *comprehensive* analysis was conducted, focusing on the links between international and national standards and the outcome of the different cases. A central part of the analysis was the role of standards in designing the overall solution. For example, comparing ePrescription 1 and ePrescription 2 revealed significant differences regarding the role of standards, in two projects that had fairly similar goals and objectives. These differences served as input to identify the three standardization strategies.

Then a *temporal* analysis was done, focusing on the development over time. This analysis documented the trajectories of the projects, but also of the various discourses in the sector. For example, the forward chaining of events served to explain intentions of stakeholders, while backwards chaining of events served to explain outcomes. Overall, the temporal analysis helped to understand the dynamics of the standardization strategies. Combining these analyses resulted in the identification of three distinct strategies, which are described in detail.

Validation of results focused on the relationship between standardization strategies and the identified outcomes, where we assessed whether differences in project attributes (such as size and context) had influenced outcomes. Our examination revealed that although the projects were quite different, the overall pattern was clear and well supported by the evidence. In addition we asked for informants' feedback at case level and at higher levels by discussing preliminary results and issues with key informants. Their input provided corrections and amendments, but also served as input to more analysis.

Standardizing Information Exchange in Health Care in Norway

This section will present the activities related to the definition/specification, implementation and use of standards for information exchange between health care institutions in Norway since the first of these activities started around 1987 and up till now (May 2011). We identify three different strategies for developing standards, as illustrated in table 2.

Table 2. Standardization strategies

Standardization strategy	Description	Cases
1.Anticipated standardization	Top-down standardization process, worked out as detailed compromises	1. CEN TC/251, KITH 2.ePrescription (1)
2.Integrated solutions	User driven projects, with standards as part of requirements specifications	3. The Elin project 4. ePrescription (2)
3.Flexible generification	Work processes and actual use determine standards, which are adapted pragmatically	5. Fürst 6. NNHN 7. DIPS Interactor

We will describe the content of the strategies; the kinds of standards developed; their implementation in ICT solutions and infrastructures; the use of these solutions and infrastructures; and, finally the degree of service innovation and the organizational benefits gained.

One of the standardization strategies was explicitly chosen after extensive discussions around 1990. A broad consensus was reached about the need for and importance of standards and how to develop them. What we here call anticipatory standardization has ever since been the official and dominant strategy. However, in our empirical material we identify two other strategies. These were not, however, explicitly formulated as strategies, nor were they discussed as such. They were mere emergent strategies (Mintzberg 1978), and they were more "strategies-in use" than "espoused strategies."

Strategy 1: Anticipatory Standardization

The development of solutions for electronic information exchange between health care institutions in Norway started when a private laboratory, Dr. Fürst's Medicine Laboratory (Fürst) in Oslo, developed a system for transmission of lab report to general practitioners (GPs) in 1987. The system was very simple and was developed in only three weeks by one person. The interest of Fürst was simply to make profit by attracting new customers. Each GP receives on average approximately 20 reports a day, which take quite some time to register manually in their medical record system. It was assumed that the system would help GPs save much time otherwise spent on manual registering, and that the GPs would find this attractive.

The system proved to be a commercial success and brought them lots of GPs as new customers. This implied less profit for the other labs. Within a few years, most non-private labs (in hospitals) developed or bought systems with similar functionality in order to be competitive. These systems were designed more or less as blue-prints of Fürst's system. There were, however, some minor, but important differences which we will return to.

CEN TC/251, KITH

Alongside the growing number of labs adopting systems for exchange of reports, an increasing number of actors saw a wider range of applications of similar technology in other areas. These actors belonged to the health care sector as well as possible vendors of such technology. They all perceived it as important that the technologies could be shared among as many groups as possible in order to reduce costs and enable interconnection of a wide range of institutions. All of them also agreed that standards were crucial to achieve this. Similar developments were also taking place in other countries.

In 1990 the Commission of the European Community delegated to CEN (Comite Europeen de Normalisation, the European branch of ISO) to take responsibility for working out European standards within the health care domain in order to facilitate the economic benefits of an European inner market. CEN established a so-called technical committee (TC 251) on the 23rd of March 1990 dedicated to the development of standards within health care informatics. Being a formal standardization body, CEN TC/251's standardization strategy had to be the of one of anticipatory standardization

In 1989 the Ministry of Health in Norway decided that standards should be developed. After some initial activities they set up a standardization program in 1991. The same year the Ministry also established KITH (Competence Centre for IT in Health). KITH was delegated the responsibility for standardization within ICT in health care and coordination of the standardization program. KITH decided that the Norwegian standardization activities should be tightly integrated with those of CEN TC/251. The focus of the program was initially the standardization of various EDIFACT messages and their so-called implementation guides. Early versions of the EDIFACT message for lab reports were implemented in some of the solutions that were established in the early 90-ies. Others were attempted implemented in a series of pilot projects. We will here describe the activity related to one such message standard: the message to be used for electronic transmission of prescriptions.

The ePrescription Project (1)

The choice of a standardization model in this project was not strictly given from the outset. But adopting EDIFACT as the basis for electronic prescriptions seemed inevitable even though alternatives were proposed. A representative of one of the vendors of electronic medical record systems (Profdoc) suggested early on that one should use bar codes instead of electronic messages. Another alternative to EDIFACT was suggested by the health insurance authorities. They proposed an architecture where prescriptions were stored in a database instead of being transmitted directly to the pharmacies. The important difference with this solution compared to a pure EDIFACT one, is that the pharmacies should retrieve the prescriptions only when the patient actually arrives at the pharmacies. This entailed that the health insurance authorities no longer would pay for prescriptions which never actually got picked up. According to the health insurance authorities, this represented a substantial loss. The database solution would also offer the patients the freedom to choose which pharmacy to get the drugs from. This was particularly important for reiterated prescriptions. In reality, however, the prescription project never seriously considered deviating from an EDIFACT message based solution in line with predominant conceptions on politically correct standardization strategies.

The message specification worked out in the pre-project (KITH 1992), together with the implementation guide, were circulated to the participants involved in the Norwegian efforts for comments before proceeding with the main project. Reactions varied greatly. The comments from the vendors of electronic medical record systems were particularly important as they were vital to make an integration of electronic prescriptions and the GPs' existing systems feasible. The two largest vendors expressed quite different attitudes. One embraced the idea. As they already had some experience with similar work in Sweden on electronic prescriptions, they were in favour of the suggestion. They expected to be able to integrate a prescription module with their medical record system relatively quickly thus giving them a leading edge on competitors. The other principal vendor of medical record systems however, was quite hostile in their comments. They questioned the very idea of electronic transmission of prescriptions. They demanded that the scenarios should be spelled out in more detail in order to make the benefits more visible. Some GPs commented that additional information going beyond what is strictly a part of the prescription also had to be included to make the systems implementing the standard possible to use. This included, for instance, information about whether the patient herself would pick up the drugs at the pharmacy or if it would be done by others.

Based on the feedback new versions of the proposed standard were worked out and again sent out for comments. However, the project maintained their focus on the specification of an electronic, EDIFACT, version of the paper based prescriptions. All comments, both from GPs and suppliers, which did not fit into this scheme, were totally neglected (Pedersen 1996).

After producing a more comprehensive requirements specification and a beta release, a pilot project in the Bergen area started in 1994. The project was marred with problems. Financing was not ensured, and was a recurring issue. An advanced solution had been specified, requiring seamless integration with other systems, (such as welfare systems, EPRs and medical registers) which were not yet available. The EPR vendors did not prioritize the solution, because of other development pressures and poor financing. In the pilot version there were so many errors that the doctors had to fax the prescription in addition to the electronic transmission. In 1996 the project ran out of steam (and money), and a project report summarized the remaining problems: the need for a central medical register, data security concerns, paying for running costs and user support.

Results of Strategy 1

The strategy adopted in the beginning of the 90-ies was the result of quite extensive discussions about the needs for standards and how they should be developed and settled. And there was a strong consensus that the traditional anticipatory standardization strategy was the right one. Independent of this specification driven approach, the standardization activities focused on defining electronic versions of exiting paper based communication entities like lab orders and reports, prescriptions, etc. There was literally no attention paid to users' work practices, or how electronic information exchange could help to develop improved services beyond speeding up existing paper based practices.

Over the past 20 years a number of (draft) standards have been specified. Some of the solutions for exchange of lab reports established in the early 90-ies implemented draft versions of standard EDIFACT messages. And these solutions helped GPs remove a significant amount of manual data entry work. With this exception, the implementation and diffusion of the standards defined have been very slow. This has increasingly been viewed as a major problem in national strategic plans for ICT in health care (HOD 1996, HOD 2008). These strategic plans have correspondingly repeated that the implementation of standards needs to speed up and more pressure needs to be put on the various actors to do so. Weaknesses of strategy 1 will be highlighted through the presentation and discussions of the other strategies below.

Strategy 2: Integrated Solutions

The Elin project represented a new standardization strategy. The focus changed from anticipatory standardization to "user driven development of integrated ICT solutions supporting communication and collaboration." This means that the focus shifted from the specification of messages representing paper forms to the user requirements and functionality needed to support collaboration involving GPs. This functionality was specified through more active user involvement, and then integrated solutions satisfying these requirements were designed. Standards were developed as a part of the design of the solutions.

The Elin Project

The Elin project was triggered by opportunities created by the governmental program BIT (Business sector oriented IT projects). This program aimed at supporting the development of ICT solutions for specific business sectors based on "committed collaboration" among relevant actors within the business sector and software suppliers.

The aim of the Elin project was basically given by the framework set by the BIT program and the project manager's own experience. He had been actively involved in the development of solutions for information exchange both as an end user and as a user representative since the early nineties, in particular in the establishment of the Northern Norwegian Health Network in 1997 (see section 4.3.2). The aim was to develop requirements specifications as a basis for user friendly standardized solutions for electronic health care related communications for GPs. The vision was phrased as "better communication and collaboration, and not just development of technical solutions for message exchange". This included the development of solutions for exchange of admission and discharge letters, lab orders and reports, illness and doctor's declarations, prescriptions, and communication with patients.

Also in the Elin project there was a strong focus on the main information objects to be exchanged, like lab orders and reports, admission and discharge letter, prescriptions, etc. But in contrast to the previous standardization activities, these objects were viewed and understood more as integrated parts of the work practices they appeared within.

The project was split into three phases. In the first, the focus was on exchange of discharge letters between GPs and hospital departments and outpatient clinics. In the second phase the focus was on exchange of discharge letters between medical specialists' offices and GPs, exchange of orders and reports between radiology labs to GPs, and information exchange with patients. The third phase focused on improving and piloting the technical solutions.

The BIT program had developed a framework for their projects which was considered quite successful. This framework included specifications for how the projects should be organized (steering group, project groups, etc.), a set of contracts between the participating organizations, criteria for selection of pilot organizations, and a process model splitting the project into a number of phases: a pre-project for planning the project, a main project developing user requirements and developing the solution, then piloting, testing and finally diffusion. This framework was further elaborated and adapted to the context of health care during the Elin-project and given the name Elin-methodology.

KITH had already proposed standards for the information objects to be exchanged in the Elin solutions. However, these did not fit well with the requirements developed in the project because KITH did not have a sufficient understanding of the work and communication processes involving orders and reports. Several important objects, such as response to admission letters (informing the admitting physician what will be happen to the patient) were not defined, and existing ones were inappropriate because they did not satisfy user requirements. Another challenge was the fact that the existing standards were all based on asynchronous (i.e. e-mail based) communication. Although this corresponded to the logic of the paper based communication patterns, for various (and often very strange and surprising) reasons, the exchange of the messages took too long time. Accordingly, new standards and messages had to be specified based on a web services model.

The project has played a major role in the development of user requirements for ICT solutions supporting communication between GPs and other health care institutions which are well aligned with user needs and requirements from health care authorities. The requirements have been implemented in solutions which have diffused to some extent, but the implementation and spreading of solutions have definitively been much slower than expected. The Elin project was, however, quite successful in establishing strong, enthusiastic collaborative networks of users and suppliers.

ePrescription (2)

In 2004, the Ministry of Health initiated yet another pilot study on electronic prescriptions. The background was a report in 2001 from the Office of the Auditor General that raised concerns on the accountability of prescription refunds from the Welfare Administration Agency (RTV). The following actors were included in the pilot study: Norwegian Pharmacist's Union, National Insurance

Administration (NIA), Norwegian Medical Association (representing physicians) and Norwegian Medicines Agency (NMA). The Directorate of Health managed the project.

The ePrescription project was established with direct funding from the parliament of about 40 million Euros from the Norwegian Parliament during the six year period from 2005 to 2010. By the end of 2010 about 60 million Euros had been spent on the project. During 2006 several detailed requirements specifications and architectural documents were written, specifying an ambitious, fully integrated solution. The Prescription Exchange was designed to handle 300 million transactions per year. This reflected that, in the designed solution, each prescription would generate approx. 10 transactions, from a national volume of around 27 mill prescription per year. As shown in figure 1 the architectural solution was based on 31 different (standardized) messages being sent to the Prescription Exchange, which would perform various controls before distributing them to other actors.

The specifications made by The Directorate of Health emphasized that the various actors were responsible for "their" modules, with a central database, the Prescription Exchange, as the key one. The project was organized in sub-projects reflecting each institution that was included in the service and five subprojects were established.

In May 2008 the first pilot implementation was inaugurated by the Minister of Health. It was carried out in a village in the eastern part of the country, and included the GPs and the local pharmacy. It turned out to be a minor disaster, and after four months a crisis was declared. The main reason for the problems was not the ePrescription solution, but that the new version of the EPR system was unstable. Somewhat unreasonably, the ePrescription project got the blame in an angry press. The main technical solution was tested and accepted during 2009, while waiting for the vendors to complete and test their new versions. A new pilot was set up in May 2010, and contracts for large scale operations were signed. The pilots were reported to be successful, but new challenges have emerged. For instance, it seems to be the case that more or less all GPs need to upgrade their ICT infrastructure - PCs, network bandwidth, and even printers – to be able to run the solution. This again raises the issue about who is to pay for this.

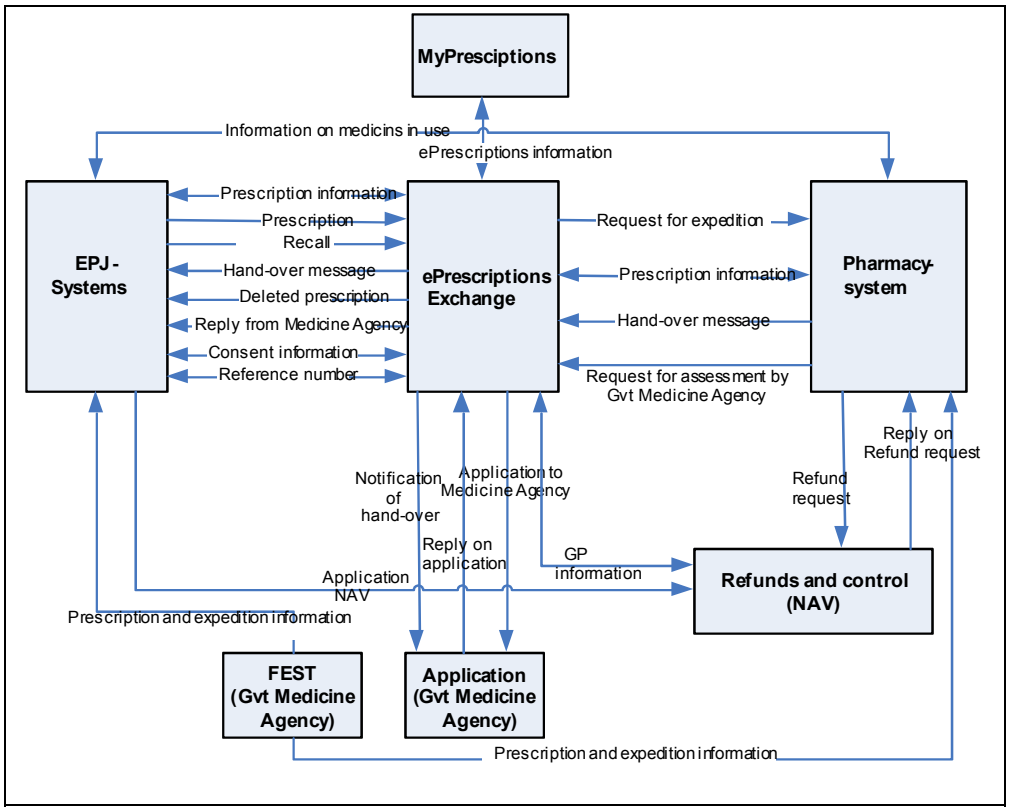

Figure 1. The ePrescription architecture

At the same time other challenges surfaced. While primary health care (the GP level, administrated by municipalities) issues 70% of the prescription, the rest is issued by hospitals. These are organized in four health regions, as separate state own enterprises. In autumn 2009 it became clear that the IT managers in the health regions had not prepared sufficiently for integrating hospital EPRs (which are different from the GPs) with the ePrescription solution. Moreover, they raised comprehensive objections to the architecture of the solution. During some heated meetings in the winter 2009-10 a kind of compromise was reached: the health regions would follow their own framework for integrating various old and new systems, while making an effort to implement a short-term solution for ePrescription. The situation facing the ePrescription program in 2011, then, was a challenging one. First, the late involvement of the key vendors made the stated goals of adoption unreachable. The EPR systems were expected to be ready in 2010, but they are still not ready. The full scale solution for the pharmacies might be ready as late as 2012. And the hospitals have signalled that they might be ready (to start) in 2013. This obviously does not mean that the ePrescription solution will be fully implemented nationally by 2013.

Results of Strategy 2

The Elin and ePrescription projects established a new standardization approach which we here call "integrated solutions." The main difference between this and the "anticipatory standardization" approach is the strong focus on user requirements in the "integrated solutions" approach. But both approaches follow a top-down and specification driven strategy.

Based on the "integrated solutions" approach a broad range of standardized messages have been defined: 14 in the Elin project and 31 in the ePrescription project. These projects clearly demonstrate important weaknesses in the original strategy with its strong focus on defining electronic versions of the existing paper documents. The contrast between the focus on one single EDIFACT message representing the prescription in the project in the 90-ies and the 31 messages defined in the current project should be a clear illustration of this. These projects also disclosed that most messages defined by following the established approach did not satisfy the users' requirements either and had to be modified.

But this strategy has not been an unambiguous success either. Some solutions have been implemented, but their diffusion and use is modest. For example the ePrescription project, has still, nine years after the pre-project started, a long way to go before it is full adopted in line with the aims of the project. This is in spite of generous funding from the Norwegian government.

While the focus on users' work practices and needs represented a step in the right direction, the top-down and specification driven approach to systems development generates an enormous complexity, both technical complexity of the envisioned solution, but also organizational complexity in terms of the number of independent actors (organizations) involved that need to reach agreement on a broad range of issues and coordinate their activities. In addition, technical and organizational issues are connected in complex ways which are hard to understand and manage.

Strategy 3: Flexible Generification

Compared to the strategy established by the Elin project, the third strategy has even more focus on users' practices and needs, a stronger focus on developing working solutions and a correspondingly lower focus on standardization as such. This strategy is close to the one followed by Fürst when they so successfully introduced services for electronic exchange of lab reports in Norway in 1987. And this strategy has to a large extent successfully been followed by Fürst ever since, and has also been adopted by a few other initiatives more recently. We will here present, in addition to Fürst, two activities we have identified which have followed the strategy we have named "flexible generification."

Fürst

When Fürst's solution for lab report transfer (see above) was successfully adopted by the lab's customers, Fürst wanted to extend the scope of electronic services offered. The natural next step was electronic transmission of orders. Fürst realized from the very beginning that this would be a different case.

Receiving reports electronically is attractive for GPs because they get faster access to the results and they save time they otherwise have to spend on manually entering the report data into the EPR. However, in the case of orders, Fürst's primary motivation for implementing an electronic solution was the reduction of manpower required internally in their lab.

Fürst started the development of a pilot solution in 1992 together with one of the vendors of EPR systems. The solution was tested in a pilot implementation in a GP office in 1993. The experience gained by the pilot users did not create much enthusiasm. The overall usability of the solution was rather poor, and the GPs did not see any immediate benefits. Reasonably, Fürst concluded that a successful solution would have to offer the GPs some new and improved services as well.

After some time Fürst came up with the idea of offering the GPs the possibility of ordering new tests of a specimen *after* the results of those ordered first were available. Usually a GP orders several tests of the same specimen. Often, which combination of tests that is most relevant cannot be decided until the results of some of the analysis are seen. Accordingly, it would be useful to order some tests, look at the results and then decide on which additional analysis that is relevant. When both orders and results are transmitted electronically, this possibility may become reality. This idea was called "interactive ordering."

Fürst also wanted to use relevant standards where such existed. Unfortunately, this solution could not be implemented based on the existing standardized EDIFACT messages, nor could it be implemented based on e-mail protocols which were the standard carriers for EDI based communication (Hanseth and Monteiro 1997). However, such a solution could easily be implemented on top of a transaction oriented on-line connection which Fürst's used in its original, non-standardized solution, except for the problem that it used dial-up connections which were considered too slow for the kind of interactivity required by Fürst's envisioned solution. Accordingly, they decided to postpone this until higher bandwidth networks were more easily available and affordable. Around 2000 Fürst considered this to be the case and they started to plan implementation of the solution. At this time they also planned to pay the costs for their customers related to broadband connections.

However, when they were about to start implementation, the idea of a national Norwegian Health Care network had emerged. Fürst decided to support this initiative as much as possible. In 2003 they became the first users of this network and started actively offering their solution to their customers. The solution has been enhanced over the years and offers the users a broad range of services beyond the possibility of filling in and sending an order. For instance, the users get an overview over which analysis they may order, guides for which analysis to order, help functions for every button to be pushed, information about each analysis, 10 years of history for each patient, information about which orders new analysis may be added to, etc. (http://www.furst.no/furst_forum.pdf). The solution also included services for communication between GPs and specialists working at Fürst. Fürst has spent about 1, 5 man years every year on developing, maintaining, and improving the solution.

The interactive ordering solution has increasingly got a reputation for being a useful tool and the growth in number of users has accelerated, by Nov 2010 to about 3.500, which accounts for more than 50% of Fürst's customers. At any time during ordinary work hours 1.100-1.200 users are logged in.

North Norwegian Health Care Network

The North Norwegian Health Care Network (NNHN) was established as a project in 1997. The aim was to set up an ICT network for exchange of information like orders and reports and admission and discharge letters among health care institutions in the Northern Norwegian health region. They applied to the Health Directorate (and Ministry of Health) for funding. The directorate (and ministry) approved the idea and decided to fund the project. They also decided that the other four health regions should do the same.

The project was staffed with people who had worked at the IT department at the University of Tromsø. They were all familiar with Internet technology and the Internet way of building networks and services, i.e. developing simple working solutions first, and then defining the standards when the solutions are working and proved useful. They had in general a very pragmatic approach to standards and standardization and the focus was on establishing services that were widely adopted as fast as possible. (The other four regional projects started instead extensive activities aiming at specifying needs etc.) The project was reorganized into an independent company, owned by the three counties of the northern health region in

1999. In 2003, when the Norwegian Health Care network was established, NNHN was merged into this organization.

The services were established in close collaboration with GPs and the hospitals. In addition to message exchange, a number of web based services were also established. NNHN decided that an important factor for successful establishment and operation of the network was to keep the complexity of the software running on the GPs PC at an absolutely minimum level. Instead as much as possible of the software functions should run at the hospitals' computers. So, similar to Fürst, NNHN also did most of the work required to integrate the communication technology with the applications, i.e. lab, radiology systems, etc. in hospitals and patient record systems in GP offices. This would increase the stability of the software in the GPs' computers, i.e. decrease the probability of errors and the need for updating the software by adding new functions, for instance when a message format is changed. So if a lab system produced reports in a standard format, the report was converted to the format read by the receiving GP's ERP system at the hospital, and then transferred in this (proprietary) format.

Overall the NNHN effort was very successful. All hospitals and GP offices in the region were connected to the network and almost all documents covered by the services were exchanged electronically. This was in strong contrast to the slow uptake of similar services in the other regions.

Well/DIPS Interactor: Interactive Orders and Referrals

In 2001 the University Hospital of North Norway (UNN) studied the use of resources and error rates related to their own laboratory activities. This study revealed that the paper orders from primary care often contained errors, lacked clinical information or had a mismatch between the paper order and the sample tube. In addition, manual and repetitive work in receiving the samples was considered a waste of resources. UNN believed electronic ordering would help improve the situation regarding both problems. They had worked together with the local IT vendor WELL for some time (as a part of the NNHN activities) and discussed how a service for electronic ordering could be designed. (Well was bought by DIPS, the market leader of Electronic Patient Record systems for hospitals in Norway, in 2009.) Both were well aware of Fürst's solutions. WELL was interested in developing a similar solution, but with the difference that it should be a generic interactive ordering product for the health care market that could be used by many labs and also support other kinds of ordering like referrals and radiology orders.

In 2006 they established a joint project. The system for electronic ordering of laboratory services was built in an iterative way and in close collaboration with the users at UNN and in general practice. Four months into the project, WELL presented a simple, but working solution which satisfied the minimum requirements to enable submission of an electronic order and which was more or less a digitized version of the existing paper-based requisition. This system was based on existing interfaces developed by Fürst, and required little or no effort from the EPR vendor. But based on the real-life use and testing of this solution the product was continuously changed and adapted to the needs of the users. The result of this incremental process was the product named Interactor. In collaboration with Akershus University Hospital and UNN, WELL extended the software to support *interactive referrals*. Interactor was in 2010 used by nine hospitals and approximately 60 GP, while a pilot for interactive referrals included six GPs.

The types of analyses a lab can perform are quite dynamic and may change continuously. This implies that the parts of the system where the GPs make their orders need to be modified every time a lab makes changes in their repertoire of analyses. In addition each individual lab offers a unique repertoire of analysis. Accordingly, the systems supporting electronic ordering need to know the repertoire of analysis offered by each single lab, and they need to be updated every time a lab changes its repertoire. WELL and UNN therefore agreed that electronic ordering had to be based on a model where the labs specify their repertoire electronically in a software module on the health network. The updated repertoire is downloaded from this module to the client who is used when orders are specified. This client is tightly integrated with and appears as part of the GPs EPR. The module for referrals is based on the same ideas and the same technology for integration as for interactive lab ordering.

The exchange of orders and referrals is based on standardized messages as far as possible. However, much of the information exchanged between GPs and hospitals had to be specified by WELL as no standards existed, for instance for the specifications of content of the analysis repertoire, requests for the latest

versions, etc. And, as for the Fürst and NNHN solutions, the interface between the Interactor modules and the GP and hospital systems is crucial.

Results of Strategy 3

The activities presented in this section focused on developing useful and well working solutions following an experimental and evolutionary approach. We see this approach as a combination of the "flexible standards" and "generification" strategies presented in the related research section. Accordingly, we call this strategy "flexible generification." This strategy share the strong focus on user needs with the "integrated solutions" strategy, but is fundamentally different in the sense that "flexible generification" is a bottom-up and evolutionary approach while the other is top-down and specification driven.

This "flexible generification" strategy has delivered a wide range of successful solutions – solutions that offered new and improved services. The evolutionary approach has been important for developing simple solutions that could be developed for reasonable costs within reasonable timeframes. This approach has also allowed early user feedback based on use of running systems which has been crucial for improving the systems to fit user needs. And further, this mere *experimental* approach has also generated new ideas about how the technology can be designed to support new and improved health care services and not just speed up existing paper based practices.

These activities have also contributed to standardization. All three cases show a pragmatic approach to standards. They implemented the relevant standards that were available and modified these when needed and defined their own messages and formats where there was no standards. When defining their own formats, they did so as much as possible by using and modifying existing ones. A typical example of this is the role of the so-called $-format. This was originally defined by Telenor, by modifying slightly the format Fürst used in its solution from 1987, when they developed the lab report transmission solution for UNN around 1990. This format was used in most of the lab report transmission solutions developed the following years and was then established as a sort of national de-facto standard. NNHN then used this format, or modest modifications of it, for transmission of most patient information exchanged between GPs and hospitals in the northern Norwegian health region. The interfaces between the communication services' GP clients and the GPs' EPR systems and other applications have evolved into de-facto standards in a similar way. And the same happened to other message definitions, like the more formally approved EDIFACT standards. This illustrates a *bricolage* like process where standards are selected and modified to fit users' needs (Ciborra 1992). Through such processes the standards are improved and made more generic to serve the needs, i.e. standards have been developed through a *generification* process. Further, this generification of the de-facto standards was quite simple just because the standards were *flexible standards*. This flexibility is illustrated by the fact that the so-called $-format was specified on one single A4 page. The specification of the first EDIFACT message defined by CEN TC/251 for lab reports was on 499 pages!

The efforts following the strategy presented in this section also differs from the two others in a more general, but indeed crucial way: how they cope with complexity. The solutions developed in all three efforts are more or less completely designed and developed by one single organization. Combined with the pragmatic approach to standardization, the focus on simple and working solutions, and an evolutionary development strategy, the outcome has been technical solutions of lower complexity. But even more important, the outcome has also been that the organizational complexity has been much lower: fewer organizations needed to be involved and agree on detailed technical specifications.

Concluding discussion

We have in this paper presented the history of development, implementation, diffusion and use of ICT standards for information exchange between health care institutions in Norway since this activity started in 1987 and up till today (May 2012). We have identified three different strategies for developing standards. Our focus is on how each of these strategies enables and supports solutions that best contribute to the overall improvement of the health care sector through the development of new and improved medical services.

The general picture in the field is that the implementation and diffusion of standards have been very slow. This has been the pattern in most national strategies for ICT in health care. But we believe that in order to

make the future of ICT standards more bright than their past, we need a critical examination of the strategies followed and the achievements.

The first strategy we identified, which we call *anticipatory standardization*, is the official and traditional one. To our knowledge, this strategy has not been seriously challenged officially by any actor within the field. The two other strategies we have identified are not recognized as such within the field; they are emergent strategies. By contrasting these strategies and their achievements, we believe important lessons may be learned both by practitioners and researchers.

The first and official strategy, anticipatory standardization, has delivered a number of standards specifications. But the standards, with their rather extreme focus only on replacing paper forms with similar information objects, turned out to be unattractive for application vendors as well as user organizations. One important reason for this was the fact that they could not be implemented in useful systems without substantial modifications and specifications of additional messages and protocols. This limitation was to a significant degree overcome in the second, the *integrated solutions* strategy. With the stronger focus on users' working practices and needs, this strategy has delivered more appropriate and complete set of specifications. But the implementation of the specifications has been a very slow process, mainly because of the complexity of the solutions specified and the organizational complexity of the coordinated implementation process the specifications require. When the standards are successfully adopted, the existing paper based services are improved. But the benefits are definitively limited as they still mimic the paper based processes. And there is a high risk that the complexity of the standards and the solutions based on them soon will emerge as legacy systems resisting virtually all change efforts and accordingly represent a major problem when one tries to improve processes in ways enabled by ICT solutions. I.e. they may inhibit rather than enable or stimulate future service innovations.

We see the third standardization strategy, *flexible generification*, as being by far the most successful one in terms of delivering working solutions that also enable the innovation of new services that go beyond existing paper based practices. Moreover, the differences between this strategy and the others are even more striking when one takes the costs and time required for implementing the solutions. This is the only strategy among the three we have identified that enables and stimulates to real service innovation.

Developing a more detailed and general flexible generification strategy for eHealth will obviously require substantial work, and is outside the scope of this paper. We will briefly comment on two important issues for further research. First, such a strategy needs to integrate formal standardization procedures into the overall development and implementation activities. Standards should be specified as the solutions are being made more generic. At the same time the standards need to be kept simple and flexible to adapt to the changing needs. Experimental development of solutions going beyond exiting standards needs to be stimulated. Such a model should be developed as a further elaboration and combination of the generification and flexible standard models presented earlier.

Second, one needs to acknowledge the relationships between the degree of standardization of the one hand and complexity and flexibility on the other. Health care is a highly dynamic and unpredictable environment and ICT solutions, including standards, need to adapt to this. Indeed, ICT solutions are important sources of this dynamic and unpredictability. This also implies that one has to give up the common held view, and which has been strongly present in the activities reported here, that the wider the scope of a standard and the more detailed it is specified the better it is. The classic argument in favour of (compatibility) standards is that it reduces complexity. If you want to link your system to lots of others' you can just implement one standard when there is one. Otherwise you need to implement one integration module for each individual system you want to integrate with. This is true. But it is only a part of the truth. As the scope of a standard increases, so do also the number of actors being involved as well as the features of the standard (if it is to satisfy the users' requirements). So at one point the complexity increases more by expanding the scope of the standard then the decrease in complexity gained by enabling more systems to be integrated based on one and the same standard. And managing change is much about coping with complexity. The successful development, implementation, diffusion and use of ICT standards in health care (as well as other sectors) is to a large extent about finding degree of standardization which minimizes complexity and maximizes flexibility.

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