Conducting Interdisciplinary Research: Evaluation of the ePrescription Pilot Scheme in Finland

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Abstract: This paper describes the evaluation of the national ePrescription system in Finland. It is based on a national ePrescription database. By the end of 2004, two hospitals had implemented the required technology and 300 ePrescriptions had been sent to the database. A multidisciplinary evaluation framework was used to help direct the design and implementation of the system, and for evaluating its impact from different stakeholders' perspectives. The theoretical foundations of the framework are depicted in detail in another article by the authors (submitted).

Keywords: Evaluation, e-Prescription, Interdisciplinary research

1. Background: the context and need for e-prescriptions in Finland

National spending on health care has been increasing over the past decades in most western countries. An increasing number of ageing people will escalate the demand for health care in the near future, and governments are being forced to seek methods to rationalize their health policies and boost the efficiency of the health care sector. (Kwak & Lee 2002; Johnston 2004; Stakes 2004.)

New technology has been seen as one remedy for rationalizing the health care sector. According to Raghupathi (2000 p.61), information technology can assist health care by "providing health-related information services and decision support on demand, as well as in managing rising costs and changing organizational needs, improving the quality of health services and patient care, and fighting illness while promoting wellness".

Electronic prescription systems (EPS) are one example of the use of information technology in health care, and these types of systems have been or are being implemented in several European countries and the USA. They are expected to solve several challenges in health care: rationalizing medication practices of physicians, providing up-to-date information on the cheapest medication available, reducing overlapping medication, reducing medication errors and adverse drug interactions, decreasing prescription handling costs, and increasing efficiency in several organizations. Electronic prescriptions will provide more accurate and up-to-date statistical information about medication practices in relation to these issues and hence increase the efficiency of pharmaceutical distribution and improve the planning of national health policy in the long run (Bell et.al 2004; Bastholm et al. 2004; Boonstra 2003; Mundy & Chadwick 2003).

In Finland, only pharmacies and subsidiary pharmacies are allowed to sell medicines to the public, except in sparsely populated areas, where medicine dispensaries owned by pharmacies may sell non-prescription products. An order from a doctor, dentist, or veterinary surgeon is needed to purchase prescription medicines from a pharmacy. There were approximately 16,500 physicians in both the public and private sector in 2003 (317 citizens per physician). (Stat 2005.)

Pharmacies are privately owned. Permission to own and operate a pharmacy is granted by the National Agency for Medicines. The University of Helsinki also has a statutory right to run one pharmacy in Helsinki as well as subsidiary pharmacies with the permission of the National Agency for Medicines. In 2003 there were a total of 601 pharmacies in Finland and pharmacies received approximately 38.5 million prescriptions in 2002, of which 28.1 million received compensation from the Social Insurance Institution. Approximately 80 per cent of all expenditure on medication is due to prescription medicines. (Stat 2005; National Agency for Medicines 2005.)
The current Finnish system for prescribing medicine is relatively sound. The patient receives a printed prescription form (filled in by hand or computer) from the doctor. It contains the patient's and physician's identification data and has place for prescribing two drugs together with space for information on dispensing and renewal. The patient brings the form to a pharmacy, where a pharmacist will feed the data from the prescription into the pharmacy program for dispensing medica-

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tion. The program calculates the price of the drugs, deducting the amount of national insurance if a social insurance card is presented. The program prints bar code labels with the price, which the pharmacist attaches to the drugs. The pharmacist marks the amount of medication dispensed on the form and returns the form to the client with the medication. The second page of prescription is left at the pharmacy so the national insurance office can be invoiced for the insurance element contained in the price of the medication. (Hyppönen et al. 2005.)

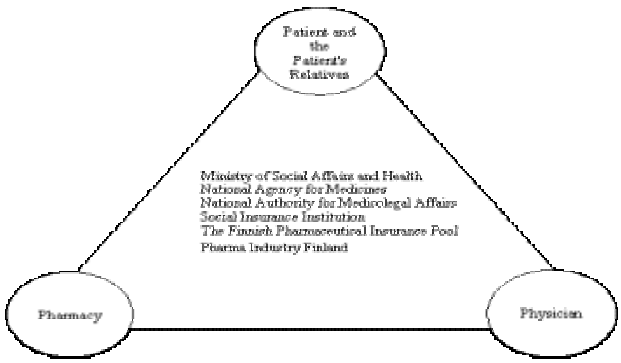

Figure 1: Key stakeholders involved in the Finnish prescription process (Adapted from. Paakkari 1997)

As part of the implementation of the national social welfare and health care technological benefit strategy, the Ministry of Health and Social Services (STM) initiated a study in 2001, which aimed to clarify the structure and objectives for developing a system for electronic prescriptions in Finland. The objective was to create a unified national system that would be efficient, safe and flexible. The use of a standardized CDA-format for the prescription contents and a common, up-to-date pharmaceutical database were defined as being the key requirements. The study recommended a model based on a centralized prescription database, hosted by the Social Insurance Institution. (Social Insurance Institution 2001.)

The model selected is based on the electronic storage and retrieval of prescriptions, which requires the patient's written consent. The doctor creates an electronic prescription with either a stand-alone electronic prescription program or a program integrated into the legacy information system (e.g. EHR or HIS system). The doctor, using a qualified electronic signature, signs the prescription personally. Instead of printing the prescription, it is transferred from the doctor's office to the national prescription database, where it is then stored. The patient receives a printed 'memory slip' instead of a prescription. Pharmacists can retrieve the e-prescription for any patient using the local pharmacy system. Access to the national prescription database requires identification and the use of a smart ID-card. A patient's prescriptions are retrieved either by using the patient's unique social security number or the prescription's unique PIN-code. Information transfer to and from the database is secured against unauthorized access with Secure Sockets Layer (SSL)-technology. For additional security the prescriptions are stored in a SOAP envelope. (Hyppönen et.al. 2005; Social Insurance Institution 2001.) In 2003, the STM issued a Decree on experimental e-prescriptions.

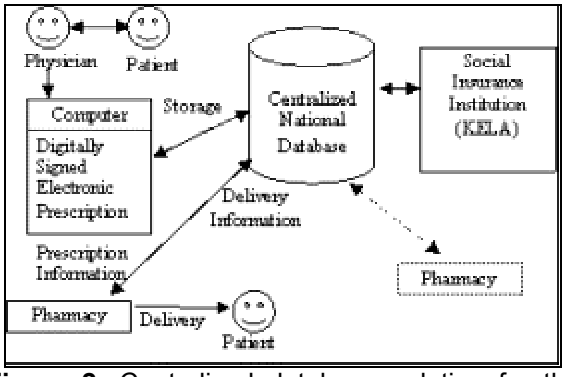

Figure 2: Centralized database solution for the Finnish Medicine Prescription System

2. Aims and methods of the evaluation

The STM called for an evaluation of the national e-prescription pilot system through its research and development organisation, Stakes. The aim was to collect information to form the basis for permanent legislation. Three main objectives were set for the evaluation: 1) to provide practical information on the development process of the e-prescription system in order to guide the process, 2) to evaluate legal and data protection aspects of the Finnish e-prescription model and compare it with other models, 3) to evaluate the functionality and impact of the system in terms of the technology, its end users and organisations.

The timetable for the evaluation was one year (2004), during which time it was intended that the pilot scheme be implemented in all four pilot sites. In order to meet the multiple evaluation needs presented by the Ministry, Stakes collected a multidisciplinary team to finalise and execute the evaluation plan. The framework is presented in figure 3.

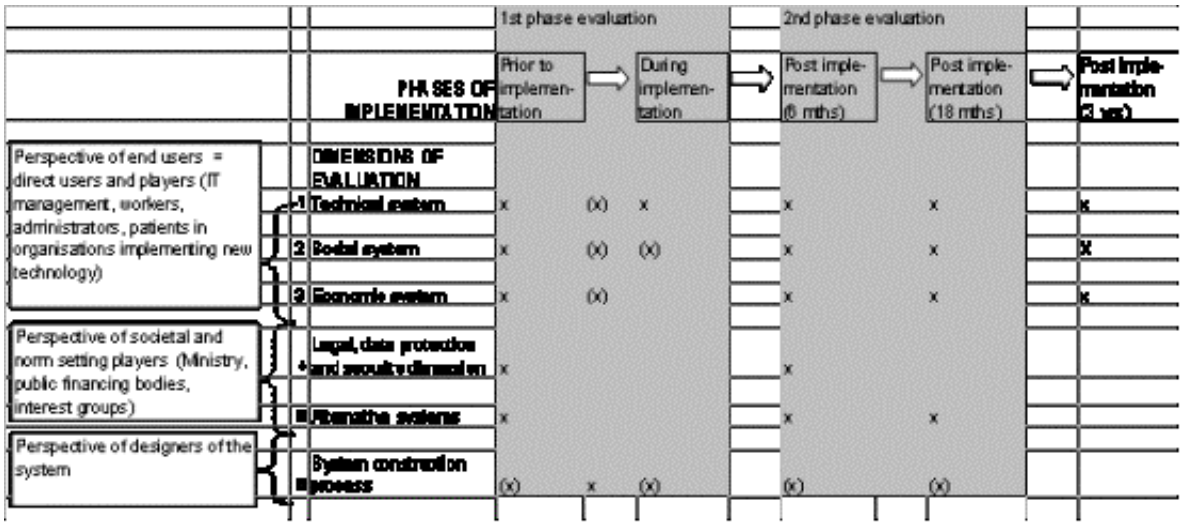

Figure 3: The evaluation framework and timing of evaluation phases

The framework needed to be flexible enough to adapt to changes in the speed of the system's design and implementation (cf. Westbrook 2002, 8). Since it soon became evident that the implementation schedule would not be achieved, it was agreed with the Ministry to split the evaluation task into two phases: 1) the contextual analysis (baseline data collection) and analysis of the system's design and implementation process 2) the impact evaluation. The first phase evaluation was conducted during 2004 (Hyppönen 2005), forming the basis of this article.

The empirical data needed to extend to activities and interaction of political decision makers, users and technology developers as well as outcomes and impacts of the interaction. The group of theories called 'the social shaping of technology' (e.g. Latour 1987; Pinch & Bijker 1987; Callon et al. 1986; Rip et al. 1995) within the field of science and technology studies, combined with interdisciplinary activity theory (Vygotsky 1978; Leontiev 1978, see also e.g. Engeström 1987; Cole 1996) inspired the overall theoretical framework of the study. The framework has been developed and used in several innovation studies (e.g. Miettinen 1999; Lehenkari 2000; Hasu 2001; Hyysalo 2004; Hyppönen 2004). Activity theory has also been applied in the field of IT studies (e.g. Nardi 1996; Gregory 2000). The theoretical foundations of the framework are described in detail in another article by the authors.

We started by collecting data from the perspective of end users about the present medication prescribing activity and users needs to change it. We studied the changes induced to it by gradual implementation of new e-prescribing tools (the top 3 rows in figure 3). Data was collected by observation (e.g. Bauersfeld & Halgren 1996), interviews, and a questionnaire to doctors and pharmacists in the piloting organisations. The usability of existing technology and the system architecture of the proposed technology together with its usability were studied using specific approaches from computer science. The organisational perspective was studied using specific approaches from economics and business administration (c.f. Daamsgaard & Lyytinen 1998).

The assignment covered legal, data protection and security issues as well as a benchmarking study. These questions were in the core interest of the societal players involved in the pilot (the middle two rows in figure 3). The juridical evaluation (cf. Aerschot 2000) was performed by comparing existing legislation, the decree on an experimental electronic prescription system and the functionality of the e-prescription system. The evaluation concentrated on data protection questions. Data security questions focused on comparing the functionality of the system with data security standards. A benchmarking study comparing the Finnish pilot system with various other systems implemented in other countries was also conducted. This was done as a desktop study. We listed key elements in the Finnish system to compare how they were realised in alternative e-prescription models.

The construction - design and implementation - of the system formed the third, designers' viewpoint of the study. It is depicted in the bottom row in figure 3. Documents produced by the steering group and participation in group meetings, were used to study the evolution of decisions taken by the group on the features and functions of the pilot system. Evaluative interpretations on the design process were presented to the steering group for discussion and to help with decision-making.

The impact analysis was planned so that the baseline data collection would be repeated in order to reveal actual changes in user activities and

outcomes e.g. prescription preparation and delivery times, reduced amount of phone-calls, reduced errors, and usability of the implemented system. Evaluation of how usable the system was for patients would also be included, as well as evaluation of the technical functioning, reliability and data protection questions of the system.

3. The needs, construction and implementation of the e-prescription system

The baseline data showed that end users in the piloting organisations were relatively pleased with the existing system. The expectations of the e-prescription system were mixed. Users wanted rationalisation of the prescription process, improvements in the safety and quality of prescriptions, and reductions in medication errors and fraud. However, they were somewhat sceptical about the extent to which e-prescription could deliver these benefits. The piloting organisations were strongly committed to the pilot but had not set any financial or functional objectives for the e-prescription system, neither had the feasibility of the proposed system within their own organisations been studied.

The piloting of the proposed system was meant to be conducted in 2002-2003. To organise it, the STM established a steering group in May 2002 to direct the implementation of the system. The steering group contained representatives from all the important stakeholder groups. Four regions in Finland were selected to pilot the system. They were to work independently and report their progress to the steering group. A pilot manager was named, but no budget or project plan detailing the division of work was set out, since the pilot was expected to be a straightforward implementation exercise. It was anticipated that by the end of 2003 two per cent of prescriptions would be electronic,by 2010 forty per cent and seventy per cent by 2020.

The initial aim was to pilot a stand-alone system (not integrated with EPSs or medication delivery systems). The decree issued in 2003 laid down provisions on preparing, signing, technical content, altering and delivery of e-prescriptions. There were also provisions on informing patients and obtaining their consent, defining the right of use and maintaining e-prescription information in the national database.

Initial tests with the stand-alone system showed that it did not work reliably. It also took a lot of time to enter medication into two separate systems in the doctor's office and pharmacy. On the basis of the results from these two regions, a decision was taken to wait until an integrated system for doctors and pharmacies was developed. This altered the nature of the pilot from being a restricted pilot test of a stand-alone system to a development project concerning four patient information systems and two delivery systems. The network-like organisation was not adequate in the new situation. The technical complexity of the piloting increased dramatically. There was no strict plan, division of work, timetable or budget for development work of this magnitude. The steering group ended up wearing two hats: acting as a working group concerned with the technical and implementation details, as well as a steering body making strategic decisions about the direction of the work, and the former took over the latter during the course of most meetings.

There were many questions to be considered by the steering group, some of which proved to be beyond the scope of the pilot, thus delaying the project. By the end of 2004 two out of the four pilot sites had implemented the system. Only one integrated EPS system had been implemented, other players were still using the stand-alone system. Apart from the delays in the technical integration between the EPS- and pharmacy systems, another integration issue emerged: the pharmaceutical databases used by pharmacies, health care organisations and EPS providers were not compatible. The pilot had agreed to use the leading pharmaceutical database provided by the Pharmaceutical Information Centre. The problem was that the EPS and pharmacy system providers, hospitals and other players using the system process the information it contains for their own use in a non-standardized way, and as a result the contents and timeliness of the databases may vary, leading to the possibility of errors in e-prescriptions. The pilot had limited powers to influence this.

There were also many questions concerning the specifications that still needed resolving, e.g. the question of specifications for electronic signature, for which there were insufficient national instructions. The Act on electronic signature had entered into force on 1 February 2003. The Act defines the quality requirements for the signature, but not the concrete technical and functional requirements e.g. the number of pharmaceutical preparations that can be signed with one pin-code (signature). Doctors wanted the possibility to sign several prescriptions with one signature to rationalise the treatment of polypharmacy patients, but data protection experts were hesitant. A decision-favouring the viewpoint of doctors was made by the Ministry in November 2004. The decision had serious implications for the prescription programs,

which were designed to allow only one signature per preparation.

The first pilot site began testing the system in May 2004, the second site in October 2004 and the third in June 2005. The fourth site has still not started. The number of e-prescriptions has been very modest to date: by December 2004, 300 e-prescriptions had been written, of which 108 had not been delivered. The main reasons for this were:

- Technical difficulties in writing the e-prescription and sending it to the national database (the existing old HW and SW did not necessarily support rapid processing of data)
- Difficulties in the delivery process (pharmacies selected by the Association of Finnish Pharmacies for the pilot were not suitable for most clients: they were too far away from the doctor's office and patients were not able to go to pharmacies which they regularly visited. Since the integrated systems were still under construction, pharmacies also had to use an unreliable and time-consuming stand-alone delivery system.)
- The above-mentioned problems caused clients to hesitate in giving their consent to participate in the pilot.

The main recommendations presented to the pilot project on the basis of the constructive evaluation phase were:

1) The pilot needed to be reorganised administratively so that it had sufficient resources, a concrete plan, working groups and a clear division of labour required in a major technology project,
2) The implementation frame needed to be simplified so that experiences could be collected more comprehensively from one or two regions,
3) The work in the pilot needed to concentrate on producing a detailed description of the information processing relating to the prescription process, (including programs used), documented technical and functional requirements of the system and a common testing system with documented results for others to learn from.
4) Emphasis needed to be shifted from technical piloting to usability and user acceptance.

4. The implemented system and its usability, functionality and security

When the ePrescription system was planned, many approaches for the system architecture were identified. The options included the following: 1) to use email messages to send and receive prescriptions, 2) to use electronic identification cards to access prescriptions, 3) to design a system using the existing commercial information system components, 4) to use a reference database to store information on prescriptions, 5) to distribute prescriptions to regional servers that are connected to each other, and 6) to use a concentrated database where all prescriptions are stored and accessed. The decision was made to implement a system using a concentrated database that allows all prescriptions to be accessed by pharmacies, physicians and the social security authorities. The prescriptions are signed using digital signatures, and prescriptions are produced in electronic patient record systems that are transmitted to the prescription database. The electronic prescription was carefully defined to cover both the structure and content of the prescription.

The system was implemented as a pilot system in some Finnish hospitals and we studied the use, usability, functionality, safety and reliability of this pilot system.

The use of the system in the pilot hospital turned out to be rather complicated, as the interfaces between the various system components did not work well. This was reflected in users' opinions of the system's usability and usefulness. The usability was considered to be poor and preparation of electronic prescriptions was very time-consuming and complicated. The pilot scheme was started too early, with regards to the facilities available, and therefore, many technical problems were also experienced.

The major usability problem occurred in situations where a physician had to use two or more separate systems to produce a prescription: First, the electronic health record system was accessed to produce the electronic prescription. To retrieve drug data and information the pharmaceutical database needed accessing. Finally, electronic signature software was used to sign the prescription together with additional software to send the prescription to the prescription database. This situation revealed that the major problem was a lack of integration between hospital systems and pharmacy information systems. Had the existing system components, i.e. electronic patient record systems and the pharmacy information systems been fully integrated with the electronic prescription database, then the system's usability and functionality would more likely have been much better. The use of this pilot system required much more time than preparing prescriptions in the old 'manual' way and therefore many physicians opposed the introduction of the system. Patients

were not satisfied because in the pilot they had to go to a specific pharmacy to collect their medication, and were not able to choose the pharmacy themselves.

In terms of the information system, the major technical problems were related to the lack of integration, the complex procedures for creating a digital signature and to the changes in the system logic when systems were upgraded during the pilot. Many of these problems are most likely to disappear once the system evolves and integration has been completed.

Current legislation requires a physician to sign ePrescriptions personally. The whole prescribing infrastructure covering legacy systems, a national prescription database and communication networks must defined and implemented in such a way that prescriptions cannot be disclosed to any unauthorized persons or entities. The integrity of all ePresciptions must also be secure during the transmission of the data and for the 20 months preservation time. ePrescription security solutions consist of PKI services, smart-card-based identification, and qualified signatures for data integrity, SSL-based mutual authentication of IT-systems and SOAP envelopes, which must all meet the necessary security requirements. One unsolved security problem is that there is no patient-doctor relationship check. All doctors and pharmacists participating in the pilot can access any ePrescriptions stored in the national database. To solve this problem access to the national prescription database and the presence of the patient-doctor/patient-pharmacy relationship at the end user level need to be monitored simultaneously.

5. Legal aspects of the system's evaluation

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. The interpretation and analysis of the legal aspects have been characterised by the lack of tradition in evaluating the functionality of the regulation in practice and the relationship between the Decree to other laws and orders. The research tradition pertaining to legal science is not involved in everyday practices and seldom contains empirical elements. Studies on the profitability and effectiveness of law are rare. There are no models, traditions, methods and references. The study of law is therefore mostly based on the interpretation of regulations.

Various regulations were used as the principal data for the juridical evaluation. The applicable regulations at issue are many in number and scattered throughout the legislation. The essential regulations taken into consideration as evaluation material included the Medicines Act 395/1987, Act on the Status and Rights of Patients 785/1992, Personal Data Act 523/1999, Act on Health Care Professionals 559/1994, Act on the Social Insurance Institution 731/2001, Act on Electronic Services and Communication in the Public Sector (13/2003), Act on Electronic Signatures 14/2003 and Sickness Insurance Act 1224/2004, while other regulations were also considered in the interpretation. Due to the delay in the pilot project it was not possible to get much empirical data for the juridical evaluation. The documentation generated during the project (consents, information processing, agreements etc.) was not available for analysis as initially planned. For this reason it has not been possible to evaluate how privacy protection has been implemented during the pilot period. One problem concerning regulation is the lack of special statutes regarding e-health in Finland.

The key elements of the legislation analysed concerned medicines, their prescription and selling, practices and professionals in health care, patient privacy and its safeguarding, the national prescription database, and electronic communication. The Social Insurance Institution (Kela) is responsible for the electronic prescription record system as laid out in the Decree. A proportion of the price of drugs is compensated by national health insurance and Kela is responsible for health insurance, too. The regulation concerning health insurance and Kela were also relevant to the study.

The questions of a hierarchical level of laws and their applicable provisions were of special significance to the juridical evaluation. Experimental enactments must be applied in the first instance if there are conflicts between their provisions and other enactments. For the pilot project this means the Decree regulating the pilot is applied first in respect of other decrees. If there are conflicts between decrees issued by the Government or Ministries and acts given by Parliament, the acts take priority. Most of the regulatory problems and difficulties in interpreting them are connected to these questions. The main aim of the evaluation was to produce information for establishing permanent regulation and activities. One result of juridical study that should be taken into consideration if permanent legislation is provided is the following: the regulation should be applied at the level of an Act of Parliament.

Another main juridical conclusion involved the question of the data file and it's Controller. According to the Decree the national prescription database is maintained by Kela, which manages it

by agreement with health care units and pharmacies on their behalf. Processing the electronic prescription requires the informed consent of patients. As a permanent arrangement, the management of the e-prescription system between 600 pharmacies and Kela will be quite burdensome. The same conclusion applies to the management of consents as well. Depending on the processes and the regulation level there are different interpretations as to whether the electronic prescription database has to be considered as a personal data file as such, or as separate files of health care units and pharmacies. These interpretations are reflected in the question of the Controller of the system. The conclusions for the permanent solution are: it cannot be based on contracts. The controller should be defined by the Act. The other data protection conclusions will be drawn as a part of the later phase of the evaluation.

6. Challenges, possibilities and limitations of the multidisciplinary evaluation

In conclusion, what was the value of the study and how did it meet the needs of the ministry? It is too early to critically analyse the impacts of our evaluation from different stakeholders' points of view. The objective to inform the ministry about the basis for permanent legislation was not fully met, since the system development was delayed. We did evaluate the implementation and functionality of the Decree on Experiments with Electronic Prescription to the degree it was possible. The second part of the evaluation will elaborate on question of the normative framework required. The objective of providing practical information on the development process of the e-prescription system in order to guide the process was met. The results were reported to the project monthly. They led to reorganisation of the entire project and concentration on the key questions raised in the evaluation. The comparison of the Finnish architecture with other models confirmed authorities that the Finnish architecture is worth pursuing. The functionality and impact of the system in terms of the technology, its end users and organisations has not been possible to evaluate at this stage.

The multidisciplinary evaluation has not been easy. Each of us has had our own approach and concepts rooted in the disciplines we represent. Generating a common language and framework for the evaluation took time. Quantifying the added value that each of the disciplines could bring to the multidisciplinary approach was also challenging. The question crystallized in creation of the framework, collection of data and formation of evaluation criteria. Even if we mostly shared them, we looked at them from different angles: as a technical, functional, juridical or economic question.

The pilot was a policy-initiated development, and the evaluation was research to order. In this type of evaluation the buyer often attaches conditions to the research, which aim to serve the buyer's interests. The subject of our evaluation - an e-prescription system - is a politically sensitive subject in a sense, because it presents one concrete application of the Ministry's social welfare and health care technological benefit strategy. Thus, the expectations for success at a political level are high. We, as evaluators, were placed in a hot spot, balancing between the sometimes-conflicting interests and presumptions of the stakeholders participating in the design of the system, end users and political decision-makers. We strived to produce a realistic evaluation with as accurate and credible results as possible, using communicative validation to increase their credibility. The multidisciplinary approach helped us maintain the voices of many stakeholder groups, which will hopefully help different groups to gain more from the study, and will help in gaining their co-operation in the second phase of the pilot, and the "multi-voiced", co-construction of the practices and IT systems.

In spite of the challenges, the multidisciplinary approach has been rewarding. Combining our expertise has helped us produce a study which none of us could have achieved on our own. We are all enthusiastic in continuing the work we have started in developing and testing our theory-based framework and methodology for conducting inter-disciplinary studies on ICT evaluation in social and health care.

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