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INNOVATION PATH IN E-HEALTH - ILLUSTRATION IN THREE FINNISH MEDICINE DELIVERY INITIATIVES

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Abstract: Modern citizens consider fast, safe, trustworthy and affordable health care systems as a natural cornerstone of a modern society. However, currently in most countries the rather well situation has not born out of nowhere, and has demanded a long chain of innovations. All innovations that have contributed to the advance in health care solutions in Finland have not been reviewed and are maybe not even identified yet. This article makes an effort to understand the typical innovation path in health care information systems in Finland. The article proposes that a natural way to develop information system solutions is to start with the structure of the domain to be developed. After appropriate structures, processes and workflows can be implemented. Based on the prior work, successful information systems can be implemented. All other ways to proceed are doomed to fail or at least to run into severe difficulties. This article concentrates on the health care information systems domain, and draws on Finnish examples, but the gained insights might help in understanding and framing system development initiatives in other domains and countries too.

Key words: E-health, health care information systems, innovations.

1. INTRODUCTION

In this article we discuss applications that fall to the domain of medicine delivery (Joumard, André, & Nicq, 2010). With medicine delivery we mean the logistics flow of medicines from medicine producing to the end user, the patient. This can be studied in general, at the population level, or as a single logistics path in the case of a single patient or patient group. A wider perspective could be that of medicine innovation to the ready product, also containing and concentrating to the product innovation and development phase. In clinical medicine, medicine delivery relates to the detailed process of getting the medicine substance to the body, for example through swallowing, inhaling or other method (Gyorkos et al., 1993).

We work on three examples: electronic prescriptions and automated drug dispensing that are at the core of medicine delivery, and as a third example we take vaccination register, that can be included into the same category, as vaccines are medicine-like solutions to harness diseases.

Medicines are often the easiest and most efficient way to tackle diseases (Karim, Pillai, Ziqubu-Page, Cassimjee, & Morar, 1996; Mongan, Ferris, & Lee, 2008). Wide and affordable availability of high-quality medicines is a cornerstone of modern health care.

In this article we discuss nation-wide ecosystem and innovations within it to make population-level delivery of medicines and efficient and effective as possible, taking Finland as an example. We present how innovations in Finnish medicine delivery have followed a natural path. Our hypothesis is that first the governance structures have to be organized, then attention can turn to processes, and finally information systems can be implemented to institutionalize the processes (Suomi, 2004; Suomi & Tähkäpää, 2003). This is shown in Figure 1. It is well known that information systems design must be integrated with process design (Dumas, La Rosa, Mendling, & Reijers, 2013). The discussion on proper market and organizational structures to support

process and then IS development is also rather developed (Brown, 2006; Ferguson, Green, Vaswani, & Wu, 2013). It is also well known that infrastructure-type IS puts new challenges to process development (Broadbent, Weill, Clair, & Kearney, 1999).

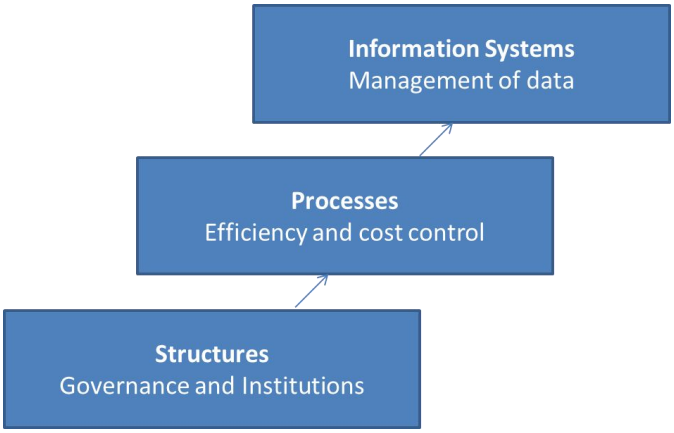

Figure 1. Productive innovation path: Structures – Processes – Information Systems

We introduce three episodes health delivery innovation in Finland:

1. Electronic prescriptions
2. Automated drug dispensing
3. Vaccinations.

These three areas are at the kernel of medicine delivery. They are selected to be discussed here as the authors have studied all of the before. All are very dependent on functioning information systems with infrastructure character and a lot of possible interfaces. As the whole of medicine, these medicine delivery systems are also heavily regulated.

It must also be remembered that medicine delivery has been though a lot of other innovation too in Finland and elsewhere, such as generic substition (Timonen, Heikkilä, & Ahonen, 2013) and the different system of reference prices for medicines (Dylst, Vulto, & Simoens, 2012). These innovations are important but are not discussed in detail here. It must be however remembered that these have deep impacts on automated drug dispensing, vaccinating and electronic prescriptions too.

2. ELECTRONIC PRESCRIPTION

2.1 Structure

Medicines are divided to over-the-counter and prescribed medicines as it comes to their delivery. With prescribed medicines, the amount of medicines allocated to a patient is medically controlled by a medical doctor. The basic structure of delivering prescription medicines through licensed pharmacies has remained the same in Finland since 1689, after the establishment of the first Finnish pharmacy. In Finland the idea has been the one strictly separating medicine prescribing and delivering, which is not the case in all countries. The position of pharmacies was officially established in year 1920, and the legislation on pharmacy products establishing the current position of prescription medicines was given in 1930. In the 2000s, electronic prescriptions were planned and implemented to the very same structures that were designed for paper prescriptions. The processes of medicine describing and medicine delivery in pharmacies were basically changed not at all, even though of course the information system interfaces used by health care professionals changed to some extent. The information contents of the prescription also remained almost the same as in the case of paper prescriptions. The new component in the total governance structure was the establishment of a prescription center that was

given as a task to the Finnish Social Insurance Institution, Kela. However it must be remembered that the whole authorities portfolio around medicines has changed a lot in Finland in the 2000s, but these changes have never been directly addressed to be causes of electronic prescription.

Already in the 1980s first local pilot projects to implement electronic prescriptions in Finland were run. They were technically modest and most probably doable, but ended up to failures. The official reason for the failures was given missing regulation. To avoid this situation, in the last run of projects that provided the current successful solution, a multitude of new legislation was given, including as an important component law a specific law on electronic prescription (Laki sähköisestä lääkemääräyksestä 2007/61).

2.2 Processes

The crucial process change in electronic prescription as compared to traditional paper prescription is that the prescription is delivered to the pharmacy through electronic means, not by the patient/citizen carrying the prescription (Spil, Schuring, & Michel-Verkerke, 2004). In Finland, for this purpose a solution of a centralized database to store the prescriptions and to be accessed by pharmacy staff was selected. For that purpose, a lot of standard messages between the prescribing units, the database and the pharmacies had to be developed.

A major problem in the electronic prescription system was that of multiple medicine databases. In the paper prescription era, there were 5-6 operative databases on medicines in Finland. The prescribing and delivering organizations might use totally different databases, and a lot of problems occurred. In the paper prescription era, these problems were solved in daily operations without a lot of publicity, but the electronic version of the prescribing process first clearly demonstrated the problem width. Nowadays, all medicines in Finland are listed just in one universal medicine database.

2.3 Information Systems

The operation of electronic prescriptions demanded a lot of operational changes to information systems around the delivery chain.

First, health record systems used by prescribing medical doctors had to be changed. This was a major task for software houses delivering the systems, and a few smaller vendors were dropped out of the competition because of this. Remember that these clinical systems had to go through a complicated and costly certification and testing procedure.

The major task was the establishment of the central prescription database, and alongside the establishment of several other databases was also needed (for example the integrated version of the medicine database discussed above). The messages to and from the database had to be structured and standardized.

Finally, information systems at pharmacies had to be changed. Again, the certification process was complicated. However, there were a handful of pharmacy systems to be updated, whereas the clinical systems or prescribers that had to be changed were counted in tens. And some pharmacy systems were run out of the market because of the changes the electronic prescription brought.

2.4 Lessons

In general, in Finland the electronic describing is now seen as a success story, and the number of users and sent prescriptions is proceeding fast. The regulation to completely abandon paper prescriptions (but to still keep them as a possible back-up system for unusual conditions) is under development.

In Finland introduction of electronic prescription has been following very much the established structures and processes that had already been in use with paper prescriptions. The early versions of simple electronic prescription however failed because of missing regulation. So, a lot of emphasis was given to decent regulation when introducing the last version of electronic prescribing to Finland. However, structures of prescribing were not changed with regulation, rather it was a question of allowing electronic version of prescribing to run within the established structures.

The core process of delivering electronic prescription, electronic delivery of the prescription to the delivering party and pharmacy, need a lot of structuring. Along the way, a lot of information systems had to be adjusted and the new central prescription database had to be established. Electronic prescription permanently and in an unforeseen way introduced changes to the health care IS landscape in Finland.

3 AUTOMATED DRUG DISPENSING

3.1 Structure

Distribution of medicines to the patients is error-prone and often laborious task (Balka, Kahnamoui, & Nutland, 2007). Many patients are simply in too bad condition to master the medicine–taking process, and even the professional nurses caring for medicine distribution often work under heavy load.

Currently different kinds of pill dispensers and pill dispensing systems have been developed to assist in this task. The traditional support tool in dispersing drugs has been that of using dosets. To them medicines can be distributed beforehand according to the day and time of taking the medicines, typically one week. The process anyway remains manual, and is thus labour-consuming, error-prone and less than perfect as it comes to hygiene.

Automated drug dispensing can be distributed to be carried either for in-patient care in hospitals, or for application in public pharmacies. Here we discuss the case of public pharmacies, where the environment is less controlled than in hospital setting.

The benefits of automated drug dispensing are many. With these systems just the exact amount of medicine needed can be distributed. Patients get just the right amount and combination of medicines. The whole process is automatic and thus extreme clean.

A drawback is that of course just pill-shaped medicines can be distributed in this way, and that not all medicines might not fit together to the package because of chemical interactions. In principle in the same process nutritional additions, such as vitamin pills, could be distributed, but this is not the case for example in Finland.

3.2 Processes

The Finnish legislation implemented regulation on automated drug dispensing in year 2010 (Lääkelaki 1112/2010 (Medicine Law)). Years 2002-2010 were under-regulated as it comes to automated drug dispensing.

Automated drug dispensing causes costs. They can be crucially high to poor patients, and inhibit the application of automated drug dispensing. Pharmacies can themselves decide what they charge from their customers for the automated drug dispensing service. A typical price these days for the patient to be paid is 8-15 euros per month. The “hidden” fact and starting point for the development is, that few if any patient pays this price, the costs are born by municipalities, that by law are responsible for delivering medicines to those people who need assistance.

In year 2009, Finnish regulation implemented to sairausvakuutuslaki (2004/1224, Health insurance law) a permanent regulation about the compensations of the costs of using Automated Drug Dispensing. The amount of compensation has been criticized to be rather low, and for example in year 2013 the Parliamentary Ombudsman of Finland gave the instruction, that Automated Drug Dispensing should not cost more to patients than other means of medicine delivery organization established by Municipalities (The Parliamentary Ombudsman of Finland, 2011). A major problem remaining in the social security is that the real cost (8-15 euros monthly) of using the service is not compensated fully to individual patients who decide to use the service. Several people who would very much benefit from this innovation cannot afford to use it.

Machines cannot dose medicines without guidance. One of the critical processes in automated drug delivery is the “programming” of the machines to dose the medicines. For that, a list of the medicines to be distributed by the machine is needed, and for that further a picture of the total medication of the patient is

needed. Some medicines, such as those in fluid form, and those to be taken just if need arises, still go through other channels. This process is called “building of the medicine card”, and it is far from structured, and takes very many different forms in different pharmacies. It is also error-prone and causes a lot of intensive work for the pharmacy works.

Another crucial delivery is the actual physical delivery of the medicines to the patient. In principle the plastered medicines could be directly taken to the homes of the patients, say through normal (but safe) post. However, the current legislation regulates that the medicine plasters still have to be collected from the pharmacies, by the patient or by an agent working for him/her. The background ideal and idea is that in the point of delivery, the pharmacist is able to deliver personal guidance to the user of the medicines. However, in the case of chronically ill people, that typically are users of automatically dosed medicine packages, this continuous guidance is typically not needed.

3.3 Information Systems

One of the established innovations is automated drug dispensing, where huge centralized machines produce patient-specific plasters for the medication purposes (Sinnemaki et al., 2013). Research has shown that blistering strongly supports compliance to medication (Wong & Norman, 1987) and reduces the amount of errors in medicine delivery (van den Bemt, Idzinga, Robertz, Kormelink, & Pels, 2009).

Figure 2. Patient-specific plasters from automated drug dispensing

In Finland in-hospital automated medicine dispensing with machines was started in year 1991, and in open care in year 2002 (Young & Quan-Haase, 2009). In year 2011, some 20 000 people use the services of automated drug dispensing in Finland (Lappalainen, 2011). In March 2013, 27 000 people utilized automated drug dispensing (Yliopistonapteekki, 2013).

3.4 Lessons

Problems of drug delivery and distribution have been around for the whole history of mankind. Prescribed and other medicines are not always being consumed as was the purpose of their prescribers and developers. Information and functionality of the medicines can also be lost on the medicine’s way towards the final consumer. Problems such as adverse effects, wrong information on the amounts to be consumed, and timing problems of medicine intake might occur. People also often just ignore the medicines prescribed for the, or get hold on and use medicines that are not meant for them - or that might even be health danger. The process of delivering medicines is always also a costly process, not least because of the special safety and guidance demands connected with medicines. Blistered automated drug dispensing is one of the most efficient methods to

secure as exact medication as possible, and also to cut down costs of medicine delivery. The practice of blistered automated drug dispensing started in Japan and USA already in the 1970s. In Finland blistered automated drug dispensing started in year 2002 in open care.

In this case, automated systems came first, and regulation and real processes followed only afterwards, but anyway rather fast. This is a good example of IS innovation that required fast adjustments to structures and processes.

4. VACCINATIONS

4.1 Structure

Vaccinations give safety against possible future illnesses (Briss et al., 2000). When given in masses, they can be very effective and cheap methods of fighting diseases. The first vaccination in Finland was given in year 1754 against smallbox (Forsius, 2005). Wide-scale vaccinations with somewhat standard procedures in Finland started in year 1802 (Finnish Institute of Health and Welfare, 2013). First year of systematic vaccinations with defined population started in year 1941 with Bacillus Calmette–Guérin against Tuberculosis (Finnish Institute of Health and Welfare, 2013).

4.2 Processes

Vaccinations were also implemented to defined processes starting from year 1941, although the concept of vaccination program was not yet established at that time.

Heavy regulation work on vaccinations giving the background for vaccination processes happened in years 1986-1987. The following laws were given:

- Tartuntatautilaki 583/1986 (Finlex)
- Lääkelaki 395/1987 (Finlex)
- Lääkeasetus 693/1987 (Finlex).

The concept of vaccination program was officially established in year 2004:

- Sosiaali- ja terveysministeriön asetus rokotuksista ja tartuntatautien raskaudenaikaisesta seulonnasta 421/2004 (Finlex).

The process of tracking and documenting vaccinations is difficult as they are often given outside the public health care system. In addition to public health institutions, vaccinations are given in private clinics and rather simple pop-up –settings, in schools, in military service, and in mass-type campaigns. Vaccinations are easy to take abroad, and some vaccinations are taken orally without the intervention of any health care professional.

4.3 Information Systems

Even though vaccinations were given according to a predefined program already from year 1941, their documentation remained sporadic and haphazard until now. For vaccination registering, different vaccination suppliers maintained their own registers, such as child health centres (in Finnish “neuvola”), army, and public and private health care institutions. Citizens were given different versions of paper-based vaccination books, that usually however were incomplete and out of date. Simply, very few persons had a good overview of their vaccinations. Cases of missing vaccinations and multiple vaccinations are very usual.

For year 2014 a central Finnish electronic vaccination register is now being promised. All vaccinations would be registered there electronically. As old vaccinations are however not reconstructed yet, it will last at least 100 years before the new electronic vaccination register is actual and trustworthy. This will be with the precondition that all vaccinations will really be reported to the database, which at this time point however is not yet self-evident.

4.4 Lessons

In the case of vaccinations, the timeframe from the first vaccination to electronically registering all

vaccinations was 260 years, if the vaccination register will be operational in year 2014. Vaccinations seem to be a difficult case in the viewpoint of established medicine: they do not clearly belong to any specialty, and a real responsibility carrier for them is hard to find in traditional medicine taxonomy.

Even with this health innovation, the base had to be laid first: vaccinations established themselves as an institution in a timeframe of 140-190 years. The process of vaccination was structured through regulation slowly over time.

For information systems, vaccinations remained a sporadic and marginal object of documentation for a long time, and even today we cannot be sure that the forthcoming vaccination register will be a success.

5. CONCLUSIONS

Major information systems even in health care are nowadays seen as infrastructures (Khoumbati & Themistocleous, 2006; Suomi & Serkkola, 2007). Infrastructures are not perfectly designed and installed in advance, but rather grow dynamically and are enabled (Hanseth & Lyytinen, 2010). Our examples demonstrate that building these systems solely as information systems run into difficulties. Rather, these systems base themselves on continuous lasting work on institutions and governance structures, which again are not solely purposefully designed, but rather "institutionalized" over a long period of time. A working solutions needs a total ecosystem around it. First in mature and stable enough environments and ecosytems processes can mature to contain established and efficient module. Based on these, information systems can finally be built.

Our case example of eHealth electronic prescribing systems can now be seen as a success story in Finland. Automated drug dispensing has proceeded rather well in Finland as compared to many other countries, but lags for example behind developments in Sweden. The vaccination register is a rather new entry, and its success is not yet possible to assess. Common for all these innovations is that they have been on the waiting list all too long.

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