Part II

E-Prescription Infrastructures

Maintaining the Pharmacy Model: The Catalan Electronic Prescription Infrastructure

5

Joan Rodon Modol

5.1 Introduction

This chapter presents the genesis and evolution of the public e-prescription information infrastructure (EPI) of Catalonia, Spain from 2000 to 2013. The implementation of the EPI required a transition from a mainly paper-based and asynchronous prescription model to a digital and synchronous one. This transition involved doing changes into the practices, systems and roles of the CatSalut (the Catalan Health Service), doctors and health providers, pharmacists and Colleges of Pharmacists, and ultimately patients. Our narrative extols those changes and how the pre-existing technological and institutional resources of professionals shaped the design, and evolution of the infrastructure. Our narrative traces those events from the perspective of pharmacists and shows how the installed base of pharmacists was used and extended in a way that maintained and strengthened the pharmacy model.

The reminder of the chapter is structured as follows. In the next section, we present the Catalan model of community pharmacies (see the Chap. 11 for a description of the overall Catalan health system). This section is followed by our narrative of the case. Next we analyze and discuss the implications of our results.

5.2 Site: The Catalan Model of Community Pharmacies

The model of pharmacies in Spain compromises multiple components operating at different levels. At the lower level, there is the pharmacist, a health agent who exercises its professional practice in community pharmacies or hospital

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pharmacies by dispensing drugs, producing patient-specific preparations, and other pharmaceutical care tasks (e.g. health promotion, tracking patients' medication record, checking drug interactions, etc.). In order to practice pharmacists must be registered in the College of Pharmacy of the province where they practice.

Community pharmacies are private health facilities of public interest. Pharmacies are the only health establishments authorized to dispense prescription-only medicines and over-the-counter medicines to the general public. Medicines in Spain are publicly funded. Until 2012 medicines were provided to pensioners for free; working age people paid 40% and those suffering from chronic illnesses paid 10% of the cost of medicines. From 2012 several copayment reforms at the regional and national level were approved that ended with this scenario (Puig-Junoy et al. 2014). First, a national coinsurance rate of 10% for retirees with a monthly income-related cap. Second, Catalonia charged temporally a linear one-euro copayment per prescription with a monthly cap. Third, a national reform stopped funding a long list of medicines indicated for minor symptoms.

The ownership of community pharmacies is limited to pharmacists (trained professionals); pharmacy chains are not allowed forms of ownership. One pharmacist or a group of pharmacists can own only one pharmacy. The establishment of pharmacies is regulated responding to demographic and geographic criteria in order to guarantee a homogeneous access of the services to citizens (99% of Spaniards have a community pharmacy in their municipality). On average a community pharmacy serves approximately 2,000 citizens. Regulations are defined at the national and the autonomous region levels. While the central government is in charge of the general coordination of pharmaceutical care and of matter related to pharmaceuticals such as registration, each autonomous region organizes the planning of the pharmacy system.

In the autonomous region of Catalonia, the main actors that constitute the field are: CatSalut (the Catalan Health Service), the Catalan Council of Pharmacists (CCP), the four Colleges of Pharmacists (which coalesce into the CCP), the community pharmacies, pharmacists, and business organization of pharmacies.[1] CatSalut is the public insurer that is responsible for planning, purchasing, and assessing health services according to the needs of the population. The CCP is a corporate and public legal entity that represents the interests of all pharmacists in Catalonia, as well as the interests of community pharmacy owners and ensures that regulations are respected.

A core component of the model of pharmacies is the agreement initially signed by the CatSalut and the CCP on January 31st 1995 that regulates the conditions by which pharmacists provide pharmaceutical care, invoice according to the contract economic regulations, temporary fund the dispensed drugs and health products,

[1] The FEFAC (www.fefac.cat) is the business organization of Catalan pharmacies. The FEFAC is non-profit federation that aims to defend the interests of pharmacy owners who voluntary enroll it. In 2015 there were about 1,600 (of the 3,000) pharmacies enrolled.

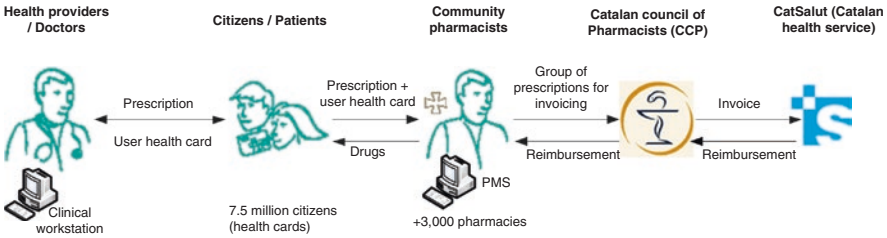

Fig. 5.1 Flows involved in the paper-based prescribing, dispensing and invoicing

continuously deliver health care information to the CatSalut, do health promotion and disease prevention, and perform pharmaceutical surveillance and security alert management of drugs and health products to the population served by the CatSalut. The agreement is continually renegotiated according to changes in the legislation, the profession, and society.

5.2.1 The Installed Base of Pharmacies

A core practice of pharmacists is the dispensing of drugs which interacts with other practices (e.g., prescribing, invoicing) and actors (e.g., doctors, patients, CCP, CatSalut), and involves flows of information, patients, money, and so on. Before the implementation of EPI, the flows were as follows (see Fig. 5.1). Once the doctor had decided the drug treatment for a patient the latter was given a paper prescription. Doctors used clinical workstations to generate the prescriptions and print them. The patient took the prescription and her health card[2] to the community pharmacy, where the drug was dispensed. Then pharmacists stored and signed those paper based prescriptions. Pharmacists used a pharmacy management system (PMS) for tasks such as the management of sales, inventory, or purchasing orders. In 2004, when the EPI project was to start, there were about 35 different types of PMS. Those PMS were developed by pharmaceutical wholesalers, software vendors or individual developers. Periodically, pharmacies grouped the paper-based prescriptions they had dispensed in a given period of time and sent them to the CCP. The CCP then checked all those prescriptions, scanned them, forwarded the scanned and paper prescriptions to the CatSalut, and handled the invoicing for pharmacies. In particular, the CCP submitted a single invoice to the CatSalut. So, the CCP, not pharmacists, was the one in charge of invoicing the CatSalut. The CatSalut reimbursed that invoice to the CCP who checked for errors and finally paid pharmacies according to the signed prescriptions they had previously sent.

[2] The individual health card has a magnetic stripe containing data fields such as the code of the insured (the citizen), the name and surname, her number of social security affiliation, type of insured (level of coverage), and the expiration data.

Method
Data was collected from three main sources: semi-structured face-to-face in-depth interviews (20 interviews), participant observation (workshop attendance; informal conversations; direct on-site observation), and archival data (more than 500 press documents, reports, meeting minutes, and videos), aiming at data triangulation (Yin 2003). Data collection has taken place in three intensive period May – August 2008, January – May 2010, and February – May 2013. We identified interviewees by referral from other subjects. All the interviews were recorded and immediately transcribed and analyzed next two the archival data and other observations. In that sense, data collection and analysis took place iteratively.

With all the data gathered, we constructed an initial timeline of events for the genesis and evolution of the EPI. We then wrote a rich chronological case story that put at the forefront the role of the installed base. We organized the case narrative into four stages covering the period 2000–2013.

5.3 Case Narrative

5.3.1 Phase 1: Genesis of the e-Prescription Infrastructure in Catalonia (2000–Mid-2004)

In 2000, the Spanish Ministry of Science and Technology in collaboration with governments of the autonomous regions and the representatives of the diverse professionals involved in prescribing and dispensing – that is, the Colleges of Doctors and the Councils of Pharmacists – started working on the foundations for a common Spanish reference model for e-prescription.

Meanwhile, in 2001 the Catalan Council of Pharmacists (CCP) and the College of Doctors led a successful first pilot of e-prescription in Barcelona for private health involving a hundred private doctors and 25 pharmacies. The CCP proposed the CatSalut to bring that pilot to the public health, but the CatSalut refused it arguing that they were involved in the Spanish project and should wait until it ended. Moreover, as an outcome of this pilot of e-prescription, the CCP and the College of Doctors created Firma Profesional,[3] a Certification Authority that issued digital certificates for those pharmacists and doctors involved in the pilot (Cordobés 2002b). Meanwhile, from October 1st 2001, the citizens insured by the CatSalut had to bring their individual health card at pharmacies in order to pick up the drugs prescribed at the public health system (Gilabert-Perramon and Prat 2001). During the dispensing process pharmacies had to check whether the individual health card matched the patient data that appeared in the paper-based prescription, and store the data of the patient, the code of the prescription and the dispensed drug. From 2003 those data had to be electronically submitted to the CatSalut (Gilabert-Perramon et al. 2010).

[3] www.firmaprofesional.com

In short, these events became catalysts for the computerization of all the Catalan pharmacies.

The first draft of the model for the Spanish e-prescription was released in 2002. The model comprised a single central database that would be used by both pharmacists and doctors for prescribing and dispensing respectively. That model dissatisfied the Council of Pharmacists who perceived and argued that the main goal of the central government was to control their practice and to reduce public expenditure on drugs, rather than the use of IT for pharmaceutical care (Cordobés 2002a). Finally, in 2004 in accordance with the decentralized health system of Spain and with the Spanish law for the cohesion and quality of the national health system (CohesionAct 2003) diverse autonomous regions started their own e-prescription projects.

It was in mid-2004 when the CatSalut set the foundations for the building of e-prescription infrastructure (EPI) in Catalonia involving all health agents (e.g., health providers, college of doctors, Catalan Council of Pharmacists). With EPI, the CatSalut sought to improve the efficiency of the health system by streamlining patients' access, containing drug expenditures, and reducing prescription and dispensation errors due to lack of coordination between the agents involved in those processes (Gilabert and Cubi 2009; Gilabert-Perramon et al. 2010). To achieve those goals, the CatSalut proposed doing changes to existing practices. For instance, doctors would not make individual prescriptions anymore but medication plans[4] (see Fig. 5.2) that would last up to 1 year; that in turn, would eliminate the need for co-presence of patients and doctors in the prescribing process and would reduce the number of patient appointments with primary care. Patients would pick up medicines at any pharmacy according to a concrete temporal window thus avoiding that patients accumulated more drugs than necessary. Patients would have to bring their medication plans and their health cards to pick the medicines at pharmacies. Medicines would be dispensed at any pharmacy regardless of the location of the prescriber.

The CatSalut defined two core requirements for EPI. First, all the data – i.e., prescriptions, dispensations, invoices, patients, drugs, health providers, doctors, pharmacies, pharmacists – should be integrated and accessible online by the diverse stakeholders – CatSalut, doctors, and pharmacists. Second, the processes of prescribing and dispensing should run in real time. Accordingly, the CHS would have information about the acts of prescribing and dispensing in real-time and would be able to influence both acts for instance by forcing the prescription of generics.

To fulfil these requirements and in line with the reference model defined by the Spanish Ministry of Science and Technology in 2002, the CatSalut proposed a model (see Fig. 5.3) consisting of a central system owned and managed by the CatSalut (called SIRE) that contained an integrated database with all the data. On

[4] A medication plan has a bar code that is read in the pharmacy (top right in Fig. 5.2) and includes (columns from left to right in Fig. 5.2): the drug, the dose and frequency, duration of treatment, doctor and health centre, temporal window with the validity of the plan, and comments and observations.

CatSalut Servei Català de la Salut
Generalitat de Catalunya
Departament de Salut

Data darrera modificació: 08.04.2011
Pàgina 1 de 2

Pla de medicació

Nom i cognoms del/de la pacient

TASA1030101002

Informació per a la farmàcia

Tractaments de llarga durada

Medicament o producte sanitari i núm. de prescripció	Dosi i freqüència	Durada del tractament	Prescriptor/a i centre	Vigència	Comentaris
METFORMINA 850MG 50 COMPRIMI RECUB PELIC EFG P1E000152759	1 Unitat cada 8 hores	Segons evolució clínica	X. Vinyals (Col: 117018036) Medicina familiar i comunitària EAP Mataró Cirera Molins	del 02.01.11 al 02.01.12	Preneu-lo amb aliments. Esmorzar 1 Dinar 1 Sopar 1
HIDROSALURETIL 50MG 20 COMPRIMIDOS P1E000729153	0,5 Unitat cada 24 hores	Segons evolució clínica	D. Castelliví (Col: 117027063) Cardiologia Hospital de Mataró	del 02.02.11 al 02.02.12	En dejú, abans d'esmorzar. Esmorzar ½

Fig. 5.2 Example of the medication plan (printed on paper) that doctors give patients

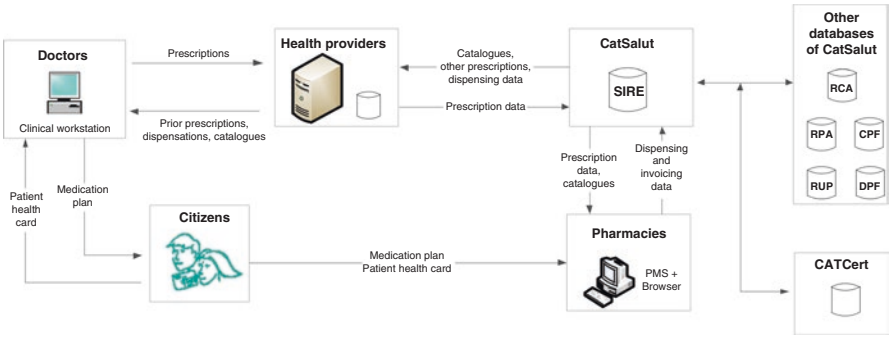

Fig. 5.3 Initial EPI model proposed by the CatSalut

the one side, the health providers would have to interconnect their systems with the CatSalut system (SIRE). On the other side, pharmacists would connect directly to SIRE – through a browser – for the dispensing and invoicing processes.

5.3.2 Phase 2: Mobilizing the Pharmacists' Installed Base (Mid-2004–Mid-2006)

Although CatSalut's model was framed as an efficient and effective way to conform to the two core requirements, the CCP argued that it was bypassed in the dispensing and invoicing and that was a threat to the existing pharmacy model. Such a direct

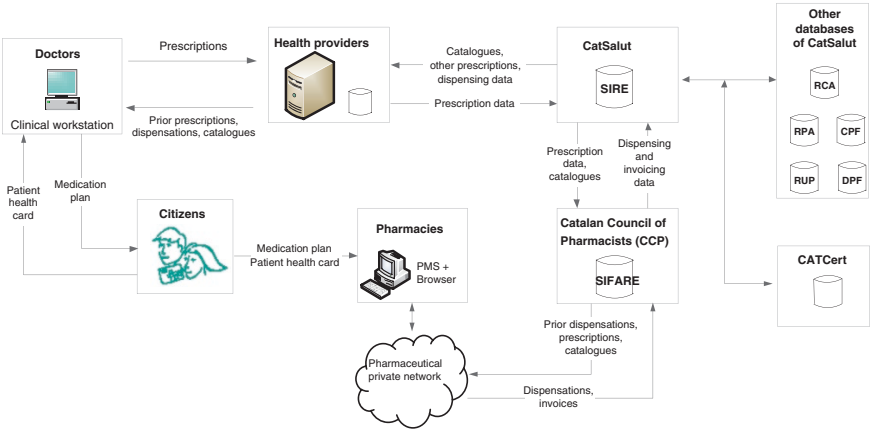

Fig. 5.4 Alternative EPI model proposed by the CCP

relationship between the CatSalut and pharmacists was against the terms of the existing pharmaceutical agreement. It weakened the position of pharmacists in front of the CatSalut who could more easily change the conditions that regulate pharmacies on an individual basis.

As a response, the CCP then proposed an alternative model on the pharmacists' side (see Fig. 5.4) consisting of a private network (VPN) that would interconnect all the pharmacies plus a central server (called SIFARE) that replicated the data of the CatSalut system that was needed for pharmacists – i.e., prescriptions, dispensations and data catalogues. Both the private network and SIFARE would be owned by the CCP. Community pharmacies would not have a direct access to SIRE (the CatSalut system) but instead to SIFARE (the CCP system) through the VPN, and the SIFARE would synchronize in real time with the SIRE for dispensing and invoicing. A vice-president of the CCP related the pharmacy model with the VPN in the following terms: "We are a network [the pharmacy model in Catalonia] that needs a network [the VPN]… Politicians argue for a capillary pharmacy model; that is, that pharmacies are spread throughout the country. We must transfer this network of pharmacies to the electronic world. It cannot happen that what is there physically does not exist electronically." Moreover, this new conceptual model guaranteed that all pharmacies would have the same conditions for dispensing and invoicing, and offered the opportunity for the professional development of pharmacists as they could implement new digital services on SIFARE and the VPN.

Initially, the CatSalut did not see the CCP's model (Fig. 5.4) favorably. The CCP was afraid that it could penalize the fulfilment of the two central requirements of data integration and real-time processes. Yet, the CatSalut saw that the CCP was a legitimized actor whose involvement in the project was critical for its success. Without the CCP, it would be very difficult to mobilize pharmacists. So, after some negotiations the CatSalut bowed to the interests of the CCP and the pharmacists, and accepted the CCP's model on May 2005. A manager of the CatSalut and leader

of the EPI project retrospectively justified the final model in the following terms: "Why do pharmacies invoice us through the CCP? Well, I think it is something that is good for both of us. It is not the same to have 3,000 interlocutors as to have just one as with the CCP. Of course it has its good and bad aspects for both sides. However, for the CCP this means empowering the collective and serving in a role as representative of a collective. I imagine that the members of the CCP [pharmacists] are interested in somebody that brings them together and defends them in the negotiations. Moreover, this relationship structure is not new, it has some history."

The governance structure of the project also helped consolidate the CCP's model. It consisted of two main committees: a steering committee, and an executive committee later called follow-up committee, in which diverse members of the CatSalut, CCP, health providers and other stakeholders were present.[5] A manager of the CatSalut and leader of the EPI project depicted that committee structure as follows "This has been an integrative project from the first day… We started doing things all together [the sector]. Accordingly, we built this governance structure consisting of multiple committees that included all the agents."

In building the architecture for the model, the CatSalut opted for an architecture for SIRE based on web services. That is, the systems of health providers and those of the CCP would interact with SIRE through web services using SOAP and XML. The CatSalut developed two sets of web services (see Fig. 5.5): one set for prescribing that would be used by health providers, and another one for dispensing and invoicing that would be used by the CCP.

A main design decision of the CCP was that SIFARE should be as transparent as possible for pharmacists such that they would not be forced to use an additional information system for dispensing and invoicing. This meant that pharmacists should be able to integrate their existing pharmacy management systems (PMS) with SIFARE in a way that minimized the changes to their practices. To achieve so, the CCP boosted in 2005 a recognition program for PMS vendors that it had launched in 2004 aiming to guarantee that PMS vendors fulfilled the needs and requirements of community pharmacists set by the CCP and CHS. The initial scope of the recognition program had been that of patient's health card reading and data transmission for invoicing. In 2005 the CCP extended the recognition program to include e-prescription. The CCP developed a set of web services for SIFARE and an application program interface (API) exposed in a DLL for the convenience of PMS vendors. Those vendors who passed the recognition program got the API from the CCP to interconnect their PMS solutions with SIFARE. That is, getting that recognition became a necessary condition for PMS vendors to remain in the market. From the about 35 PMS solutions that existed in 2004, only 9 got the recognition. Of the nine recognized PMS, five PMS got the recognition in 2005, one in 2007 and three in 2008. Five of those nine recognized PMS were developed, commercialized and

[5] In 2014 this organizing structure was still running. The steering committee meets every quarter, and the follow-up committee meets monthly. Likewise, working groups are created when new domains of study are required (e.g. prescribing and dispensing by active ingredient, prescribing and dispensing of narcotics, professional filters, certification and authentication of professionals).

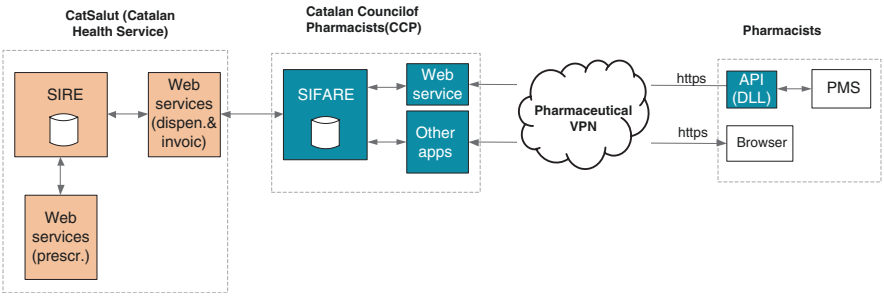

Fig. 5.5 EPI architectural components on the pharmacists' side.

supported by pharmaceutical wholesalers, and the other four by software vendors. The rest of PMS solutions were progressively discontinued.

Overall, the EPI architecture (Fig. 5.5) was modular in production. It decomposed the EPI into loosely coupled components: SIRE, SIFARE, and PMS that were interconnected through web services, and it influenced the role of actors in the project. For instance, the CPP would be in charge of (1) building the virtual private network (VPN) for pharmacies, (2) developing the SIFARE and (3) assuring that pharmacists integrated their PMS with SIFARE.

The security model, a central component of the EPI architecture, was defined by the Catalan Certification Agency[6] and included the following kind of requirements (eSignAct 2003): electronic certificate for professionals for their authentication (SAML authentication), digital signature of all the professional tasks, verification of signature, data encryption to ensure integrity and confidentiality, and obligatory use of patient health card and security code to access patient data. For the communication between SIRE and SIFARE they established a secure channel (SSL-Two-Way) ensuring the origin and destination of information and confirming that they are who they say they are. The CCP would act as a Registration Authority ensuring that any digital certificate is bound to the pharmacist to whom it is assigned in a way that assures non-repudiation.

Regarding the communications, pharmacies would be connected through a virtual private network (VPN). After a tender for the VPN in 2006, the CCP signed an agreement with a telecom provider. That agreement homogenized the service and price conditions for all the pharmacies, regardless of their location or size. Each pharmacy would have an asymmetric digital subscriber line (ADSL) and a backup integrated services digital network (ISDN) line to connect to the central server of the CCP – SIFARE. CCP would coordinate the rollout of the VPN with that of the EPI. From 2012 some pharmacies started setting up 3G back-up connections.

[6] The Catalan Certification Agency is a governmental agency that was set up in 2002 in order to implement and rollout the digital signature in all the Catalan governmental institutions and provide services to those organizations ensuring that the electronic transactions fulfill the legal guarantees.

5.3.3 Phase 3: Pilot and Rollout of EPI (Mid-2006–2010)

In 2005, the CatSalut had worked on a detailed list of functional requirements, and made a public tender for the development and implementation of SIRE. The goal was to launch a pilot by early 2006. With the first version of the SIRE web services for dispensing and invoicing, the CCP developed a first version of the SIFARE web services and the first API for PMS vendors. With that API, PMS vendors had to adapt their solutions for e-prescription, and install and configure the new version of the PMS in pharmacies.

In 2006 the CatSalut and the CCP signed an appendix to the pharmaceutical agreement which established the clauses for the development of the pilot for the EPI, and made explicit the role of the CCP. This appendix helped stabilize the EPI by clarifying the roles of actors. On April 2006 a first pilot was inaugurated. However, due to repeated technical problems and errors, the CatSalut stopped the pilot and started a new version of SIRE that addressed those problems. On May 2007 the Catalan Parliament passed an act that regulated e-prescription (ePresDecree 2007; ePresOrder 2008). By the end of 2007, the CatSalut resumed the pilot involving five basic heath areas in two of the seven health regions of Catalonia (Girona and Terres de l'Ebre). The general practitioners, pharmacies and patients of those heath regions were gradually added into the pilot; the general practitioners decided which patients should be prescribed electronically. On May 2008 the pilot was satisfactorily completed. The pilot had involved 63 doctors, 39 pharmacies and 15,000 patients, and more than 300,000 prescriptions had been dispensed (Gilabert-Perramon et al. 2010). Then the rollout of the EPI in primary care started. It was organized into five phases, each involving one or more health regions (see Table 5.1).

The fifth phase of the rollout involved the health region of Barcelona where there were about 2,200 of the more than 3,000 pharmacies in Catalonia. This last phase was also a very critical one as it could destabilize the whole project. First, since it took place in Barcelona, news about any failure would spread fast and that would have a greater political impact for sponsors. Second, it involved a considerable increase in the number of transactions, health providers, pharmacies, and patients. Accordingly, it required upgrading the technological infrastructure. On the side of pharmacists, the CCP re-scaled the hardware of SIFARE four times from 2006 to 2012 in order to accommodate the growth in the number of transactions derived from the scaling of EPI (see Table 5.3).

Table 5.1 Roll out of the EPI at primary care

Phase	Health regions involved	To start on
1	Girona, Terres de l'Ebre	May 2008
2	Camp de Tarragona	October 2008
3	Lleida, Alt Pirineu – Aran	October 2008
4	Catalunya Central	April 2009
5	Barcelona	May 2009

An important concern for the CCP was the cost of the technical infrastructure for the CCP and pharmacists. To overcome that concern, the CCP actively sought funding for SIFARE and VPN as well as the investments that pharmacists had to carry out (e.g. the connectivity services to the VPN, upgrading of PMS, the digital signatures, swipe card and swipe card readers). On the one hand, the main idea for funding the technological infrastructure of the CCP was that the reduction of cost related to the processing paper-based dispensations for invoicing (e.g. scanning and checking of dispensations) would be dedicated to pay the new technological infrastructure. Likewise, in 2008 the CCP got a subsidy from the Center of Innovation and Development of the Catalan Government. On the other hand, regarding the funding of pharmacists' investments, by early 2008 the CCP signed an agreement with a Spanish bank. According to that agreement, the bank would partially assume the connectivity costs of pharmacists and provide them with digital certificates and swipe card readers for free.[7] Later in 2010 the CCP received some financial aid from the Department of Health of Catalonia for the connectivity of pharmacies. Moreover, a condition for those PMS vendors passing the recognition program was that they would assume the costs of adapting their systems to interconnect with SIFARE and the costs of upgrading the PMS for their customers (the pharmacies).

Additionally, in order to support pharmacists during the rollout, the CCP created in 2008: (1) an e-newsletter to inform them; and (2) an IT Operations Center to support pharmacies in resolving technical problems, performing a baseline audit to check whether pharmacies were ready for e-prescription, informing them about the calendar for the rollout in their area, and support pharmacies in their daily practices with EPI. Later the CCP extended the scope of service of the IT Operations Center to include the monitoring of the infrastructure in order to detect failures before pharmacists realized them. The aim was to anticipate problems, keep pharmacists informed, as well as force and help the telecom provider to resolve incidents.

The rollout was completed during the third quarter of 2010. At that time all the more than 3,000 Catalan pharmacies were using the EPI. On August 2010 the prescriptions dispensed electronically accounted for 50% of all the prescriptions being billed[8] (see Table 5.2 for an evolution of electronic prescriptions being dispensed). In 2011 the CatSalut estimated that the e-prescription had saved around 5,100,000 patient appointments with primary care centers for collecting recipes. During 2011 the EPI was rollout at the specialized care and was completed by mid-2014. The rollout was extended to the geriatric residences and home care in 2012, and to mental care in 2013.

[7] Those conditions applied to pharmacies having a certain volume of business with the bank. In 2012 the funding agreement with the bank was still in place and the number of pharmacies benefiting from it had remained constant (around 1,300).

[8] In 2010 electronic prescription was only running at primary care, not at hospital and specialized care. The CatSalut encouraged the use of EPI among health providers by means of incentives defined in the multi-annual contracts that CatSalut signs with health providers.

Table 5.2 Electronic prescriptions being dispensed

Year	% (Electronic prescriptions/prescriptions billed[a])	Daily volume
2011	73,6	385.000
2012	85,3	430.000
2013	91,2	460.000
2014	95,4	522.100

Source: CatSalut

[a]Prescriptions billed includes the sum of electronic and paper-based prescriptions of all the primary care levels

5.3.4 Phase 4: Adaptation and Innovation on the Side of Pharmacists (2011–2013)

The functional evolution of the EPI has come from on the one hand, adaptations that are triggered by the CatSalut and the Catalan Spanish Governments, and on the other hand, new services that the CCP launches independently of the CatSalut.

In the first case, from 2006 to 2013 the CatSalut released 29 versions of SIRE web services with new functionalities (e.g. the inclusion of prescribing filters, the prescription by active ingredient, messaging among professionals, overdosing, and consult generic alerts). These functionalities reflect the approval of new laws, new requirements from the CatSalut and health professionals, and the new EPI rollouts at specialized and mental care, and geriatric residences. When the CatSalut creates a new SIRE web service for the dispensing and invoicing processes, the CCP immediately creates a new SIFARE web service and updates the API for PMS vendors. For instance, in 2012 the Catalan Government approved the "euro per prescription" tax that forced patients to pay an extra-euro for each drug dispensed at pharmacies (EuroPerPresAct 2012). To support this new tax the CatSalut developed three new web services. Then the CCP created three new services and the API 3 so that PMS vendors could adapt their applications to support such a tax. On average it takes between 6 and 8 months from the moment the API is delivered to PMS vendors until they update their PMS and install them in all the pharmacies. Similarly, in 2011 and 2012 the Spanish government passed two co-payment acts (copaymentReform 2011, 2012) which entailed that pensioners would have to partially pay medicines based on their income and with a monthly cap. The calculation of the final amount and the payment took place in the pharmacy when the patient picked the drug. This act entailed making changes to SIRE and SIFARE web services and to PMS.

However, it did not always happen that the release of a new version of an existing SIRE web service was followed by a new release of the corresponding SIFARE web service, and in turn, a change in the API for PMS vendors. That happened for instance, when a new feature included in a new SIRE web service was not mandatory (not required by law). Then the CCP might consider that the new feature did not add enough value to pharmacies, or that pharmacies were not ready, or that the CCP itself or the PMS vendors were not ready to implement that new version. Accordingly,

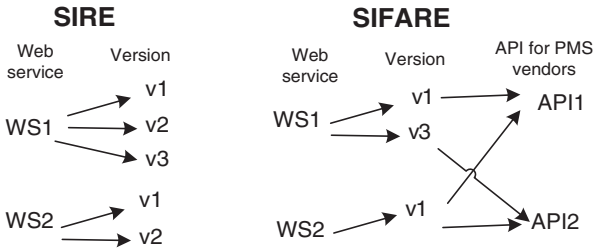

Fig. 5.6 Interdependencies between SIRE and SIFARE web services and API

the modular architecture of the EPI (Fig. 5.5) created a sequential interdependency between the CatSalut, the CCP, the PMS vendors and pharmacies in the development and release of new services (Fig. 5.6 illustrates this idea). This enabled the CCP to set the pace of evolution of the EPI by accommodating the changes triggered by the CatSalut to the needs and capacities of PMS vendors and pharmacists and its development resources.

The CCP has developed five versions of the API (which includes more than 30 web services): a first version in 2006 coinciding with the EPI pilot; a second one in 2009 before the massive roll-out in Barcelona; a third version in 2012 coinciding with two regulatory changes – the "euro per prescription" (EuroPerPresAct 2012) and co-payment act (copaymentReform 2011, 2012)–; a fourth version in 2012 to support the inclusion of paper-based prescriptions (e.g. generated at specialized care or other public mutual insurance companies) into EPI in order to dispense them electronically; and a fifth version in 2013 to support new professional services for pharmacists that are part of the SIFADATA initiative (which aimed to leverage on technology to digitalize pharmacists' processes and do analytics of the data at SIFARE).

On the other hand, the evolution of the EPI also came from new functionalities and services that the CCP developed on its own initiative –i.e., independently of the CatSalut. The rationale for those services was consistent with the vision of the CCP about the model of EPI. In particular, the CCP saw the EPI as an opportunity to re-professionalize the practice of pharmacists. For instance, from 2008 the CCP has been developing web apps to support pharmacists' work (e.g. tools to support the invoicing, management of alerts, management of users, and management of digital signature). Another example of a professional services tied to SIFARE was the SIFADATA initiative that the CCP launched by on 2012. This initiative involved redesigning other (than dispensing and invoicing) processes that pharmacists carry out daily and leveraging on the SIFARE and the VPN to digitalize them; this included for instance, the management of recipe and narcotics books, or the pricing of magistral formulae. In the case of the management of recipe and narcotics books, although most of the PMS stored those documents, pharmacists still had to periodically print those documents and carry them to the Department of Health. As part of the SIFADATA initiative the process was redesigned in a way that data would not only be locally stored at the PMS but also at SIFARE. Then pharmacists would electronically sign and submit the data stored

at SIFARE to the Department of Health without any need to print them. With the development of this new kind of services, the CCP helped pharmacists by channeling their work practices through the PMS. At the same time the CCP boosted the use of the SIFARE and the VPN, and strengthened its role as service provider of pharmacists.

An assumption underlying this initiative was that the entry door for pharmacists to all those services must be the PMS. This requires the cooperation and involvement of PMS vendors who are expected to adapt their solution to the new services. In order to achieve so, the CCP leveraged the governance structure with PMS vendors. From the early stages of the project, the CCP created an advisory committee for technology and communications which brings together every quarter the CCP and the recognized PMS vendors to discuss about the status of the EPI and agree on its evolution – e.g. agree on the new requirements and services, on the pace of implementation of those services. What happened until 2012 was that, most of the adaptations that required developing new web services were triggered by the CatSalut, so eventually the PMS vendors had not choice implement them. However, with the development of professional services that are independent from the CatSalut, the PMS vendors cannot be obliged to implement them. Hence, PMS vendors became central actors in the strategy of the CCP regarding the new professional services. The CCP saw that for the launch of those professional services, the consensus with and involvement of the PMS vendors was much more critical. So the CCP felt the need to adapt the governing strategy with PMS vendors. To do so, in 2013 the CCP reoriented the focus of the recognition program more towards technical aspects and professional services.

Regarding those services that exploit the VPN, in 2011 the CCP set up a company called TicFarma seeking to transform all the pharmacies into a corporation which offered telecommunication services to the same pharmacies and pharmacists. With TicFarma, the CCP leveraged its ownership of the VPN to increase its bargaining power in front of telecom providers. TicFarma was a tool to: (1) reduce the connectivity costs for pharmacists, and (2) launch new telecommunication services for pharmacists. Moreover, the CCP used TicFarma's profits to pay the cost of the technological infrastructure consisting of the SIFARE and the VPN. Through TicFarma the CCP reinforced its role as a service provider for pharmacists.

5.4 Analysis and Discussion

Prior section has depicted the evolution of the Catalan e-prescription infrastructure (EPI) from the perspective of pharmacists. In particular, this chapter has narrated the transition from a paper-based asynchronous prescription model to a digital synchronous one. Our narrative has focused on how the Catalan Council of Pharmacists' (CCP) shaped that transition by appreciating the installed base and the potentialities of the EPI. Table 5.3 summarizes the evolution of the EPI according to several dimensions (timeline of events, regulations, and governance and architectural components).

Table 5.3 Evolution of EPI from the perspective of pharmacists

	Phase 1: genesis of EPI in Catalonia (2000–mid-2004)	Phase 2: mobilizing the pharmacists' installed base (mid-2004–mid-2006)	Phase 3: pilot and rollout of EPI (mid-2006–2010)	Phase 4: adaptation and innovation on the side of pharmacists (2011–2013)
Events	Spanish e-prescription project starts	Negotiations over the model for EPI between CatSalut and CCP	Pilot of EPI starts	CCP sets up TICFarma
	Pilot private e-prescription project in Catalonia	Tender for the VPN	1 PMS gets the recognition	Rollout at specialized care and geriatric centers starts
	Use of health card in dispensing	The development of EPI starts	Rollout of EPI stars (primary care)	CCP starts the SIFADATA initiative
	FirmaProfesional is set up	5 PMS get the recognition	3 PMS get recognition	New services at pharmacies (e.g. informing patients about treatments)
	Conceptual model of Spanish e-prescription is released	Agreement with a telecom provider for the VPN	Agreement with a bank to support pharmacies	Farmaguia mobile app
	Computerization of Catalan pharmacies	CCP becomes a Registration Authority	Rollout of EPI starts in Barcelona	
	Catalan EPI project starts		Rollout at primary care is completed	
			CCP launches web apps to support pharmacists' work	

(continued)

Table 5.3 (continued)

	Phase 1: genesis of EPI in Catalonia (2000–mid-2004)	Phase 2: mobilizing the pharmacists' installed base (mid-2004–mid-2006)	Phase 3: pilot and rollout of EPI (mid-2006–2010)	Phase 4: adaptation and innovation on the side of pharmacists (2011–2013)
Regulations and other social structures	Pharmaceutical agreement since 1995	Spanish Law on rational use of medicines	Catalan decree that regulated e-prescription	Co-payment acts
	Spanish laws for the cohesion and quality of the health system and about digital signature	CCP sets up a recognition program for PMS (data transmission and health card reading)	Order developing the decree	"Euro per prescription" tax
	Decree that regulates the use of health card	Setting up the Steering and Executive Committees for e-prescription	IT operations center to coordinate rollout and support pharma-cists	IT operations center extends its role
		CCP extends recognition program to include e-prescription.		Appendix to pharmaceutical agreement that reflects co-payment acts
		Appendix to pharmaceutical agreement		Changes to the recognition program (to support SIFADATA initiative)
		Advisory committee with PMS vendors		
Architectural components	Decentralized architecture with pharmacies using PMSs that were not connected to any central node and stored data locally	The centralized/hierarchical architecture is replaced by a new one involving two central nodes (Fig. 5.4) and modular (Fig. 5.5)	2 servers (up to 4 Million monthly dispensations)	Update of the VPN according to TICFarma requirements
	PMS progressively adapted to read health cards (data stored locally) and to use digital signature (data stored locally and asynchronous communication with central node)	The security model for EPI	SIFARE API 2 (before massive rollout in Barcelona)	SIFARE API 3 and 4 (to support co-payment reforms)
	Initial centralized/hierarchical architecture (only SIRE, Fig. 5.3)	SIFARE architecture (data stored at central nodes and locally at PMS)	6 servers (to support up to 6 Million monthly dispensations)	7 servers (to support up to 12 Million monthly dispensations)
		SIFARE API 1 (for the pilot)		SIFARE API 5 and new servers (to support new services from SIFADATA initiative)
		1 server (to support up to 100 Ks of monthly dispensations)		

On the one hand, our study shows how in building EPI, the exploitation and expansion of the installed base of pharmacists helped maintain the existing pharmacy model. Some of the technical components of EPI (e.g., SIFARE, the VPN, the security model) were built on and reinforced the installed base involving the pharmaceutical agreement and the pharmacy management systems (PMS). This also demonstrates that in building the EPI, the CCP thought in terms of what might happen – e.g. what might happen if the initial model for EPI proposed by the CatSalut (Fig. 5.3) was finally built. The CCP's concern was that the initial architecture proposed by the CatSalut could fragment the existing collective pharmaceutical agreement into individual agreements between CatSalut and pharmacists. So the CCP's counter-proposal for the EPI architecture protected the existing pharmaceutical agreement by avoiding any direct relationship between CatSalut and pharmacists.

Yet our narrative shows that the decision of the CCP to go for a new architectural model (Fig. 5.4) cannot be viewed simply as a radical shift at one point in time involving only individuals deliberate planning –i.e., choices and goals, matching means and ends–, but as a series of cumulative capabilities and events occurring from year 2000 that conferred legitimacy to the CCP –e.g., the pilot of e-prescription in the private health in 2001, the computerization of all pharmacies in 2003, the early version of the recognition program in 2004 to support the reading of individual health cards at pharmacies, and the implementation of health card recognition technologies.

On the other hand, this chapter also shows how the CCP also thought of EPI in terms of potentialities. For instance, on the side of pharmacists, the new recognition program and SIFARE API gave continuity to pharmacists' practices (pharmacists could keep using their PMS) while at the same time shifted the relationship between PMS vendors and pharmacists because the pace of updates and innovations of PMS would now be set by the pharmacists themselves (through the CCP). Moreover, the core components of EPI (SIFARE, VPN and recognition program) have enabled the CCP to act as a service provider and to foster innovation on new services for pharmacists (e.g. the SIFADATA initiative, TICFarma) and also for citizens (e.g. health information services offered through a portal www.farmaceuticonline.com, an app called farmaguia for locating pharmacists and informing about opening hours).

Finally, this chapter has presented a trajectory of an electronic prescription infrastructure. We argue that the longitudinal nature of our study (which covers the period 2000–2013), and our focus on the continuous causal interactions among multiple socio-technical components of the infrastructure has enabled us to give prominence to the role of the installed base in the evolution of the e-prescription infrastructure.

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The ePrescription Initiative and Information Infrastructure in Norway

6

Ole Hanseth and Bendik Bygstad

6.1 Introduction

Several ePrescription initiatives were taken in Norway, the first in the early nineties. All failed, but, finally, an ePresecription II was built and widely adopted in the health care sector from 2011 onwards. There is a broad consensus that this solution and the initiative[1] behind it has been a great success. However, this success came after a long and painful "birth." The successful solution was developed with a strong focus on the involvement of GPs in the prescribing process even though the scope was intended to cover the whole chain. Later the solution was modified and extended in a number of ways: hospitals, support of multi-dose dispensing, becoming used as a crucial service for the national summary care record solution, and, hopefully, support for the rest of the primary care sector (i.e. midwives, public health nurses, home nurses, nursing homes as well as dentists).

The installed base, and the approaches for coping[2] with it, played a major role in the initiative, and was a key source of the challenges the initiative was

[1] The activities related to the ePrescription information infrastructure presented in this chapter, have been organized in different ways throughout its history. It started as a project. A couple of years later it was reorganized into a programme, and when the adoption process was getting momentum, the organizing of the activities changed into a more complex structure. For this reason, we use the term "initiative" to cover all these organizational forms which are described in more detail later in the chapter.

[2] The ePrescription initiative has never used the concept of "installed base" or related ones – at least we have never seen any traces of such concepts. Accordingly, the initiative did not have any deliberate strategy for dealing with the installed base either. We use the term "approach for coping with the installed base" for describing what would have been the initiative's operational strategy if it had been explicitly formulated.

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struggling with up to 2011. During 2011 they changed their approach to coping with the installed base. This change was an unintended result of an ad-hoc solution, a "quick fix," to a problem that had become urgent – the delayed development of a new EPR system by the vendor of such solutions having the largest market share. This change in the approach to coping with the installed base turned out to be a major contribution to the success of the solution – first the development of a solution that could be adopted by larger user groups and later the development of required of functionalities supporting multi dose dispensing and a major revision of all the involved.

All initiatives, also the latest one, has been based on the EDI paradigm with a strong focus on information sharing through message exchange between applications where the messages are specified and approved as standards and then implemented in the solutions. This approach is based on a classical specification driven approach to software development that implicit assumes that the new solution will be of a stand-alone kind developed from scratch. This contributed to make the initiative's approach to coping with the installed base schizophrenic: one the one hand the solution was designed as just extensions of existing applications like EPR systems and pharmacy applications (in addition to a central server and a secure network), on the other hand, it did not take seriously into account any challenges related to integrating the additional functionality to the existing installed base. This is true both for the existing applications and the platforms (PC hardware, operating system, network technologies, etc.) the applications were running on.

Methods

Our research approach was a case study conducted in the Norwegian health sector during a period of 7 years, from 2008 to 2015. Data collection included interviews with central stakeholders in the Ministry of Health, the Directorate of Health (who managed the project), and project developers and vendors, some of them several times during the study. In addition, we had access to the written materials of the project. This included the Government Budget documents, the project management documents, the system specifications and IT architecture documents.

Data analysis was conducted in the following steps. First a temporal analysis was done, focusing on the development over time. The identification of key events was done through interviews with central stakeholders and by a systematic analysis of the annual budgets of the Ministry of Health. Then a comprehensive analysis was conducted on the interplay of actors in the long project, such as government authorities, vendors, and users. Finally, we assessed and validated our findings by on-going presentations and discussions with key actors.

6.2 The Norwegian Health Care Sector

The Norwegian health care sector is primarily publicly funded. Until 2003 (most of) the hospitals were owned and managed by the 19 counties. By January 1st 2003 a reform was implemented. This implied that the government was taking over the ownership of the hospitals and organized them in 5, later four, regional corporations called Regional Health Authorities.

The primary care sector is managed at the municipal level. There are in total 428 municipalities in Norway – of these Oslo is the largest with app. 659,000 citizens and Utsira the smallest with only 203 citizens. GPs are either employed by municipalities or operating a private medical practice. These two groups are roughly of the same size.

Until March 1st 2001 the pharmacy sector was strictly regulated. Only pharmacists were allowed to own and run pharmacies and each pharmacist was allowed to own only one pharmacy. During 2001 the sector was liberalized and within a fairly short period more or less all pharmacies were taken over by large pharmacy groups, five in total, like for instance Boots.

6.3 Case Narrative

6.3.1 Establishment and Diffusion of a Solution for GPs

The ePrescription initiative starting 2004 was the most ambitious, well-funded, and professionally managed one among the efforts aiming at developing IIs for information exchange across institutional borders in the healthcare sector in Norway. Table 6.1 provides an overview of the timeline for the initiative.

In 2004, the Ministry of Health initiated a 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. The following actors were included in the pilot study: the 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 of 40 million Euros from the Norwegian Parliament during 2005–2010. By the end of 2010 around 70 million Euros was spent on the project. During 2006 detailed requirements specifications and an architectural document was written, specifying an ambitious, fully integrated solution. Figure 6.1 illustrates the architecture of the II as it is presented in official project documents. The boxes represent the central data base server in the middle and applications (eight different EPR systems from six vendors used by hospitals and GPs, one pharmacy system used by all pharmacies, the MyPrescription module gives patients access to their prescriptions, and various applications run in three different government institutions). The blue arrows represent 31 different

Table 6.1 Timeline for the Norwegian e-prescription initiative

Timeline	
2001	Report from the Office of the Auditor General sent to the Parliament
2004	E-prescription project started
2006	Detailed design specification and architecture document released
2006	Invited EPR system vendors into the project
May 2008	First pilot. "Disaster"
2009	ePrescription exchange tested and accepted
June 2010	Pilot in Os municipality
Sept 2010	Pilot in Larvik
Autumn 2010	GPM developed
Spring 2011	GPM tested in lab
2011	Large scale deployment started
March 2012	Solution is deployed to about 280 GP offices and 134 pharmacies in 67 (of 428) municipalities distributed over 4 (of 19) counties. More than 1 mill prescriptions were sent
August 2012	Started extending the solution for Multi-Dose Dispensing (MDD)
Autumn 2012	GPM adapted to Dips and tested in hospital
2012	Started the development of version 2.5 of all standardized messages
June 2013	GMP adopted by all hospitals in the western health region
May 2014	First MDD pilot
Nov 2014	60 GP offices participating in MDD pilot

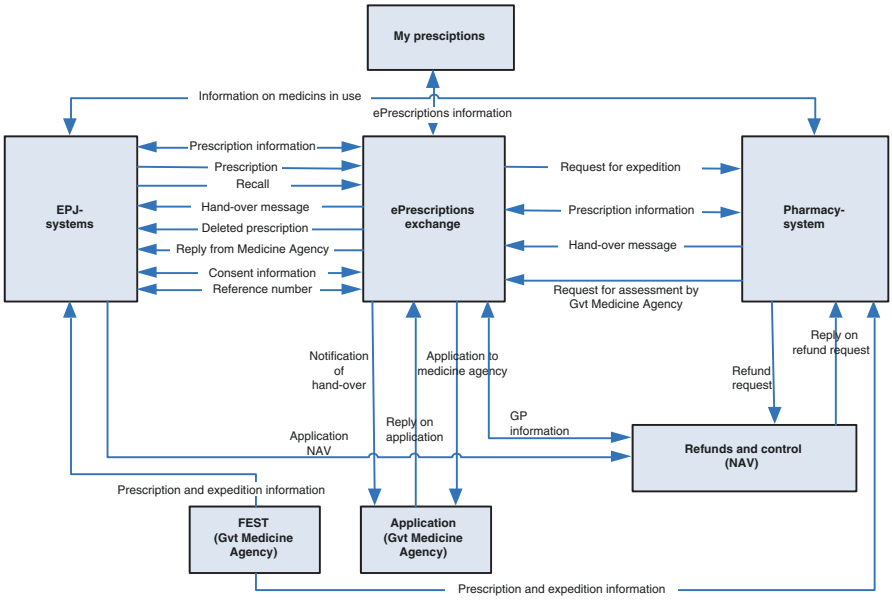

Fig. 6.1 The ePrescription solution: main components

(standardized) messages carrying information between the applications. It illustrates well the basic assumption of the EDI paradigm and ACA: information exchange is taken care of by enhancing existing applications.

The requirements specification of The Directorate of Health emphasized that the vendors and public agencies involved were responsible for their modules. The programme was organized in five projects. The six main EPR vendors were invited into one of the projects in 2006. Of the three suppliers of EPR systems for hospitals two were too busy to participate. In addition the suppliers of the hospital EPRs demanded a more specific requirement specification before they were willing to start development activities. Eventually, only the biggest vendor within the GP market, Profdoc,[3] agreed to develop a pilot version of electronic prescription. At this time Profdoc had two different EPR systems in the market and they had started to develop a new version that should replace both. They decided to develop an ePrescription module only for the new version. The ePrescription programme management accepted this. Later the two other vendors of patient record systems for GPs, Infodoc and Hove, also joined the initiative.

In May 2008 the first pilot implementation was inaugurated by the Minister of Health. It was carried out in a small town in the eastern part of Norway, and included the GPs and the local pharmacy. It turned out to be a disaster, and after 4 months a crisis was declared. Said the municipal health manager to the local newspaper; "the system is so slow, and has so many errors and deficiencies, that we will stop the whole pilot". The local authorities also raised concerns about patient safety. The main reason for the problems was not the ePrescription solution per se, but that the new version of Profdoc's new EPR system was full of errors and was very unstable. Somewhat unreasonably, the ePrescription project got the blame in an angry press.

The ePrescription Exchange was tested and accepted during 2009, while waiting for the vendors to complete and test their new versions. A new pilot was planned in March 2010, and contracts for large-scale operations were signed. The pilot testing started in Os municipality in Western Norway in June 2010, including two GP offices and one pharmacy. A second pilot started in Larvik in September 2010 including two pharmacies and a handful of GP offices. All GP offices in the pilots were using EPR systems from the same vendor, Infodoc (having app. 25% of the GP market for EPR systems). Infodoc's solution was the only one being ready for pilots at that time.

Infodoc integrated their patient record solution with the ePrescription II by developing a brand new version of their existing medication module. This new module included the functionality of the old plus those specified as part of the ePrescription programme. It was based on the same logic and user interface as the old one.

At the time the Os pilot was about to start it was uncertain when new EPR system from Profdoc would be ready. Actually, the new owners of Profdoc (CompuGroup Medical) was so unhappy about the progress (or rather lack of) of the development of the new product that they informed that management of the

[3] Profdoc was later taken over by the international company CompuGroup Medical and change name to CGM Norway. For reasons of consistency we use the name Profdoc only in this chapter.

ePrescription initiative that they were considering abandoning the whole project. Profdoc had at that time about 70% of the GP market for patient record solutions. Accordingly, having a solution for Profdoc users was absolutely necessary for the ePrescription initiative to succeed. So the programme management decided to develop a separate prescribing module with the functionality needed by GPs that could be used in combination with the two Profdoc solutions in use. This module, which later was given the name GPM, was running in parallel with, and only loosely integrated with, the EPR systems. That means that the users were filling in prescriptions using this module and all information exchange with other components of the ePrescription II was taken care of by this module and not the ERP systems. (This is explained in more detail below.)

The module was developed during the second half of 2010. The development costs were modest; around five MNOK. Users in lab settings tested the module during the first half of 2011, and real use testing and deployment started in the second half of 2011. Overall the tests were found to have a positive outcome. There were, however, challenges related to the fact that the GPM module was developed to run on later versions of available PC (Wintel) platforms while Profdoc's existing EPR systems were to a large extent running on old, some very old, ones.

All pharmacies in Norway were using the FarmaPro solution developed by NAF-Data;[4] NAF-Data started the development of a new version (v 5.0) of their solution in 2005 and planned, just like Profdoc, to implement the ePrescription module for pharmacies only as a part of the new solution. This solution should have been ready for deployment by 2008, but was delayed. In June 2011 it was still uncertain when the solution would be ready for full-scale deployment. At a meeting with the Minister of Health, the Minister made it clear that this uncertainty was beyond what she could accept. For this reason, and based on the positive experience with the GPM module, the management of the initiative decided to adapt this to the needs for users at pharmacies. This decision was, however, reversed. The initiative' management decided instead to put more pressure on NAF-Data so that they speeded up their development work. And so they did.

The evaluation of pilots concluded that they were successful - in particular user satisfaction was found to be high (PWC 2011). But some new challenges emerged. For instance, the evaluation also concluded that more or less all GPs needed to upgrade their ICT infrastructure – PCs, network bandwidth, and even printers – to be able to run the solution (ibid.). This again raised issues about who was to pay for this.

During 2011 Hove completed the extension of their medication module with the required functionality and its diffusion started. The same happened with the generic GPM module that was combined with Profdoc's two existing EPR systems. During 2012 Profdoc's new EPR, later called CGM Journal, was ready for deployment together with an integrated ePrescription/medication module. From early 2011 the ePrescription solution has been deployed at GP offices and pharmacies at a steady speed. By early march 2012 the solution is deployed to about 280 GP offices and

[4] NAF Data is owned by the Pharmacists' association in Norway.

134 pharmacies in 67 (of 428) municipalities distributed over 4 (of 19) counties. More than 1 mill prescriptions were sent. According to the plan the solution would be deployed to GPs and pharmacies in all municipalities by the end of 2013. By February 2013 1.200 GP offices were up and running using the GPM module while around 200 GPs using the new CGM journal solution. During the spring 2014 500–600 CGM customers had converted to the new CGM journal while Hove and Infodoc were taking over about 200 CGM customers during 2014.

The development of the GMP module for GPs, and the adaptation of this to hospitals, represented a change in the project's approach for how to cope with the installed base, and it was an ad-hoc modification of the architecture to speed up the development. This architectural change did indeed speed up the development activities by decoupling the solution from the ERP systems and their vendors' other development activities. These modules are seen as temporary solutions that will be used only until the "final" solutions are available. Whether they will be in use only temporarily or permanently remains to be seen.

6.3.2 The Hospital Sector

The primary healthcare system (the GP level, administrated by municipalities) issues 70% of the prescriptions; the rest is issued by hospitals. These are organized in four health regions, as separate state companies. In the autumn 2009 it became clear that the IT managers in the health regions had made very little preparations 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 2009–2010 some 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 South-East Health Region decided to postpone the integration of ePrescription until their preferred permanent solution was ready. This meant integrating the ePrescription solution with their regional chart and medication solution which has been under development for quite a few years and which was not expected to be ready until 2014–2016 (Nasjonal IKT 2009). The western region, however, was keener on adopting the ePrescription solution. Being informed about the existence and positive evaluation of the GPM module, the head of ICT in the western region asked the Health Directorate if they could get access to the module's software and adapt it to fit their needs, which the programme management gladly accepted. The western region started, then, in the second half of 2012 a project adapting the GPM module to the needs of users in outpatient clinics and hospital pharmacies and to run in combination with the Dips EPR system. Adapting the module was quite straightforward and pilot testing was successful. The main challenges involved were related to the security solution, modification of the GPM module and integration with Dips, and changes to the underlying communication platform. The security solution requires all physicians to sign the prescriptions they produce

with an id card. For this reason they had to buy and install hardware that could read the cards and procedures for distribution of such id cards. The GPM module had to be modified a bit and extended with some additional functionality to satisfy the needs of prescription procedures in hospitals. This was primarily related to the prescribing of magistral[5] drugs. The GPM module was integrated with Dips in the following way: Dips has a menu where programs that can be started from Dips are listed. The GPM module was added to this menu. In addition, Dips transferred the patient id to GPM. Further, Dips added an API to its system that the GPM module could use to get access to information about the patient that may be important when deciding which drugs to prescribe. The prescription is not stored in Dips, but can be retrieved from the Prescription Exchange when needed. However, relevant information from the prescription can by copied from the prescription and pasted into a document that is added to the patient record. In addition, they also had to do some modifications in their communication platform used for the exchange of other kinds of messages (like lab orders and reports and admission and discharge letters). Finally, the version of the PharmaPro solutions used by hospital pharmacies had to be modified.

Deployment of the solution at the largest hospital in the region, Haukeland Hospital in Bergen, started at the beginning of January 2013 and fully implemented at all hospitals in the region by June 2014. Overall, ePrescription has been a great success in the western region. The costs related to the adaptation and integration of the generic module were modest, the deployment process smooth, and the users are very happy with the solution.

The western region's decision to implement ePrescription based on the generic module was taken against the recommendation of the Dips company. Dips started during spring 2012 a more ambitious project where ePrescription functionality will be an integrated part of their new module for handling of medication within hospitals which will be an integrated part of their EPR system. They argued that it would be better for the region to wait until this tightly integrated module was ready. The western region said they would continuously consider if they should switch to this alternative solution. So far, i.e. by late September 2015, they are very happy with the existing solution, but they plan to have a discussion about whether they should switch "soon."

Dips' integrated module was tested out in a pilot at UNN that started in 2014. The further adoption of this solution in the northern region has been very slow. However, it was successful implemented in one of the largest hospitals (called AHUS) in the South-Eastern Region during the first half of 2015. This solution will be adopted by the other hospitals in this region during 2015 and early 2016.

The hospitals in the Middle Region of Norway were using a patient record system developed by Siemens. The management of the region has announced that this solution will be replaced with a different one within the next few years. For this reason the regional management and Siemens have agreed to implement a simplest

[5] Magistral drugs are drugs which are produced at the pharmacy as specified by the physician on the prescription.

possible solution (i.e. minimal integration between the EPR system and the module) based on the GPM module. This solution was implemented in a pilot at three hospitals early in September 2015 and was planned to be scaled to the rest of the region later during 2015.

6.3.3 Adding Multi-dose Dispensing

Multi-dose drug dispensing (MDDD) is a service by which patients receive their medication packaged in bags with one unit for each dose occasion. The packaging is taken care of by machines. This service is intended for patients (mostly elderly) suffering from chronic illnesses for which they need to take several drugs throughout the day on (more or less) permanent basis. (There are about 70.000 such patients in Norway.) The traditional way of dealing with this is by means of a card (called ordinations card) filled in and signed by the patient's GP. A signed card is usually valid for 1 year. The card is taken care of by the patient herself or institutions responsible for the patients' home care or a nursing home. It is used as a prescription when the patient is buying drugs in a pharmacy. In addition, most patients are using a cassette containing the pills to be taken during 1 week. This cassette has one column for each day (seven in total) and one row for each time of the day a patient may take drugs (i.e. morning, noon, afternoon, evening). Such a cassette is then filled once a week either by the patient herself or a family member, but mostly by a home nurse or a nurse working in a nursing home. These processes are considered to contain two weaknesses which multi-dose (i.e. machine packaging) and e-prescribing solutions as expected to solve (at least partially). The first is that drugs may be mixed, for instance when the various pills are distributed across the cassette. Secondly, a patient may visit and receive prescriptions from more than one GP and she may be hospitalized for some reason and then being sent home with a number of drugs prescribed for a period. This may case various medication errors. The first of these problems are supposed to be solved by the multi-dose packaging machine and the second by the so-called drugs-in-use functionality in the ePrescription solution. The drugs-in-use functionality means that all ("active") prescriptions of one patient are compiled into one list. In addition, the GP of a patient taking drugs on permanent basis is given the responsibility of being the "editor" of the patient's drug-in-use list. That means that if a patient is admitted from hospital with some new prescriptions, the prescriptions are sent to the central database, the drug-in-use list is updated and sent to the GP. The GP then has to take action if necessary. Normally a multi-dose package contains drugs for 2 weeks. That means that in the electronic solution, a patient's drug-in-use list is sent to the Information System controlling the packaging machine every second week.

In Norway all pharmacies belong to one of the five chains (Boots, Apotek1 Vitus, Ditt apotek or Apotekergruppen). Each of these has one multi-dose machine serving all their pharmacies. The pharmacies started offering multi-dose packaged drugs about 10 years ago (2005).

Implementing support for multi-dose in the ePrescription solution started in August 2012. Specifications were worked out by a project group including the multi-dose project group in the Health Directorate and representatives for GPs and pharmacists. The first version of the specifications was approved by the Change Council (see below) 1 year later. These included modifications in the PrescriptionExchange (PE) module to generate and store the drug-in-use object and functionality for exchange of the new drug-in-use message between the PrescriptionExchange and the EPRs, FarmaPro, and the systems controlling the multi-dose packaging.

The EPR vendors were all hesitant in getting involved in this project, so the implementation started by adding the required functionality to the GPM module in addition to the Prescription Exchange and PharmaPro. The project managed to bring one of the chains of pharmacies, Apotek1, involved early on. A rather small team of actors, those responsible for GPM, PE, FarmaPro and Apotek1's system, then, succeeded in developing first a prototype and then through a few iterations a well working solution.

Apotek1 has a proprietary solution controlling the packaging machine, so coordination with Apotek1 about the required changes to their system has been rather smooth. Boots was enrolled into the project after the first version of the solution had stabilized. However, they have a system delivered by Visma, which is also delivered to other customers. Compared to Apotek1 this case involved a larger number of actors that had to reach agreement about how to implement the required functionality and the coordination of the implementation has been more demanding. Currently the Boots solution is in test. It was assumed to be approved before Christmas 2015.

Piloting multi-dose (based on version 2.4 of the standardized ePrescription messages) started in Jevnaker municipality in Eastern Norway in May 2014. They started with a small and controlled pilot with a limited number of actors and then gradually scaling up by including municipalities with a larger number of GPs and pharmacies from the autumn 2014. From September to November 2014 about 60 GPs in the municipalities Sandnes, Klepp, Time and Gjesdal were included in the pilot.

Among the EPR vendors Hove was the first to start implementing multi-dose functionality in their System X EPR system. Currently (September 2015) their solution are in "integration test." Infodoc plans to be ready for a pilot during 2016 while it is still unclear when CGM will adapt their solution (CGM Journal) using the integrated module for prescribing. When the other suppliers of multi-dose dispensing (Vitus, Ditt apotek and Apotekergruppen) will integrate their solutions with ePrescription is still unclear. So at the moment (September 2015) only municipalities using Apotek1 as multi-dose dispenser and GPs using Profdoc's old EPRs combined with the generic GPM module can participate in the pilots.

The pilots have been evaluated by two master students as their master thesis project (Ertesvåg and Tselischeva 2014). They found that overall the users very satisfied with the solution, however, desirable improvements of the solution were identified.

6.3.4 Other Developments

In addition to the changes to the ePrescription II mentioned above, a number of smaller changes have been made after the large scale rollout started. This includes a more or less continuous process of making the solution more robust. A number of smaller changes have also been made because of changes in regulations of the prescribing of drugs. This includes changes in the regulation of patient reimbursement for drugs and procedures for how to apply for individual patients to get reimbursed for specific drugs.

One important change is the definition of few new messages and functions that integrate ePrescription with the more recent national Summary Care Record II. These two IIs are integrated in the sense that all data from the PE are also copied to a similar service of the Summary Care Record (SCR) II. So every night all updates of the PE during the last 24 h are copied to the SCR data base. The reason for this copying is that the two IIs are under different jurisdictions. The ePrescription II are only allowed to store prescriptions as long as they are valid (or "active") while the SCR II stores this information for 3 years.

Some work has also started to adapt the II to new user group. Most important among these are employees of the elderly care sector like home nurses and nurses working in nursing homes. Unfortunately, the regulations established for the ePrescription deny nurses access to the II. However, they are allowed to access the SCR II which also includes the same information about prescriptions. Public health nurses in municipal service and midwives have some rights to prescribe some drugs (for instance contraceptives) and they are planned to be given access to ePrescription. Further, work is going on to provide ePrescription to dentists. Giving these user groups access to ePrescription requires the vendors of the applications they using to be modified for this purpose. Most vendors seem to plan to integrate their solutions to the II by means of the GP module. Visma has already started adapting their Profil solution and will start running a pilot later in 2015.

During 2012 activities started aiming at a major revision of the II with a focus on specifying new version of the standardized messages. The overall scope of the activities was approved in February 2013. This activity is defined as the specification of version 2.5 of the messages. This new version will include modifications representing a huge range of smaller and bigger modification of the functionality of the II based on practical use of the II, corrections of errors discovered, and modifications triggered by regulatory changes. The new version of the message standards are first implemented in the PE and GP modules. PE was scheduled for being able to send and receive version 2.5 messages by October 10 2105. It is not clear when other modules will be modified.

6.3.5 Operations and Governance

When the full-scale rollout started an operational model and governance structure was established. First of all, the only way of getting access to the II was through

connection to the National Heath Network. The PE service was operated by the data center Evry. In the Health Directorate a permanent organization was established for coordinating the maintenance and further development of the II. They also established a governance structure. The main elements of this structure are the Change Council and the Change Forum. The latter were constituted by representatives of the "operational resources" from all actors, i.e. representatives of vendors etc. The Change Council includes representatives from user groups and health care authorities.

6.4 Concluding Discussion: Installed Base Strategy

The ePresecription II was built and widely adopted in the health care sector. There is a broad consensus that the solution and the initiative behind it has been a great success.[6] However, this success came after a long and painful "birth." The first running pilot was operational about 6 years after the initiative started and having spent about 500 million Norwegian kroner (about 55 million Euros) of funding from the Norwegian government. In addition, the vendors involved allocated substantial resources to the initiative not covered by the grant from the government.

The solution being piloted and subsequently adopted was developed with a strong focus on the ordinary prescribing practices of GPs and similar dispensing practices of pharmacies, i.e. the production of a prescription for an individual patient during the patient's visit and the dispensing of the prescribed drug when the patient visits the pharmacy. Later, the solution was successfully extended with required functionality to support a broader range of practices related to prescribing, dispensing and consumption of drugs, i.e. prescribing in hospitals, support of multi-dose dispensing, becoming a platform for the national summary care record solution, and, hopefully, support for the rest of the primary care sector (i.e. midwives, public health nurses, home nurses, physicians working in nursing homes, and dentists).

We see the approach to coping with the installed base followed by the initiative as a key source of the challenges it was struggling with up until the successful pilots started in 2010 as well the later successful diffusion and extensions of the overall solution (or II). Initially the ePrescription initiative was based on the dominant EDI paradigm with a strong focus on information sharing through message exchange between applications. According to this approach the messages are specified and approved as standards and then implemented in the solutions. This EDI paradigm is based on a classical specification driven approach to software development that implicit assumes that the new solution will be of a stand-alone kind developed from scratch. This contributed to make the initiative's approach to coping with the installed base a bit schizophrenic: One the one hand the initial design was drawing extensively upon the existing installed base as the overall solution, or II, was

[6] By the end of 2014 about 75 % of all prescriptions were transferred between prescribing physicians and pharmacies by using ePrescription II.

designed as just extensions of existing applications like EPR systems and pharmacy applications (in addition to a central server and a secure network). On the other hand, the design did not take seriously into account any challenges related to integrating the additional functionality to the existing installed base. This is true both for the existing applications as well as the platforms (PC hardware, operating system, network technologies, etc.) the applications were running on. This strategy turned out to be problematic for a number of reasons:

- The number of independent actors (vendors, authorities, health care institutions, professional associations representing various user groups) involved;
- The complexity of and amount of work needed to modify all applications according to the specifications;
- A huge number of users are running ole software running on old computing platforms (PC hardware, operating system, networking technology, printer, etc.) which they might have to upgrade (i.e. replace);
- The level of details the actors had to reach agreement about;
- The degree of coordination of all activities; etc.

The struggles the initiative was fighting until 2010 clearly illustrates this. Up to that point, Profdoc was the only vendor seriously working on the development of a module supporting GPs' practices. However, due to the complexity of this module they decided to develop the module only as a part of their new product. And when the development of that product was delayed, the whole ePrescription initiative was stalled. Other vendors and the hospital sector were too busy with other, and for them more urgent, tasks to be seriously involved in the ePrescription initiative. The ePrescription strategy presumed that all stakeholders involved or affected (vendors, GPs, municipalities, government agencies, etc.) had the capacity and willingness to do exactly what they were assumed to – and in a coordinated manner. These assumptions were proven not to be valid.

A key factor leading to the end of failure stories and the "birth" of the successful solution was a change in approach for how to relate to and deal with the installed base. The GPM module represented this change in "installed base approach". The generic prescription module, GPM, embeds a different strategy for relating to the installed base. It draws equally much on the installed base as a resource, but it is much more loosely coupled to this, and accordingly demands much less modification of the installed base, and accordingly resources to be spent by vendors as well as on coordination among independent actors. Furthermore, this module could be developed by the Health Directorate without the involvement of Profdoc or any other vendor.

The GPM module turned out to have a positive impact on the establishment and evolution of the ePrescription II far beyond Profdoc users. The module was, next, used by the ICT unit of the hospitals in the western region, meaning they could adopt and use ePrescription without waiting for Dips to develop an integrated module. Then the middle region did the same. In this case Siemens did not want to develop a module on their own because they were informed that their product would

be replaced with another within a few years. Finally, the module is planned to be used by vendors of patient record systems for home nurses, public health nurses and nursing homes. The generic GPM module has also play a crucial role in the prototyping and piloting of support for multi-dose dispensing and version 2.5 of the messages. The module gave the project group in the Health Directorate opportunities for developing support for multi-dose dispensing through an experimental and evolutionary approach together with users without involving vendors and without being dependent on their engagement from the very beginning. The GPM module then also allows the users to adopt this service before the vendors make changes in the EPR solutions. And the vendors may want to do so until the specifications of a solution that works well have stabilized.

The development of the GPM module was anything but a strategic decision. It was a "quick fix" to an extremely urgent problem. And as such, it did definitively not represent a deliberate change in the initiative's strategy for how to cope with the installed base. But over time, however, the role that this module could play contributed to a change in the overall development approach. This change happened as those involved discovered the possibilities the module opened up for speeding up the adoption of the II among users of various vendors' patient record systems. This change of overall approach is most visible in the development (prototyping, piloting) and diffusion of the support for multi-dose dispensing.

The change in architecture and development approach was taking place in parallel, and dependent upon, changes in the organizing and governance structures of the initiative. When the adoption and diffusion of the II were getting momentum, more formal governance structures were established as described above. This happened at the same time as more and more of the development activities were transferred from vendors to the project group in the Health Directorate. We see the combination of these changes (i.e. changes in architecture (flexibility in integration between EPR systems and the prescribing module); development approach (from specification driven to a prototyping/evolutionary approach); and organizing and governance structures) as the key to the (final) success of the Norwegian ePrescription initiative.

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Cultivating the Installed Base: The Introduction of e-Prescription in Greece

7

Polyxeni Vassilakopoulou and Nicolas Marmaras

7.1 Introduction

E-prescription was introduced in Greece during times of financial turbulence with the aim to enhance control over pharmaceutical expenditure and also, to improve doctor-pharmacy collaboration and patient safety and to support evidence-based policy development. In that sense, the introduction of e-prescription is not yet another technology project but rather, a socio-technical intervention with infrastructural nature. In this chapter we explore the national e-prescription service's surprisingly swift deployment. Specifically, we identify how a series of pragmatic tactical decisions allowed building upon a "good-enough" installed base by exploiting its latent potential without perpetuating all of its weaknesses. Furthermore, we show how hedging against obsolescence was practiced through continuously addressing exogenous shifts in the installed base. Finally, we point to the pivotal role of the technical architecture implemented for enabling installed base cultivation. A combination of novel technological affordances, standards and architectural patterns made possible the development of a technical solution which supports openness, evolvability and scalability.

In our study we position e-prescribing within the overall Greek health system and we describe how the new electronic service evolved to inscribe specific

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prescribing policies, to provide clinical decision support, and to facilitate the processes and roles of policy and financing stakeholders. Our case description spans the period from 2010 to 2015.

Data Collection

To (re)construct e-prescription's trajectory: extensive documents' review including legislation and guidelines, policy documents and strategic plans, press releases (from Social Security Funds, the Ministry of Health, and IDIKA), public consultation documents, presentation documents from various professional and academic events, posts in professional electronic forums, articles in specialised press and journals.

To develop an understanding of the e-prescription solution: on-site observations of e-prescription use in pharmacies. The observations were repeated in 2 month intervals. Additionally, we studied the user manuals for pharmacists and doctors.

To elicit practitioners' perspectives: seven semi-structured interviews.

The remaining of the chapter is structured as follows: in Sect. 7.2 we present an overview of the Greek healthcare system and the situation with respect to information systems, in Sect. 7.3 we present the rationale for the introduction of e-prescription in Greece, we provide an overview of the e-prescription service and we describe its evolution over time, then, in Sect. 7.4 we discuss the relationship to the installed base. Finally, in Sect. 7.5 we provide some concluding remarks.

7.2 Healthcare in Greece

7.2.1 Overview of the Greek Healthcare System

Healthcare delivery in Greece is based on both public and private providers (mainly in primary care and diagnostic tests). The Greek national health system (ESY) was established after a major healthcare reform in 1983 with the aim to guarantee universal healthcare coverage for all (universal healthcare rights are stipulated by the Greek Constitution). Public health provision is coordinated by seven Health Regions that are supervised by the Ministry of Health. Secondary healthcare is provided by public and private hospitals and clinics. Primary healthcare is provided through rural health centers and provincial surgeries in rural areas, the outpatient departments of regional and district hospitals in urban areas and contracted doctors with private practices (OECD 2013a). Unlike what is common in many other European countries, Greek residents do not have to register with General Practitioners (GPs) and GPs do not have a gate-keeping role. Individuals can access the entire spectrum of specialists for consultations and can be directly referred by them for reimbursable

tests and examinations. Because of the structure of healthcare provision, and the lack of a GP referral system, free choice of provider is a key characteristic of the system. The ownership of pharmacies is limited to pharmacists. Pharmacies are licensed by the government on the basis of criteria for population coverage and distance from the nearest existing pharmacy.

Key health indexes for the Greek population are good. In the 2000 report by the World Health Organization on health systems' performance, the Greek healthcare system was ranked 14th worldwide in terms of overall performance and 11th on level of health (World Health Organization 2000). During recent years, healthcare cost containment has been the main Government's concern. This concern is induced both by the rise in healthcare services demand (due to the aging population, the increase of patients living with chronic conditions and citizens' pressures for increasing the supply of quality healthcare services) but also, by the need to address the ongoing public debt crisis.

As in nearly all European countries, the public sector is the main source of healthcare financing. Financing is provided mainly by social security funds (although out-of-pocket-payments and direct health financing from the national budget of the central government are also significant). Most of the funds are public entities (legal persons governed by public law), and while they are autonomous, they operate under the control of central government. The funds cover both pensions and healthcare for particular socio-professional groups (i.e. there are different funds for farmers, public servants, etc.) on the basis of personal contributions but the state also contributes to their financing. The number of funds was brought down from 130 to 13 in 2008 (OECD 2013a) and there is further consolidation underway. For healthcare, the aim is to merge all healthcare coverage schemes (that relate to different funds) to a single one. On March 2011, the healthcare schemes for farmers, freelance non-professional workers and public servants were subsumed by the scheme for non-public sector salaried employees (IKA). All together came under the umbrella of a new organisation named "National Organisation for Health Services Provision" (EOPYY, incorporated with Law 3918/2011) which started operating in 2012. EOPYY is still being expanded to cover the beneficiaries of all other social insurance funds and is gradually becoming a single public buyer of healthcare goods and services. Figure 7.1 provides an overview of the main actors involved in healthcare regulation, provision and financing.

Aggregate public spending for health is moderate compared to EU and OECD averages (OECD 2013b). Although the overall expenditure is moderate, the statistics indicate room for improvement especially within pharmaceuticals where the annual expenditure both per capita and as a share of the Gross Domestic Product is high (about 40% more than the EU average) (OECD 2013b). This high expenditure has been a key concern for the Government also because health goods are predominantly financed by public funds (74% of expenditure is publicly financed in Greece while only 54% in Europe as an average (OECD 2013b)).

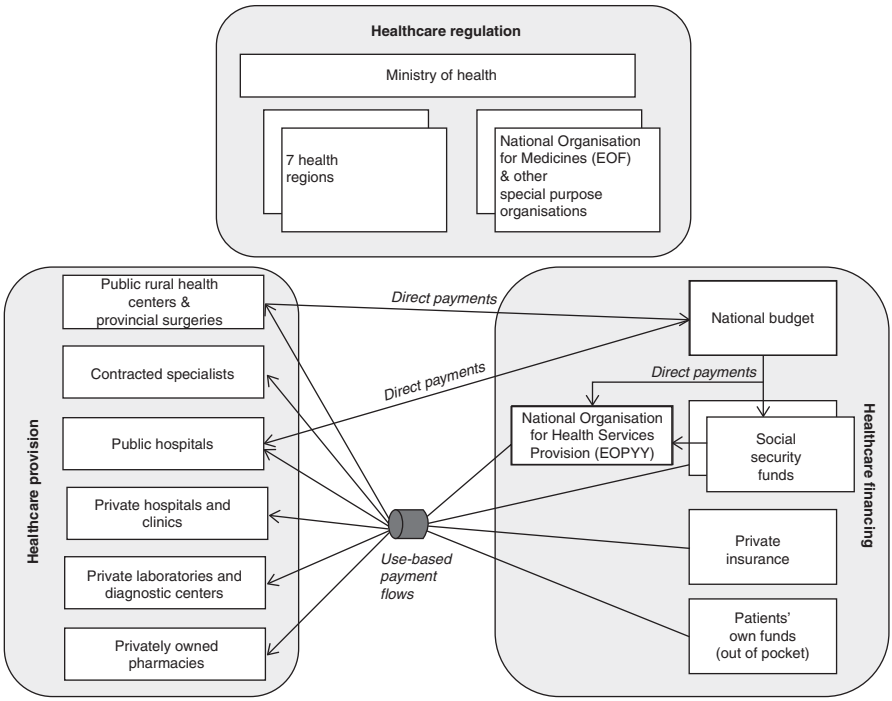

Fig. 7.1 Greek healthcare: regulation, financing and service provision (as of 2015)

7.2.2 Information Systems in Greek Healthcare

Initial efforts for the introduction of information systems within Greek healthcare date back to the 1980s (Fragidis and Chatzoglou 2011). Nevertheless, although a series of national plans were drafted and pursued (e.g. most recently, the national 2002–2006 Action Plan "ICT in healthcare" and the national eHealth roadmap 2006–2015), the progress achieved has not always been significant.

Notwithstanding the delays, there has been a clear positive trend in information systems' use over the years. Practically all pharmacies use information systems. Within primary care, as of 2013, 99% of GP practices had computers in the consultation room as opposed to only 66% back in 2007, 99% of practices were connected to the internet or a dedicated GP network and 24% had their own website (European Commission DG Communications Networks Content and Technology 2013). The electronic storage of medical patient data is relatively common among GPs although it is not universally exercised: around 70% of GPs store electronically the medical history of their patients and more than 60% register electronically their clinical notes, symptoms and ordered tests (idem). Health information exchange is much less developed among GPs (idem): only around 22% receive laboratory reports electronically and around 20% exchange medical patient data with other healthcare

providers and professionals (excluding prescriptions), electronic interactions with patients are also limited (27% of GPs).

As of 2013, practically all hospitals (99%) used computer systems; billing management (90%) and discharge letters (76%) were the most common hospital applications (European Commission Joint Research Centre Institute for Prospective Technological Studies (JRC-IPTS) 2014). Hospital-wide electronic health record systems shared by all clinics were used in around half of the hospitals (52%) another 13% used multiple local systems, while 35% had no health record system in place (idem). Only 24% of hospitals exchanged health information (excluding prescriptions) with entities outside the hospital (e.g. other hospitals, external specialists, GPs) (idem).

Medical data exchange has been impeded by the lack of a single personal identifier for all Greek residents up till recently (the obligatory social security number – AMKA was only introduced in October 2009 (Greek Ministry for Labour 2012)), the delays in establishing a secure network (the secure network "Syzefxis" that connects all public entities including healthcare was only initiated in 2004, became operational in 2006 and it is still under development although it has now achieved significant coverage) and the multitude of solutions with different logics and limited standardization (Emmanouilidou and Burke 2012; Bogdanos et al. 2008).

7.3 The Introduction of E-Prescription

7.3.1 Rationale for E-Prescription and Key Milestones

Greece introduced e-prescription to enhance control over pharmaceutical expenditure, to improve doctor-pharmacy collaboration and patient safety and to capture data required for evidence-based policy development. The aspired benefits were clearly set-out in the law that provides the legal basis for e-prescription (Law 3892/2010). The year when the e-prescription law passed (year 2010) the Greek economy was facing a severe public debt crisis which captured global attention. In return for loans from the International Monetary Fund and European Institutions, the Greek government agreed to accelerate reforms including structural reforms of the healthcare sector and the introduction of new electronic tools. The strong financial motivation behind the e-prescription initiative is demonstrated by its inclusion in May's 3rd 2010 "Memorandum of Economic and Financial Policies" between Greece and the International Monetary Fund and subsequently in the "Hellenic National Reform Programme 2011–2014" issued on April 2011.

The introduction of e-prescription was swift: development started in 2010, a pilot was run in October of the same year and the official launch was on January 24th 2011 (Table 7.1). By the fall of 2011 around 40% of prescriptions were covered, and by fall 2013 almost full coverage was reached (Papanikolaou 2013). E-prescription was one of the initiatives that contributed to the reduction of the total pharmaceuticals' expenditure by approximately 33% between the years 2009

Table 7.1 Greek e-prescription: key facts

Function		Users	Temporal evolution	
Guide prescribing behaviour, support registration and circulation of prescription and dispensing information		General practitioners and specialists in primary care, private and public hospitals	Initiated in 2010	
			Launched in January 2011 (pilot October 2010)	
		Pharmacists		
		Reimbursing authorities	Almost full coverage (98%) by 2013	
		Public health policy makers		
	Fall 2010 (pilot)	**Fall 2011**	**Fall 2012**	**Fall 2013**
Pharmacists	~8,500	~8,500	~10,800	~10,800 (98% of total)
Doctors	~4,100	~10,100	~37,500	~41,000 (90% of total)
Prescriptions (monthly)	~8000	~2,500,000	~4,500,000	~6,000,000 (98% of total)

and 2011 (Greek e-Government Centre for Social Security 2011). In the next sections we present the trajectory followed starting with a brief presentation of the situation before the introduction of the new electronic service.

7.3.2 Information Handling Before the Introduction of E-Prescription

Before the introduction of e-prescription prescribing was supported by "prescription booklets" issued by Greek social security funds. These booklets were kept by the patients and used during their interactions with doctors and pharmacists. The booklets were personalised: they contained a photo, identity information such as name, birth date, address, registration id (for the fund's internal registry), national tax id and a unique identification number per booklet. Each booklet contained fifty double-sided prescription pages and their carbon copies (a white coloured original and a yellow coloured copy). Each prescription page had on the one side fields to be used by the prescribing doctor (including doctors' information, diagnosis, drugs description and quantity) and by the dispensing pharmacist (including pharmacist information, drugs' cost and patient's cost share) and on the other side a template for attaching identifying adhesive labels from the packaging of the drugs dispensed. These labels are mandatory for all drugs circulating in Greece. Drugs carry a serial number that identifies each pack uniquely. Serial numbers are used for preventing reimbursement fraud and monitoring consumption and expenditure. The booklet format was defined in 1998 (presidential decree 82A/1998) and revised in 2008 to include the national insurance number (AMKA) and a barcode. Figure 7.2 presents the standard prescription template that was in use before the introduction of e-prescription.

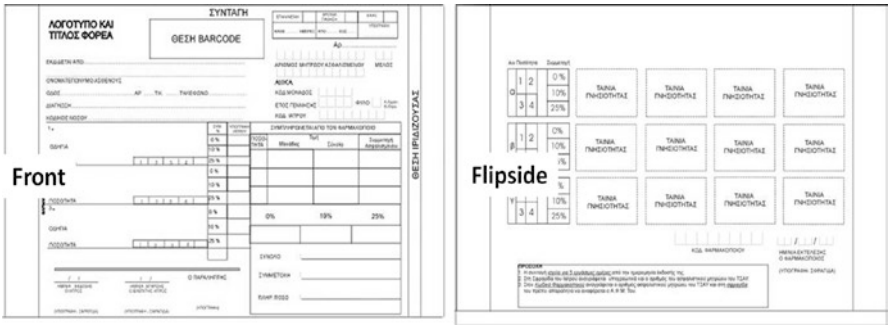

Fig. 7.2 Paper prescription template

Patients carried with them their prescription booklets when visiting a doctor. Doctors would use a page for prescribing drugs, sign and stamp the page and hand the booklet back to patients. Afterwards, patients could visit any pharmacy, hand the booklet to the pharmacist who would then complete the remaining fields on the front of the prescription page, sign and stamp, tear off the page (the yellow copy remained in the booklet), fetch the prescribed drugs from storage, detach the identification labels from the drug packages and attach them to the page, handover the drugs to the patient and collect payment (patient's share of cost). Periodically, pharmacists would send to social security funds lists with filled prescriptions attaching the white prescription pages in order to be reimbursed. The booklet's yellow pages served as records for the medication history of each patient.

For social security funds, processing prescriptions' data required resources and a dedicated infrastructure. For instance, IKA (the largest social security fund) conceptualised a project in 2005 for the electronic processing of the white prescription pages received. A request for proposals was published in 2007 and a contract was signed in 2009 for the development of a scanning and processing system and its initial operation for 2 years (with a total cost of approximately 6 million Euro). The system was in place in April 2010 and made possible the scanning, checking and clearing of 2.5 million prescriptions per month (IKA 2009; Hararis 2011). The systems that social security funds have developed for scanning, checking and clearing prescriptions are part of the overall prescriptions' installed base and had to be eventually linked to the e-prescription solution (see also Sect. 7.3.4).

7.3.3 Information Handling After the Introduction of E-Prescription

A graphical representation of the Greek e-prescription service is provided in Fig. 7.3. Web-based access is provided to prescribing doctors and pharmacists. Access is controlled at the user level (registered users go through a username and

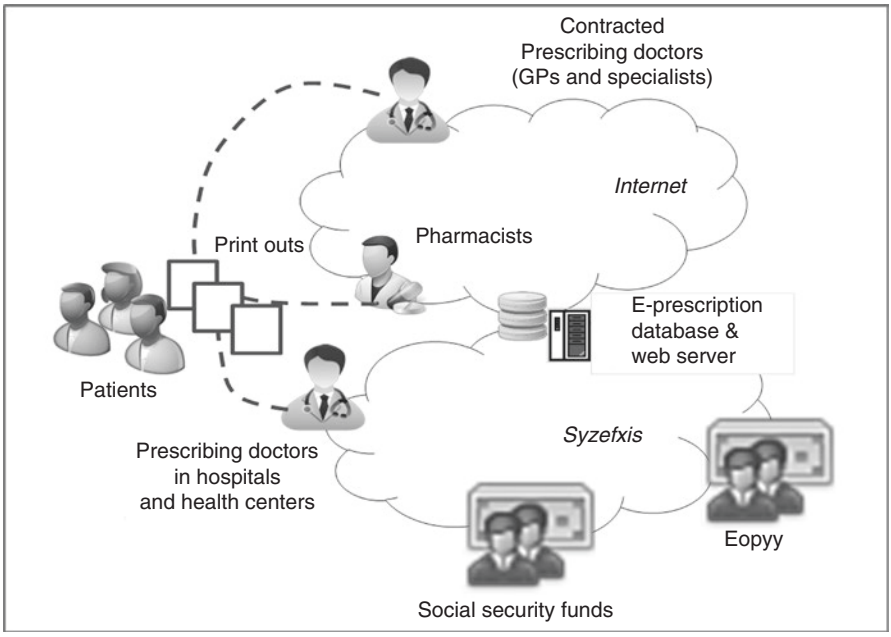

Fig. 7.3 E-prescription in Greece

password identification process) and a central repository of all prescriptions is maintained nationally. Hospitals access the service over the closed secure network Syzefxis, all other healthcare users use their private internet connections. Prescribing doctors register key information (including the patient's name and social security number, the diagnosis encoded according to ICD-10, and the medications prescribed) and then, print a summary page which is handed to the patient. Patients can visit any pharmacy in order to obtain prescribed medications. Pharmacists take the printed prescription summary page and scan the barcode to retrieve the prescription from the national central repository (alternatively they can type). Before delivering medications, pharmacists scan the medication packages' barcodes which are then matched to prescription details. In case of mismatch an error message appears on the screen and processing cannot be completed.

As with the previous fully paper-based process, pharmacists detach package labels and attach them to the prescription printout before handing over medications to patients and collecting payment (patient's share of cost). The bottom part of the printout contains designated positions for placing the labels (Fig. 7.4). Periodically, pharmacists send to reimbursement authorities lists with the prescriptions they filled attaching the printouts that include the identification labels of the medications dispensed. Doctors can use e-prescription for retrieving the full prescriptions' history per patient (pharmacists do not have access to this functionality). Patients do not have direct access to e-prescription data.

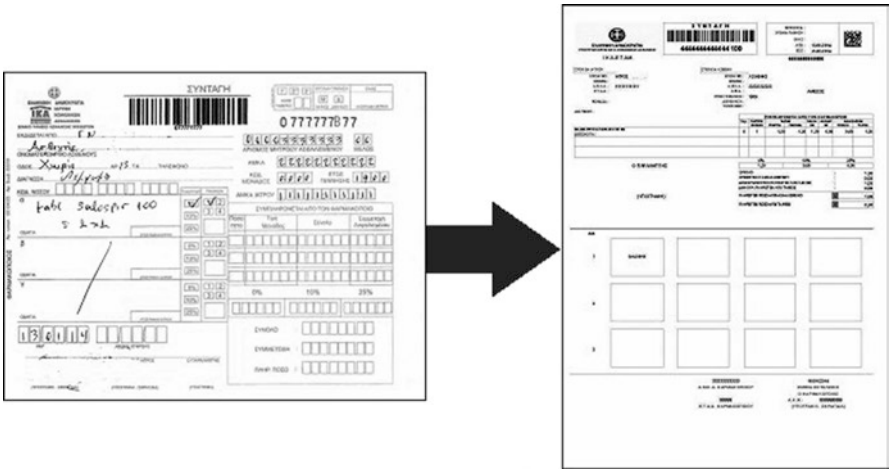

Fig. 7.4 Prescriptions in Greece: from booklet pages to printouts

The e-prescription solution is hosted and maintained by the Greek e-Government Centre for Social Security (IDIKA) which has developed it in-house. IDIKA is supervised and controlled by the Greek Ministry of Labour, Social Security and Welfare; it is mainly financed by the social security funds and is responsible for the implementation of information and communication technology within the social security sector. E-prescribing was initially piloted in October 2010 for patients covered by one specific social security fund (the fund for self-employed workers – OAEE). For the piloting of the service almost all pharmacists were enrolled along with doctors contracted by the specific fund (see also Table 7.1). In January 2011, the service was officially launched and three more social security funds were added: the fund for non-public sector salaried employees (IKA) which is the largest in the country, the fund for farmers (OGA) and the fund for public servants (OPAD). In 2012 a number of additional funds were included: in April, the fund for seafarers (NAT), in May, the fund for bank employees (TAITEKO), in November, the fund for employees in the mass media (ETAP MME) and in December, the fund for lawyers, engineers, doctors, dentists, veterinarians and pharmacists (ETAA). Each addition necessitated information exchange with additional fund-specific registries. The establishment of the new "National Organisation for Health Services Provision" (EOPYY) which started operating in 2012 and gradually assimilated the healthcare insurance schemes of multiple funds (as described in Sect. 7.2.1) helped in the establishment of common rules but the different funds retained their separate registries.

The software development for e-prescription was initially contracted to external providers and the first versions launched were not developed in-house. Two low-budget contracts were signed with two relatively small software houses (the total value including contract extensions for accommodating additional social security

funds was approximately 200,000 euro (ΑΓΓΕΛΟΠΟΥΛΟΥ 2012)). At the beginning of 2012 IDIKA started the in-house development of a new e-prescription solution which was successfully launched in May 2012 (Sfyroeras 2012b). The new in-house development aimed to remedy a series of issues: slow response times and concerns about scalability, reliability and usability. It also provided the opportunity for expansions and service improvements in a flexible incremental way. The in-house development was an interim solution which became necessary as the procurement of the fully-fledged solution through a public tendering process (which was initiated in 2010) was delayed due to administrative procedures (Pangalos and Asimakopoulos 2015).

7.3.4 System Evolution

The in-house version of e-prescription was launched in May 2012 and included enhanced functionality. For instance, it supported the automatic retrieval of basic patient information, it provided doctors the option to use multiple affiliations (i.e. doctors working both for a private practice and a private clinic), it simplified the repeat prescriptions' process and offered improved search functionalities. This was the start of a continuous effort for incremental improvements and extensions.

Connections and Extensions

The initial versions of e-prescription were only accessible via web browsers. There was no connectivity to the EPRs already in use by doctors or to pharmacy information systems (PISs). A major improvement was the publishing of Application Programming Interfaces (APIs) that allowed connectivity with doctors' and pharmacists' systems. In the spring of 2012 IDIKA initiated discussions with system providers for the APIs that were under development. The APIs were initially tested in 400 pharmacies during August 2012 (Πετρόχειλος 2012). They were subsequently used by multiple system providers connecting the majority of pharmacies (by the end of 2012). In 2015 the APIs for doctors' EPRs were launched (Tagaris 2015). The web service APIs developed adhere to REST architectural constraints (RESTful APIs) and to the Clinical Document Architecture (CDA) markup standard to specify the encoding, structure and semantics of exchanged documents. The introduction of the APIs and their exploitation by third party system providers not facilitated everyday work for pharmacists and doctors that could now conclude their tasks without having to use multiple applications. Figure 7.5 provides an overview of the key architectural components for e-prescription (adapted from Asimakopoulos (2012)). The figure depicts also the link with the scanning and processing systems (for prescription printouts and attached medication labels) of the social security funds (Scan SFF).This was an additional extension implemented during the same period. The e-prescription team collaborated also with the European project epSOS for cross-border interoperability of summaries of electronic health records and

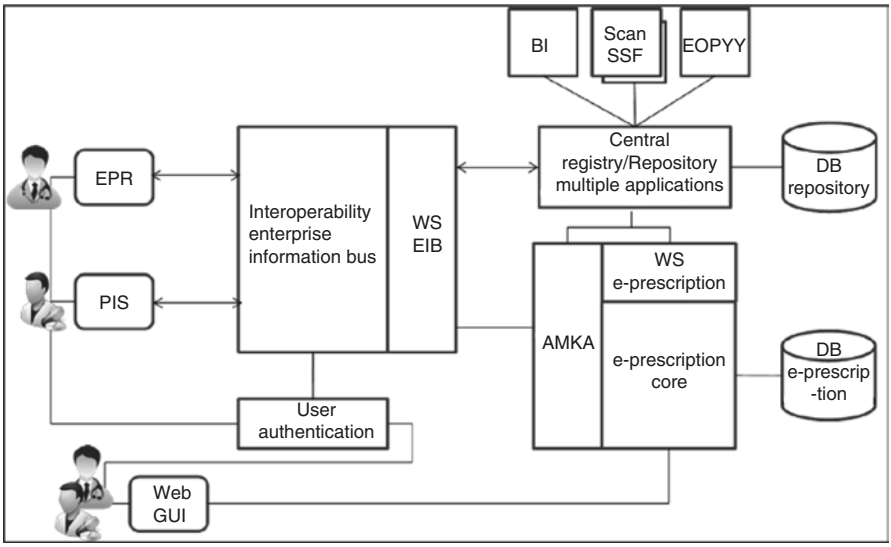

Fig. 7.5 Key architectural components of the Greek e-prescription

e-Prescriptions. Hence, the system can process epSOS friendly prescriptions for cross-border healthcare.

The publishing of APIs and the subsequent adaptation of the local EPRs and PISs, made possible for doctors and pharmacists to prescribe and dispense medications without having to shift between the web interface and their local systems. Still, doctors that needed not only to prescribe medications but also to order diagnostic tests (e.g. diagnostic imaging and blood tests) had to access an additional system (named e-diagnosis) via a web interface. The electronically supported process for test ordering is similar to the process for electronic drug prescribing: doctors register key information (including the patient's name and social security number, the diagnosis encoded according to ICD-10, and the tests ordered) and then print a summary page which is handed to the patient. Patients can visit public or private contracted laboratories and diagnostic centers for performing the tests. The e-diagnosis system for test ordering was initially launched in October 2010 (for patients covered by the social security fund for public servants – OPAD) and was developed and maintained by a private software company. In May 2011, it was decided to simplify use by applying a common user authentication scheme for both e-prescription and e-diagnosis but the two systems were kept separate. After the successful launch of the in-house version of e-prescription, IDIKA decided to extend its functionality by including test ordering. In January 2013, a new extended version of e-prescription was launched that made possible for doctors to prescribe drugs and order tests from within the same environment.

As medications are reimbursed mainly by social security funds, information about patients' affiliation with a specific fund is needed for prescribing medications (to apply specific reimbursement rules). When e-prescription was first introduced the funds were maintaining multiple electronic registries for their members and several of those registries were incomplete (for example, most registries did not include information about children that are fund beneficiaries when one of their parents is a fund member) (Sfyroeras 2012c). Before the introduction of e-prescription, doctors and pharmacists would find information about a patient's affiliation by simply looking at the prescriptions' booklet. The booklets also contained information on the status of patients as insured members (status relates to the payment of dues to the fund – benefits can only be claimed if dues are paid). For the digital process both affiliation and status information needed to be electronically available. IDIKA was already responsible for the national registry for social security (ΑΜΚΑ-ΕΜΑΕΣ) that contains national social security numbers (AMKA) and basic information per individual (name, date of birth, parents' names). The AMKA registry did not contain information about the status of individuals' relationship with particular funds. In an initiative parallel to e-prescription, a new system named ATLAS that includes a new national registry for all healthcare beneficiaries was developed and launched by IDIKA in 2014. ATLAS links multiple registries and supports the flow and storage of information on insurance status and social insurance contributions. ATLAS is not dedicated to healthcare, it is also meant to support the calculation of pensions. This new system was linked to e-prescription in the summer of 2014.

Inscriptions of Administrative Rules and Clinical Knowledge

Overall, several rules related to reimbursement are inscribed to e-prescription. To start with, the electronic service was designed to replicate the simple constraints of the paper-based system that was previously in place. Up to three different medications can be included in one prescription (see also Fig. 7.4); in case that more are needed, separate additional prescriptions have to be issued. Furthermore, specific rules for medication quantities are also in place – rules differ for chronic patients, specific types of medications etc. Since June 2012, substance-based prescribing (instead of naming pharmaceutical products) was electronically imposed. The classification of active ingredients of medications is based on the ATC international classification system. This new rule (substance-based prescribing) was subsequently relaxed so e-prescribing was readjusted. Recently, (September 2015) the rule was reintroduced in the system after yet another change in the reimbursement regulations. The rules for patients' cost-sharing are also inscribed in the electronic solution (and are being updated each time they change). The general rule is that patients contribute 25% of medications' cost but there are many special patient and/or therapy-specific categories for which the contribution is 10% or even 0% (e.g. chronic patients, pregnant women, patients with transplanted organs, etc.). Additionally, there are rules for the maximum amounts that patients may pay. Specific constraints on

what can be prescribed by doctors according to their specialty are also implemented. Additionally, there are specific rules for prescribing doctors that limit the number of prescriptions that can be issued and define upper bounds (caps) for the total permitted cost per prescription (since 2013 different methods for calculating caps were applied based on simple data analytics e.g. by taking into account the prescribing history of individual doctors or specific specialties and geographic areas).

The rules inscribed to e-prescription are not only related to costs and reimbursements. Therapeutic prescribing protocols for a series of conditions (i.e. diagnosis-based prescribing guidelines) have also been electronically implemented. Practically, this means that e-prescribing gradually extended to become a decision support tool for doctors. The protocols include medication of "first choice", secondary medications, alternative therapies and rare cases. The medication options are described on the basis of active substance. These protocols are developed by specially appointed committees for condition categories defined by the National Organisation for Medicines (EOF) and are approved by the Central Health Council (KESY). A total of 160 protocols were developed and approved on October 2011. The first protocols were launched within e-prescription in October 2013 (for osteoporosis) and since then, their number has been continuously increasing. Up to September 2015 15 different protocols were implemented (e.g. for dyslipidaemia, diabetes, arterial hypertension and rheumatological conditions) while there are several more under development with the aim to be launched before the end of 2015 (for dementia, Parkinson disease, epilepsy, chronic obstructive pulmonary disease, chronic bronchitis, asthma).

Working Around Complications in National Plans

The national eHealth roadmap 2006–2015 included a plan for the introduction of smart cards in healthcare. The smart cards would be used both for identification and authorisation purposes (for patients and healthcare providers) and also for storing data (administrative identification, clinical emergency data, prescriptions and insurance status) (Angelidis et al. 2010). Small-scale experimentations with smart cards for healthcare have been taking place in Greece since the 1990s (Karounou and Vassilakopoulos 1995). However, the plan for national level deployment of smart cards for health has not been materialised till today. The exploration of the whole spectrum of issues that impede the national deployment of smart cards for health in Greece is outside the scope of this chapter but we can briefly mention issues related to the cost and complexity of extending the existing physical infrastructure to include card readers, the need for large-scale organisational and regulatory adaptations and discussions/disputes around data security and data ownership. Nevertheless, as smart health cards are part of the national plan the introduction of e-prescription was linked to the use of the cards and that was clearly stated when the consultation process for the development of the new electronic prescription services was initiated back in 2010 (the use of PKI-based smart cards was part of the requirements).

IDIKA was also involved in small-scale experimentations with smart cards. Specifically, a pilot was launched in 2012, in the prefecture of Corinthia were 2500 individuals insured by the social security fund for municipal employees (TYDKY) were provided with personalized smart cards. The pilot was discussed in public by IDIKA management: the stated aim was to explore and prepare for national scale implementation; it was also announced that IDIKA was planning to provide 60.000 smart cards to healthcare providers (covering all prescribing doctors and pharmacies) to enhance e-prescribing security (Πετρόχειλος 2012). The use of smart cards for e-prescription was never scaled-up but the pilot showed the preparedness of the system to accommodate the national strategy for smart cards in healthcare.

The government's intention for nationwide deployment of smart cards in healthcare has been recently reconfirmed and the current plan is to use the cards both for healthcare and social benefits (Greek Ministry of the Interior and Administrative Reform 2015). Still, the necessary arrangements for nationwide deployment are not in place while the e-prescription service is deployed nationally. Given the current situation, the much awaited security enhancement of e-prescription is being currently implemented with the introduction of USB tokens for healthcare providers (launched in June 2015). While till recently access healthcare providers were accessing e-prescription using their user name and password, with the introduction of the tokens authentication is performed by the combination of the password and the USB token (two-way authentication).

The new authentication component is an outcome of the large-scale e-prescription project that was awarded to a consortium of companies. As already mentioned the in-house developed system is a makeshift solution that was put in place for the interim period required to implement the system acquired through a public procurement process. This process was initiated with a public consultation on the design and implementation of the e-prescribing system (February–March 2010). This was followed by another public consultation which was specific to the implementation stages for e-prescription (April 2010). Subsequently, the tendering documents were made available for public consultation in April 2011. After that, a two-step tendering process was initiated. An open call for the project (budget Euro 24,6 million – duration 36 months) was published in September 2011, four consortia were pre-selected (March 2012) and subsequently three of them submitted proposals (August 2012). The proposals were evaluated through a lengthy process that culminated in the contract award (June 2014). The value of the contract was significantly lower than the original budget (approx. 40% lower) and the duration was set to 18 months. The new e-prescription solution was still under development at the time of writing.

The overall system evolution described in this section is graphically represented in Fig. 7.6. The figure depicts key milestones for the system-in-use and also for the public procurement process (for the fully-fledged solution) which has been running in parallel.

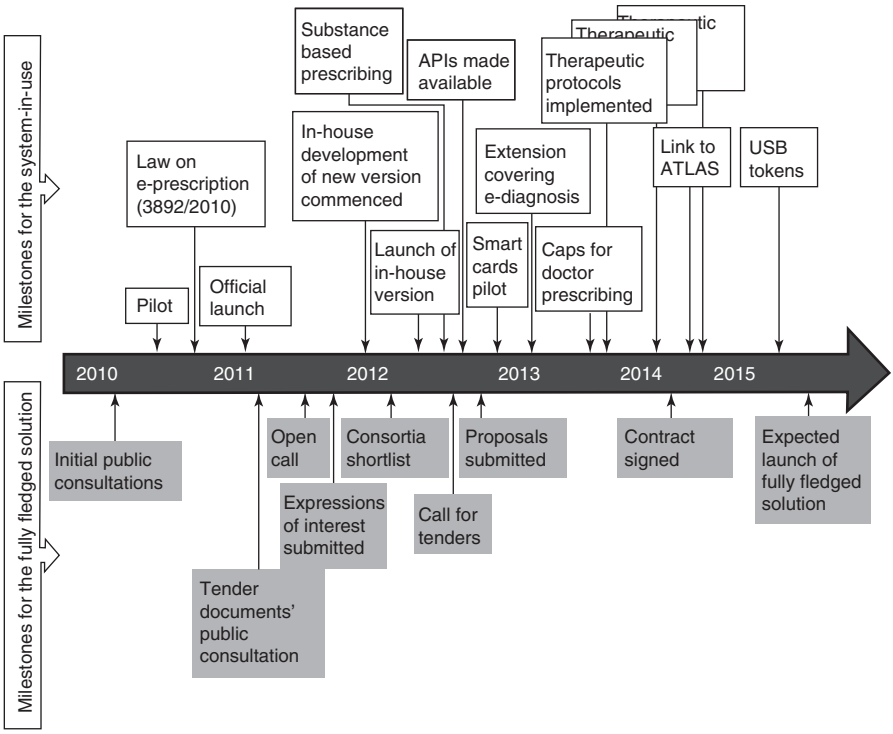

Fig. 7.6 Key milestones for the Greek e-prescription case

7.4 Discussion: Relationship to the Installed Base

7.4.1 Building Upon an Installed Base That Is "Good Enough" Without Perpetuating All Weaknesses

Gaps in the backbone of the country's information infrastructure caused difficulties to previous eHealth initiatives. Efforts to harmonize Greek healthcare with European "best practices" have repeatedly failed to deliver expected results and some of them were abandoned altogether (Economou 2010). Heath data exchange was impeded by the lack of a single personal identifier for all Greek residents (each social security fund used its own registry with its own identifiers) and the lack of a secure network to connect healthcare facilities. A number of recent initiatives with infrastructural nature filled some of these gaps and created a more favourable environment for the initiation of e-prescription. A new secure network (Syzefxis) supports connections among public institutions and provides gateways to the internet. A single national social security number (AMKA) was introduced in October 2009. Furthermore, computer-based information systems were present in practically all hospitals, primary healthcare units and pharmacies although as recently as 10 years

ago this was not the case (see also Sect. 7.2.2). Additionally, standards for information codification like the International Classification of Diseases (ICD), the Anatomical Therapeutic Chemical (ATC) classification and HL7 Clinical Document Architecture (CDA) were already mature and readily available. E-prescription was built upon these enabling components and would have been challenged without them. Moreover, software architectural styles that allow client-server separation of concerns and simplify modular implementation (such as REST) were established. So, the development of the software capitalised on relevant technical knowledge and experience.

The installed base included also a complicated arrangement of multiple social security funds and national actors including the Ministry for Health, the Ministry for Labour Social Security and Welfare, the National Organisation for Medicines, Doctors and Pharmacists Associations. All these actors were involved by setting rules and providing datasets required for digitising the prescribing process. The Chief Executive Officer of IDIKA stated in an interview in 2012 that the main challenges faced were not related to the technical development but rather to the coordination of all involved actors (Sfyroeras 2012a). He also stated that the lack of interoperability among systems and the absence of a national registry for the beneficiaries of healthcare were assessed as showstoppers by some participants during the early stages of the initiative. Moreover, he pointed to other key components that were missing when the development of e-prescription started: lack of a full list of medications available in Greece (not just a list of approved medications), lack of a common identifier for medications, lack of a unified doctors' registry (multiple registries in place).

Although a number of key components were missing, the new system was not merely built upon the installed base perpetuating all of its weaknesses. Instead, several initiatives were taken to fill some of the gaps. For example, it would have been possible to circumnavigate problems with the national medications' list by allowing users to enter free-text medication descriptions. This would facilitate the circulation of messages between doctors and pharmacists but would be an inefficient solution for monitoring prescribing practices. The lack of standardised medications' lists is a problem in many other countries including USA were free-texting of e-prescription medications is common (Dhavle and Rupp 2014). However, in the Greek case, it was decided not to follow such an approach, instead, comprehensive lists were created and maintained, new registries were put in place, and new connections were implemented.

Overall, a pragmatic approach was adopted: some gaps were filled while others were worked around. For instance, for almost 5 years access control to e-prescription was rudimentary. Authentication was performed by means of user name and password. The implementation of mechanisms for two-factor authentication required the deployment of a physical infrastructure (smart cards or usb tokens) which was costly and logistically demanding. Hence, it was initially postponed and was eventually implemented in 2015.

7.4.2 Handling Continuous Exogenous Shifts in the Installed Base

The situation within the installed base kept changing during the 5-years trajectory not only as a result of initiatives triggered by the need to put e-prescription in place but also because multiple initiatives related to wider reforms within healthcare took place. The institutional environment changed with the establishment of the National Organisation for Health Services Provision (EOPYY) which started operating in 2012 and is gradually becoming a single public buyer of healthcare goods and services. Additionally, a number of social security funds were merged. Furthermore, the distribution of roles and responsibilities among existing actors changed. For example, since October 2012 the price lists for medications are issued by the National Organisation of Medicines and not by the General Secretariat for Trade. The e-prescription service had to adapt to all these changes. Moreover, new potentially useful infrastructural components were created after the initial launching of e-prescription. For instance, therapeutic prescribing protocols were made available in 2011 and were subsequently progressively included in e-prescription.

Although several of the installed base changes were planned and known in advance, e-prescription would not be developed by taking them for granted as it is not uncommon to experience delays or even radical twists in national plans (a good example is the situation with smart cards for health where there is practically no significant advancement till today). Consequently, all decisions had to be based on the situation at hand while maintaining openness to accommodate changes. Part of the overall uncertain situation was the public procurement process for a fully-fledged system which was under way but without any certainty about the timing of the delivery. Hence, there was a need to adapt swiftly and cost-effectively since it was already known that the system in use would be replaced at some point. What was pivotal for this continuous effort to develop and maintain e-prescription through adaptations was the clear ownership and dedication by a single institution (IDIKA). This institution took the seemingly paradoxical decision to develop in-house at the beginning of 2012 a new version (even though the fully-fledged solution was already planned), replacing the one that was in place and was already reaching its limits (see also Sect. 7.3.3).

7.4.3 Installed Base Cultivation vs. Specifications-Driven Development

The tactics described in the two previous sections can be summarised as pragmatic exploitation and expansion of a “good enough” installed base, and continuous adaptation to exogenous shifts within this base. This can be characterised as a “cultivation” approach. In that approach, the installed base is not considered as a given and stable foundation for further developments that can be fully planned. Instead, the

dynamics of this base are acknowledged and hence, interventions are attempted in an active interplay with it (Ciborra 1992; Ciborra and Hanseth 1998). Such an approach towards the installed base necessitates a requisite technical design that supports openness, evolvability and scalability. These were key characteristics of the new version of the system that was developed and launched in 2012. Specifically, the architectural configuration of the new system (Fig. 7.5) allowed loose coupling among components, offered the possibility for continuous new releases and supported component modifiability to meet changing needs.

A cultivation approach to the installed base entails incremental and evolutionary development which is drastically different to the conventional specifications-driven approach that was followed in the past for national systems. For instance, the tax authorities' system was launched after 7 years of systematic design and implementation efforts (Prasopoulou 2012), while the system for social security reached countrywide implementation after almost two decades of planning and multiple discontinuities in the design and development process (Avgerou and McGrath 2007). For the procurement of the fully-fledged system the specification-driven approach was also adopted and it would be interesting to know how e-prescription would turn out without the prior experience of cultivation for over 5 years.

7.5 Concluding Remarks

E-prescription played a key role for the establishment of new rules and norms disrupting existing practices within healthcare. The introduction of the new electronic service was legitimised by referring to the expected economic impact (Greek e-Government Centre for Social Security 2011; Sfyroeras 2012a; Vassilakopoulou and Marmaras 2015) and to obligations towards the International Monetary Fund and European Institutions. The need for cost containment was undisputed as expenditure on pharmaceuticals had reached very high levels: per capita pharmaceutical expenses in $ purchasing power parities (PPP) rose from 461 in 2004 to 840 in 2009 (OECD 2015b). The government managed to reduce the annual bill for pharmaceuticals by €1.8 billion between 2009 and 2013 (OECD 2015a). This significant cost cutting cannot be attributed to e-prescription alone. It was the outcome of several concurrent measures some of which were related to e-prescription e.g. favouring the use of generic medicines via substance-based prescribing and introducing caps per prescribing doctor. Additional measures not related to e-prescription include a new reference pricing model that takes into account the three EU countries with lowest prices, and the renegotiation and reduction of pharmacy and wholesaler margins on reimbursed drugs (OECD 2013a; Siskou et al. 2014; Deloitte Centre for Health Solutions 2013). The sense of crisis certainly facilitated change nevertheless, this by itself is not sufficient. The overall outcome was made possible by a combination of institutional leverage, novel technological affordances, and pragmatic tactical decisions.

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England's Electronic Prescription Service

8

Infrastructure in an Institutional Setting

Ralph Hibberd, Tony Cornford, Valentina Lichtner,
Will Venters, and Nick Barber

8.1 Introduction

Primary care computing in the UK has been presented as a national success story for health informatics development and use (Benson 2002a, b). Despite each UK nation having its own devolved National Health Service and developing its own systems, primary care health professionals in England, Northern Ireland, Wales and Scotland all use electronic patient records, on-screen prescribing decision support, and electronic prescription printing. Recently this has been augmented by the adoption of electronic transmission of prescriptions (ETP), with each devolved nation's NHS developing their own version to meet local needs. The subject of this chapter is the solution adopted by England's National Health Service (NHS), which takes the institutional form of the Electronic Prescription Service (EPS).

England's EPS was designed to support the processing and management of increasing primary care prescription volumes, which have shown a consistent growth of around 5% a year for the last two decades. Currently, England's 56 million citizens receive over 1,000 million prescription items from NHS primary care services. Whilst the potential for electronic prescription transmission has been long recognised, the development and deployment of EPS as a national system has taken over 13 years (2003–2015). As of early 2016, deployment is

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ongoing, although the service looks to be gaining widespread acceptance as it has now been installed in 98% of the 11,844 community pharmacies, and 78% of the 7,803 GP practices in England (Health and Social Care Information Centre 2016).

In this chapter, we examine the making of EPS and the forces that shaped its present form and status. EPS has been assembled as an operational service from decades of technical development and pilot implementation efforts brought together within a specific project under the NHS National Programme for Information Technology (NPfIT) – the decade long centrally mandated initiative running from 2002 to 2013. It also drew heavily from (and at times changed) the established work practice in primary care. Our analysis adopts three interlinked temporal perspectives to trace the influence of existing systems, old and new infrastructures and wider interests in the way EPS has been assembled. These are expressed as; (1) a causal past represented by history and the installed base, (2) a concurrent present of established practices and change programmes seeking to influence them, (3) desired futures as reflected in policy goals and visions. Thus EPS is assembled from its past, its present and its future(s). This process is traced out using three interwoven perspectives; the realization and negotiation of *constraints* found in the wider NHS context that limit change, as *inertia* arising from limited resources and weak incentive structures, and in a purposive *fidelity* to existing institutional culture, seen here most directly in the history, practices and ethos of the NHS (Fig. 8.1).

This chapter draws data from a commissioned evaluation of EPS (see Box on Methods and Data), reported in Cornford et al. (2014), although the analysis here is new. In particular we focus on how the EPS entering wide scale use today (2016) draws on extant technologies and installed bases of infrastructures, and how this relates to and reflects the practices and interests of multiple stakeholders. EPS draws from, and contributes to, the long history of UK health informatics (Fig. 8.2). This is a history characterised by incremental development and pilot deployments, recurring local and national initiatives, and successive policies looking for service transformation through technology. The history begins with the computerisation of hospital admissions and hospital pathology laboratories in the 1960s (Brennan 2005), and continues into the present with a promise of an Integrated Digital Care Record (NHS England 2013). This history is punctuated by occasional failures, for example with the Care Records Service (CRS) component of the National Programme for Information Technology (Matheison 2011). Still, the NHS continues to pursue, with undimmed enthusiasm, the new frontiers of health informatics. Thus current informatics policy is focused on supporting a transformed service that embodies integrated patient-centred care, accountability in care provision, and the capture and curation of aggregated data for NHS management, research and the promotion of better health and healthcare (NHS England 2013).

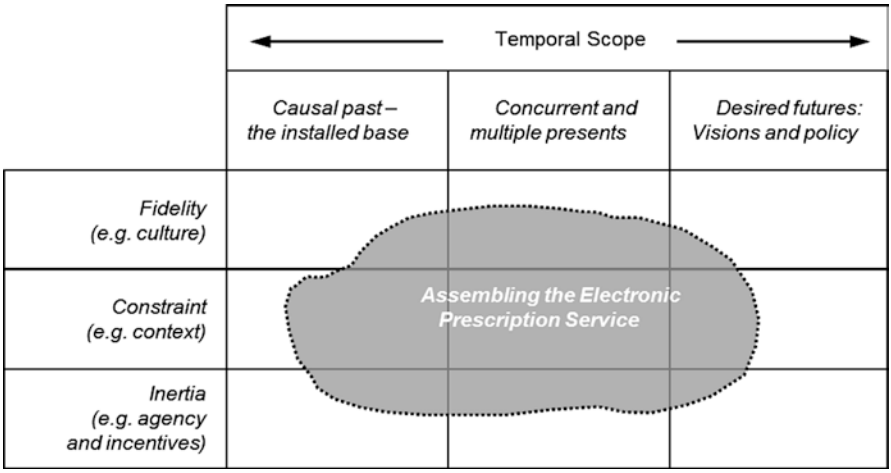

Fig. 8.1 The analytical model used

Methods and Data

This chapter draws from work conducted as part of the Evaluation of the Electronic Prescription Service in Primary Care, a project which ran from 2008 to 2013 and was funded by the Connecting for Health Evaluation Programme (Cornford et al. 2014; Hibberd et al. 2012; Petrakaki et al. 2012; Lichtner et al. 2012). In writing this chapter we identified from the project data key exemplars of where the installed base, which can be thought of as a multi-layered set of socio-technical systems, based on Cornford et al. (1994), constrained or influenced the development of the service.

The evaluation encompassed both a historical analysis and an examination of the contemporary development of the service through interviews with key stakeholders from the agencies and software companies developing the systems, end-users in the form of patients, GPs and community pharmacists, as well as observations of practice. This data provided an understanding of the intent of the system, its operation in various settings, and examples of operational surprises which often revealed unforeseen influences of the installed base.

The EPS has undergone further development since the evaluation research ended. To reflect this we also examined contemporary public literature from the EPS delivery agency, the Health and Social Care Information Centre, and from practitioner organisations, such as the Pharmaceutical Services Negotiating Committee, an organisation that has been an influential stakeholder in the development of the EPS.

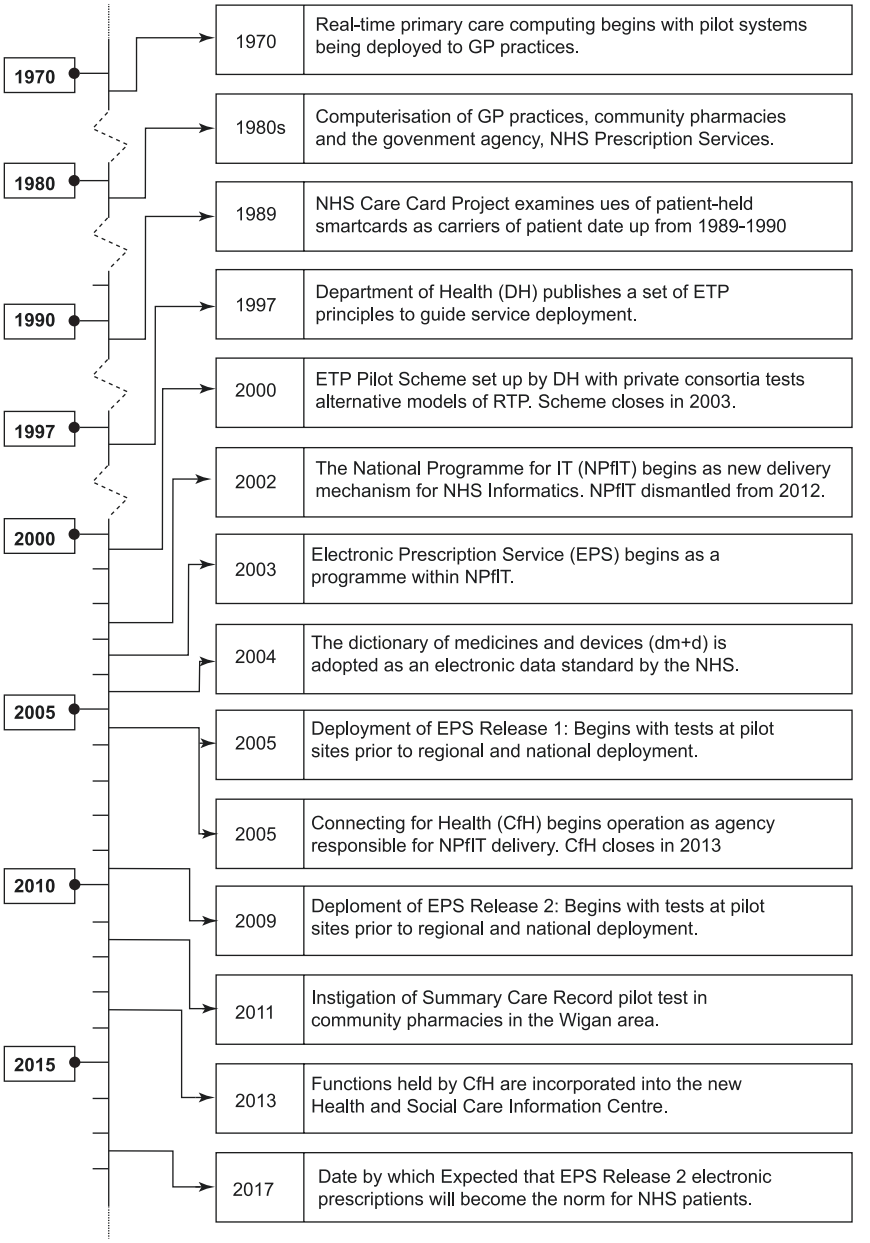

Fig. 8.2 Timeline of electronic prescription development in England

8.2 Primary Care and Health Informatics in England

The NHS commissions and delivers healthcare at a population level, supporting the development of health informatics to help achieve its broader remit for care. Funding for the service is through both general taxation and the charging of capped co-payments for some services, including primary care prescriptions. It commissions care from both public and private healthcare facilities. The NHS has also developed an unenviable reputation for reorganization of its core management structures (Talbot-Smith and Pollock 2006). Current policy, following the Health and Social Care Act of 2012, places emphasis on devolution of decision-making, service commissioning and budgeting. This landscape might appear incompatible with national informatics programmes such as EPS, and indeed EPS did emerge from a different economic and political era, being conceived in 2003 as part of the National Programme for Information Technology (NPfIT) that sought to direct informatics initiatives from the centre (Takian and Cornford 2012).

From its foundation in 1948 primary care in the NHS has been delivered mostly by private sector providers (Talbot-Smith and Pollock 2006). A rough division can be drawn between those who diagnose, prescribe and refer on to secondary care, typically general practitioners (GPs) and those licensed to provide therapeutic aids and drugs to patients, typically community pharmacies in high street shops. Both constituencies represent private businesses providing services to NHS patients though local and national commissioning contracts.

The devolved structure of primary care presents a challenge to new informatics based initiatives, insofar as any new service requires that primary care providers adopt compatible systems that are themselves supplied through competitive private sector markets, and to assent to sharing of data with both other primary care service providers and NHS secondary use services (Cornford et al. 2014). Thus NHS primary care providers and their informatics contractors, can and do at times hesitate and resist when asked to deploy new services and systems. Provision and use of health informatics services also reflects, in most cases, espoused health policy visions and strategies and come with some associated incentives. Thus, in the case of EPS there is a policy vision of community pharmacy as a resource that can support prescribers and patients by undertaking a greater role in the management of drug therapies for patients with chronic illness.

8.2.1 Prescribing, Dispensing and Reimbursing Primary Care Drugs

The typical pattern of prescription management in primary care is for the general practitioner to issue a prescription and for a community pharmacist to dispense against this, as appropriate. This division was first enshrined in the 1911 National Insurance Act which removed from prescribers the right to provide therapeutic drugs as part of a single care package (Anderson 2006). This had the effect of

supporting an emerging pharmacy profession that gained greater and greater importance over the next 80 years as an ever-expanding catalogue of pre-packaged ready to use, experimentally proven drugs displaced the remedies traditionally compounded by pharmacists (Wade 1993).

More recently, during the period from 1979 to 2013, the average number of prescription items dispensed in primary care per capita each year has increased from 6 to 19 (Government Statistical Service 1991; Comptroller and Auditor General 1992; Health and Social Care Information Centre 2015), with those over 60 years of age receiving on average over forty prescription items per year. Increasing life expectancies and the associated increases in co-morbidities suggest that the prescribing and dispensing activities of primary care will become more central to care, more complex and could also have greater potential for harm (Banarjee et al. 2011). In response, community pharmacy has been promoted as needing to have a greater role in management of therapeutic drugs (Zermansky 1996), which is reflected in policy around service digitalization and repeat dispensing (Cornford et al. 2014).

8.2.2 Computers in English Primary Care

Development of EPS has been able to exploit a substantial installed base of NHS primary care informatics which has emerged from over three decades of initiatives in community pharmacies, GP practices and by the agency responsible for reimbursing primary care contractors for therapeutic drugs dispensed, NHS Prescription Services (Hayes 2008). But despite computerisation efforts in all three of these constituencies since the 1980s, it was not until the EPS programme in 2002 that a concerted effort was made to digitize the exchange of prescription data. Prior to this data flowed between the three main constituencies using hand-written, and more recently, computer-printed, paper prescription forms, officially known as the FP10.

Of these constituencies, GP practices have the longest history of computerisation, stemming back to batch processing experiments in the 1960s and real-time computing with a shared primary and acute care electronic patient record in the 1970s (Hayes 2008). The advent of the personal computer in the 1980s, schemes to support the adoption of primary care computing such as the Micros for GPs scheme (Project Evaluation Group 1985), and a reorganization that placed emphasis on documenting care provision as well as experiments in GP fundholding, led to the development of GP practice computing in earnest with many vendors entering the market (Brennan 2005; Hayes 2008). The numbers of vendors of GP practice systems subsequently declined through the 1990s, following the imposition of mandatory accreditation, but adoption of computerisation increased, reaching 96% of GP practices by 1996 (Hayes 2008).

Adoption of these systems by GP practices was initially driven by the value that the systems held for these businesses in the face of contractual change. In community pharmacy, computerisation was also driven by business concerns. In the 1980s pharmacy wholesalers recognized the opportunity for computers to support

pharmacists in managing stock, and themselves in supporting ordering. These early systems, initially promoted and supplied by wholesalers, were subsequently developed as a platform that could integrate new clinical functionality. Thus as new professional requirements, such as maintaining patient medication records (PMRs) and creation of printed labels for dispensed items, came into force, these software systems were adapted (Shepherd 2008).

Given that it was the business opportunities provided by computers that drove the adoption of informatics by primary care providers, it would have been surprising if NHS Prescription Services (NHS PS) had failed also to adopt new informatics in support of its role of remuneration for prescription drugs dispensed. Although some prescriptions do attract a fixed patient co-payment (currently £8.20 ≈ €10.00 per prescribed item), the majority of funding for primary care dispensing is from the NHS, and is managed by NHS PS. Pharmacies make claims for the costs of dispensing therapeutic drugs to NHS PS using the prescriptions they have dispensed. Thus a prescription represents an invoice to be checked and paid as well as an authorisation to supply therapeutic drugs. It also provides a means to capture data on prescribing practices, and to collate data that can show how prescribers and GP practices are prescribing in comparison to their local and national peers (NHS Prescription Services 2011b, 2012).

NHS PS started computerisation in the 1970s as it became apparent there were no longer sufficient numbers of recruits to support the paper intensive process (Shepherd 2008). A later automation initiative, the Capacity Improvement Programme (CIP) launched in 2007 during EPS development, was similarly a response to concerns over the year-on-year prescription volume increases (NHS Prescription Services 2008, 2011a). The CIP was however still focused on the paper based system, using sophisticated optical character recognition to render prescription forms into digital data for processing.

8.2.3 Early ETP Experiments and Pilots

Computerisation of the NHS in the 1980 and 1990s inspired two in-vivo ETP experiments prior to the development of EPS. The first of these was the NHS Care Card programme of the late 1980s, which used the then novel technology of microprocessor based smartcards held by patients to transfer health record and prescription data between suitably equipped health care providers (NHS Management Executive 1991). Although this experiment, run in parts of England and Wales, did successfully demonstrate the service's concept, concerns over the cost and durability of the smartcards, and also of the lack of a back-up network to transfer data in case of smartcard failure, led to the abandonment of this solution (Hayes 2008; NHS Management Executive 1991).

At the turn of this century, ETP was revisited with a second NHS experiment using the new technology of electronic data interchange (EDI) and web services. The ETP Pilot Programme of 2000 invited private sector consortia to set up regional pilot projects in order to support the development of a set of standards that could underpin an England-wide ETP service (NHS Prescription Pricing Authority 2000).

From the start it was proposed that the outcomes of the ETP Pilot Programme would be reflected in a new ETP service that would be deployed in English primary care by 2004, although this timetable was later revised to 2008 as it became apparent that the institutional texture of the primary care environment was more complex than imagined. Some suppliers in the pilot believed that this could also provide an opportunity for at scale deployment of their pilot service, but the ETP Pilot Programme closed in 2003, as originally envisaged (Mathieson 2003).

The conclusions drawn were that the solutions developed were unable to meet stated institutional requirements around ensuring continuity of existing business flows between GP practices and community pharmacies (Department of Health 2004; Sugden 2003). More importantly, the pilot systems were incompatible with the new NPfIT vision of service integration, national systems, and shared resources (Brennan 2005). However, the vision of ETP as an EDI and network-based service remained and influenced the subsequent EPS.

8.3 Assembling the Electronic Prescription Service

EPS at its simplest just offers more reliable data transfer between the three main stakeholders using a digital version of the existing FP10 prescription form. Still, the influence of EPS inevitably leads to practice change across these institutional settings. Claims made for consequential change were often expressed as benefits to be realized and illustrate the service's expected influence on practice. Anticipated benefits included support for faster, more efficient prescription processing, reduced risk through elimination of transcription errors and the availability of electronic cancellation, reduced clinician prescription management workload, and increased patient convenience. Another suggested benefit, which was not pursued, was the expectation that the service could provide a proxy record of patient adherence to treatment through a record of dispensing events (Harvey et al. 2014). Concurrent changes in prescription management (discussed below) would later bring repeat dispensing prescriptions into the dialectic around EPS, and became more dominant as managers and policy makers became familiar with the possibilities this could offer (Cornford et al. 2014).

8.3.1 Transforming the Prescription

The benefits of EPS follow from one principal goal, replacing the paper form – known in the NHS as an FP10 – as the legal prescription by an electronic and digitally-signed equivalent. This form has traditionally been handed from prescriber to patient to dispenser and then passed onto NHS PS for reimbursement. Over the years, the FP10 has evolved to encompass a number of different functions for prescription management. The example shown below (Fig. 8.3) is for a repeat prescription. The left hand side represents the prescription which is dispensed against and will be used by the

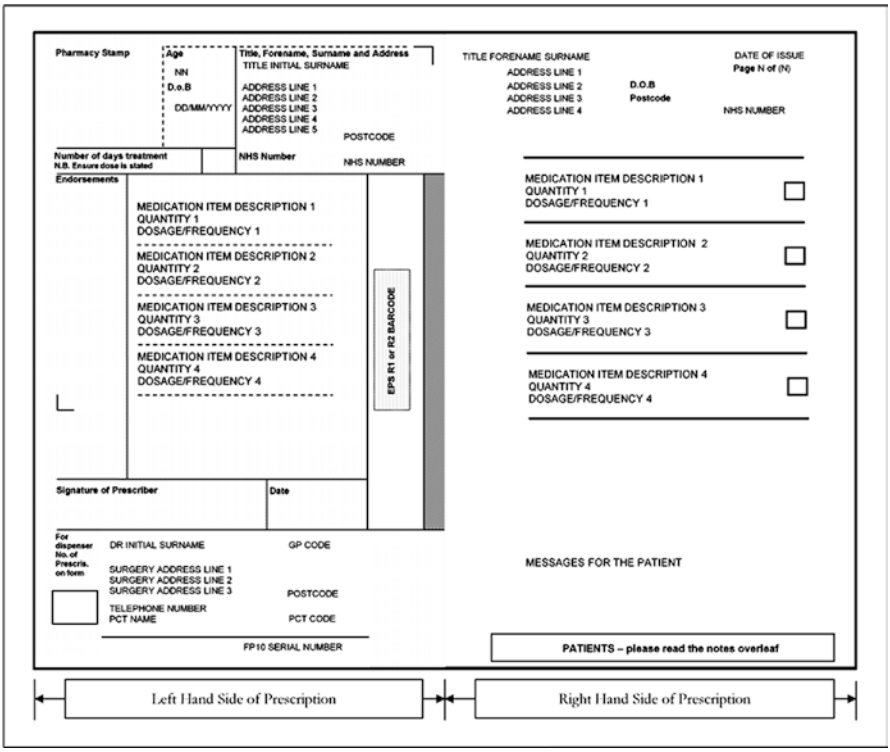

Fig. 8.3 English primary care FP10 prescription form (Gooch 2007a, b). Copyright © 2016, Re-used with the permission of the Health and Social Care Information Centre, also known as NHS Digital. All rights reserved.

dispenser to claim for what has been dispensed. The right hand side of the FP10 is a tear-off reorder form for use by the patient. Re-ordering is allowed for a set number of times until a review date has been reached, without the need for a GP consultation on each occasion. The right hand side also can be used by the GP practice for health promotion messages, or to advertise services, such as flu vaccination, which GP practices and community pharmacies might compete to provide. The back of the form (not shown) includes a signed declaration for those claiming free prescriptions.

Development of the EPS coincided with changes in how prescriptions can be managed. Prior to 2015 prescribers issued either acute or repeat prescriptions (Table 8.1). However, concerns over the capacity of GP practices to effectively monitor repeat prescriptions (Zermansky 1996) led to a new model of prescription management, the repeat dispensing prescription, where the activities of monitoring and control of prescriptions for chronic illness were handed to community pharmacy. This in turn triggered calls for change in the institutional relationship between prescribers and dispensers, principally around giving dispensers access to the concurrently developed national electronic Summary Care Record (SCR).

Table 8.1 Types of Prescription Used in English Primary Care (Cornford et al. 2014)

Type	Application	Management
Acute prescription	A one-off prescription for short term illness issued following a consultation between patient and general practitioner (GP)	The prescription is presented to the community pharmacist. Clinical checks are conducted by the pharmacist to ensure the prescription is appropriate for the patient. If the prescription is appropriate the relevant drugs are dispensed to the patient
Repeat prescription	Prescription is issued for the management of a long-term condition following a consultation between patient and GP. It is agreed by both parties that the prescription can be re-issued a set number of times until a review date without further consultations	Prescription is presented to the community pharmacist and checked and dispensed against as for acute prescriptions. The prescription is re-ordered from the GP practice using an order form printed with the prescription, and will be re-issued unless a review date has been reached or there are concerns over patient adherence
Repeat dispensing (introduced 2005)	Prescription is also used for long-term condition management. All issues of a prescription that the patient is expected to need until the review date are issued as a single batch. On paper these prescriptions are sent to a single pharmacy. With the use of electronic prescriptions each issue is a separate entity that can be dispensed against at any pharmacy	A batch of prescriptions is handed to the community pharmacist. Each issue is dispensed against when requested by the patient. Prescriptions are dispensed against in the same manner as an acute prescription with the addition of a check by the community pharmacist of patient's use of the medicine

8.3.2 Architecture

As a part of the NPfIT portfolio of projects EPS was explicitly designed alongside efforts to build services that met agreed national informatics standards. NPfIT was based on commitment to a common infrastructure through which constituent components such as EPS, SCR, the Care Records Service and others could connect and exchange data. At the core of this was a data-center and communications backbone, known as the Spine, providing common services and enabling the transfer of data between NHS computer systems. NPfIT also established a national secure network for the NHS – known as N3. The services used by EPS included the N3 network, extended to include links to high street pharmacies, and two principle Spine Services to manage the delivery of prescriptions: an Identity Agent service to establish the validity of prescribing and dispensing endpoints, and the NHS Smartcard to implement role based access control for prescribers and dispensers (Fig. 8.4). In addition a new underlying drug dictionary (dm+d) was developed – described below.

EPS functionality for prescribing and dispensing would however be delivered to health professionals by the vendors of community pharmacy and GP practice software, and to do so would make use of these core infrastructures and central data

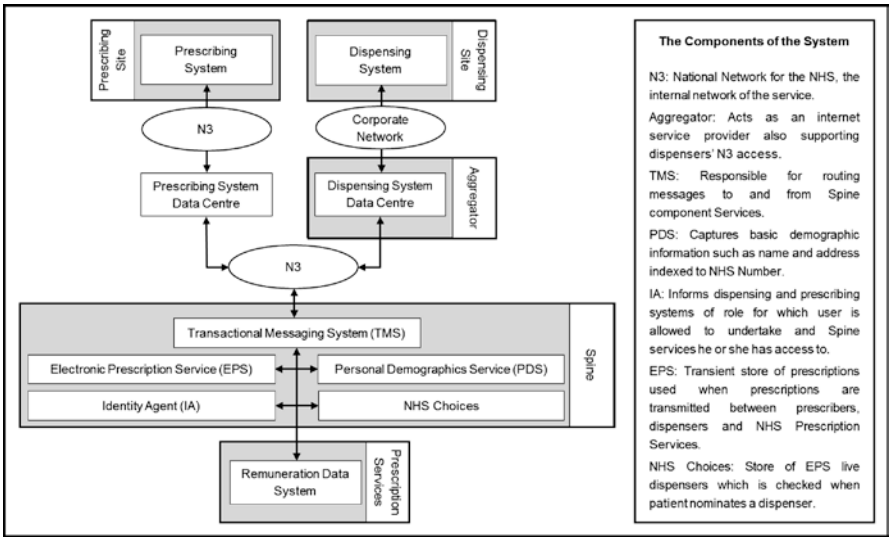

Fig. 8.4 Components of the electronic prescription service (Health and Social Care Information Centre n.d.). Copyright © 2016, Re-used with the permission of the Health and Social Care Information Centre, also known as NHS Digital. All rights reserved.

services. A set of output-based specifications were made available to software vendors that described how the EPS software for doctors and pharmacists should manage and process electronic prescriptions (Gooch 2007a, b). Compliance of software with these specifications was assessed through a multi-stage common assurance process (CAP) managed centrally (NHS Connecting for Health 2012). These specifications provided a partial definition of the operation of the service, but details as to the management of user interfaces and circumstances for the creation of paper versions of the electronic prescriptions was placed in system suppliers' hands.

Electronic Drug Dictionaries

Prior to EPS there was no single database of therapeutic drugs available for use within GP practice systems, system vendors choosing from a number of commercial suppliers, such as First Databank Europe, or opting to develop their own, as EMIS, a major software supplier, did. In parallel NHS Prescription Services compiled a monthly Drug Tariff based on manufacturer data, marketing authorisations, and latterly, dispensing volumes. One consequence of EPS was that a new and common underlying database to describe medicines as they were prescribed, dispensed and paid for was developed, the dictionary of medicines and devices (dm+d). This ontology can represent therapeutic drugs at multiple levels depending on how the data was to be used. To support access to existing decision support systems manufacturers might chose to map dm+d coding to their own dictionaries, which also allows the development of decision support across multiple international markets

8.3.3 Release Strategy and Deployment

EPS was structured and delivered to users as two sequential releases. The releases differed in their functionality and the demands made on dispensing and prescribing health professionals. This approach allowed for tests of the technical infrastructure to be conducted in the first release, including networking and the Spine services developed for NPfIT (Brennan 2005).

EPS Release 1 (EPS R1) focussed on augmenting the paper prescription with digital data (Fig. 8.5). A unique identifier for each prescription was created at the time of prescribing and printed on the prescription as a barcode. A digital copy of the prescription was then sent to the Spine. A pharmacy could scan this barcode and download a digital copy to be used to populate the patient medication record (PMR) in the pharmacy system and help in stock control and label creation. Although a dispenser could forward the digital version of the prescriptions to NHS Prescription Services, this functionality simply served as a test of prescription transmission with no immediate benefit for community pharmacy. In many ways EPS R1 was a partial parallel run of digital and paper systems side by side from which much was learned about the network and the software.

EPS release 2 (EPS R2) expanded the administrative and clinical functionality and enabled electronic and paper artefacts to trade legal status (Fig. 8.6). In EPS R2 the digital message has the legal status as a prescription, and is dispensed against and used to claim for remuneration. In addition, new clinical functionality in the form of repeat dispensing prescriptions and safety functions, such as electronic cancellation of prescriptions were added, with the expectation of more timely and effective delivery of prescription drugs to patients as well as efficiency benefits for GPs, pharmacists and NHS PS.

At the time that EPS R2 was ready to be deployed NHS primary care was composed of a number, of local health authorities, known as Primary Care Trusts (PCTs). In order to issue digitally signed electronic prescriptions, the PCT had to have Secretary of State Directions (e.g. permission). This was issued based on the readiness of the PCT to manage the local deployment process. Control over which prescribers could issue electronic prescriptions was at the discretion of the PCT. A GP practice would only be allowed to use EPS R2 when at least 80% of their existing prescription volumes could be sent to dispensing sites that had EPS available. This ensured both that there were local places to send prescriptions to, and helped avoid market distortion.

However, whilst a prescriber might be authorised to issue electronic prescriptions, not everything prescribed could be sent electronically, specifically certain schedules of controlled drugs –drugs that can be abused or employed for nefarious purposes (Department of Health 2014). Following a high profile case of murders committed using diverted controlled drugs, the department responsible for drugs policy, the Home Office, revised the Misuse of Drugs Act to restrict the

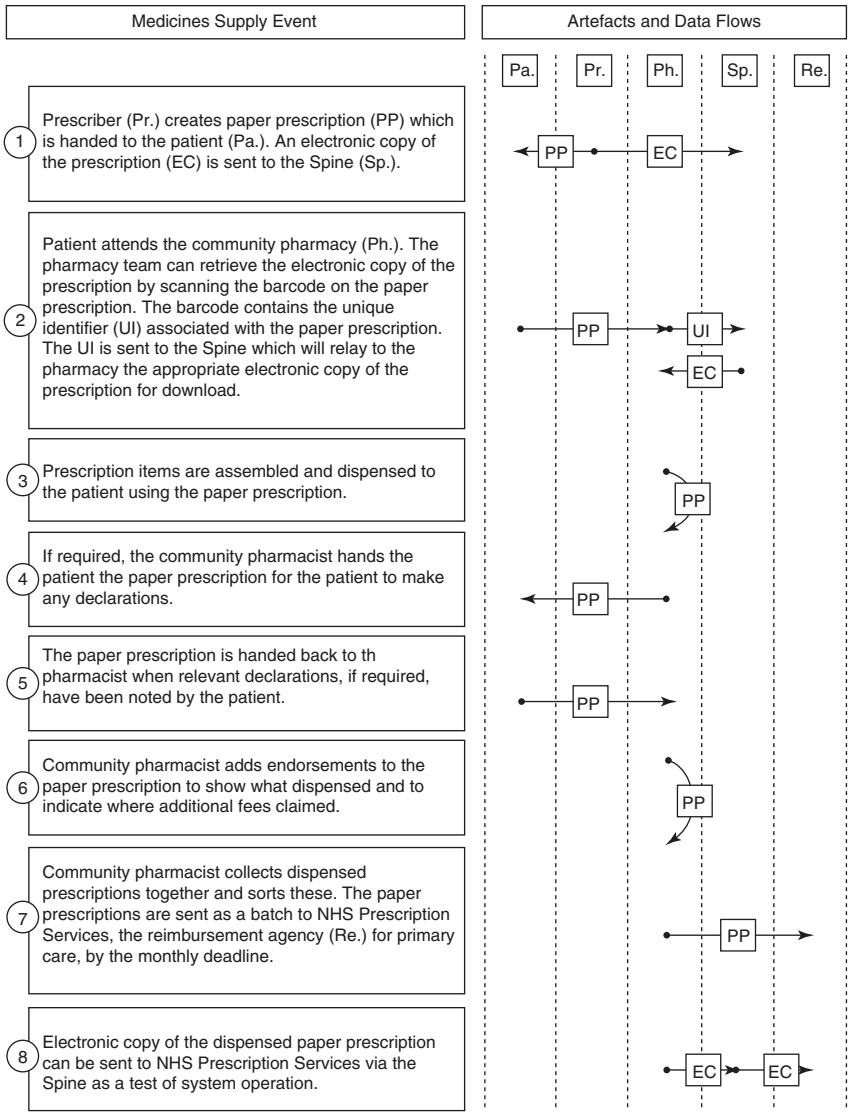

Fig. 8.5 Operation of the electronic prescription service release 1

opportunities for diversion. So, despite the potential that EPS had in restricting and auditing supply, it was not until July 2015, that the Misuse of Drugs Act and other regulations were amended to allow for full electronic prescribing of controlled drugs (Department of Health 2015).

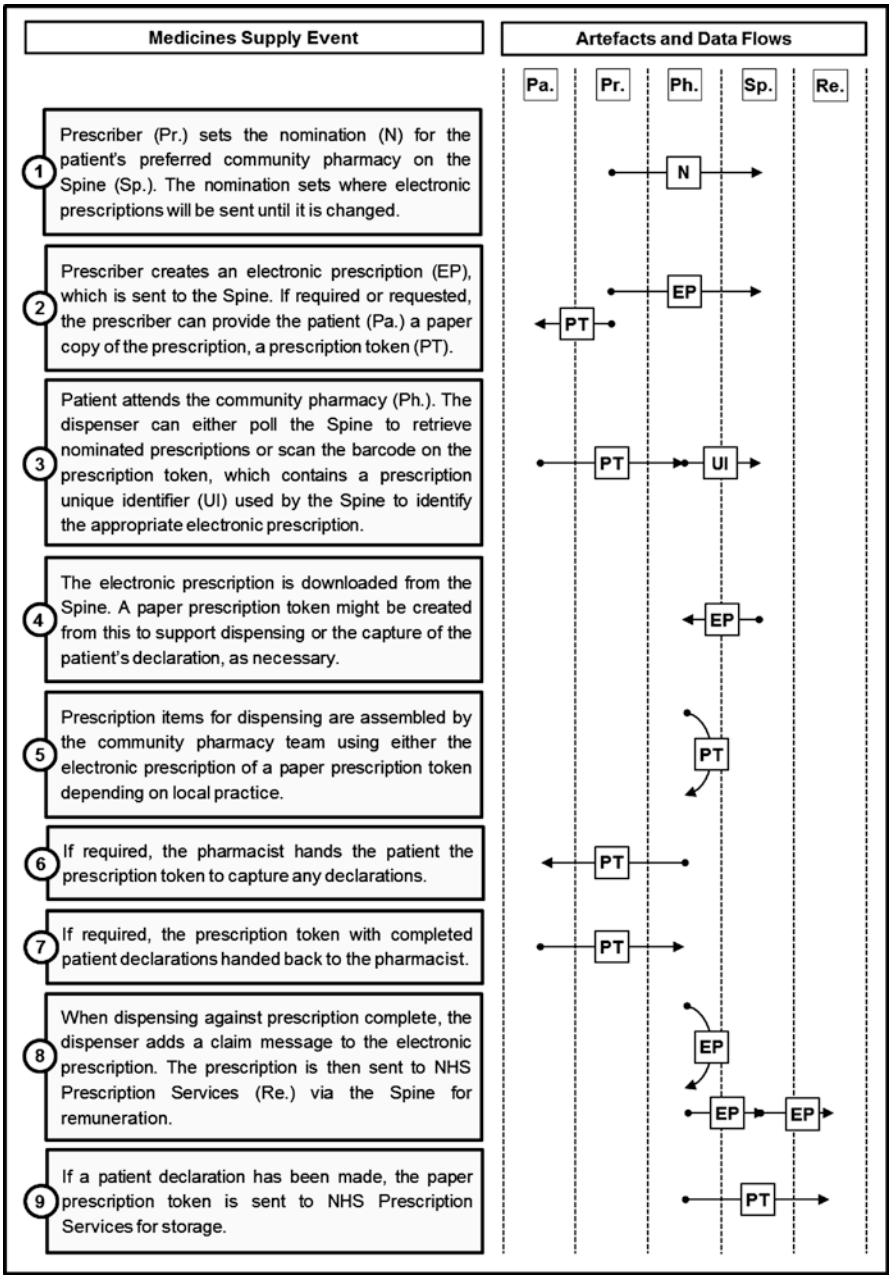

Fig. 8.6 Operation of the electronic prescription service release 2

8.4 Assembling EPS as Past, Present and Future

In this section we consider the nature of the work needed to assemble the EPS we see today. We do this using a model that identifies the work of assembly in terms of *constraints* imposed within the context of EPS development and deployment, *inertia* resulting from unaligned incentives and lack of resources, and finally concern to maintain *fidelity* to the mission of the broader NHS, its culture and practices (Fig. 8.1).

8.4.1 The Physical and Material in a Digital World

We start by considering EPS in its technical/architectural form employing a range of digital services to support communication of relationships about the physical world in terms of medicines, people and locations. General communication standards introduced across the NHS by NPfIT such as ebXML, HL7 and the clinical coding terminology SNOMED CT, provide underlying substrates for this communication. Other specific new services were developed, for example, electronic verification of users and sites by Spine Identity Agent which check both validity of role-profiles on individuals' Smartcard and the identity of endpoints through Organisational Data Services (ODS) codes. As noted above, the therapeutic drugs that can be prescribed using EPS are described in a new electronic dictionary of medicines and devices (dm+d) developed for EPS.

These protocols, databases and services each fulfill necessary roles and functions in the new EPS, but EPS must also show some fidelity to established structures, practices and professional roles within the NHS. A primary example is the FP10 prescription form. The FP10 endures within EPS in many ways and links it to the past and facilitates its viability in the present. The continuing presence of the FP10 within EPS is in part a means of overcoming inertia and institutional constraints in implementation and also a demonstration of fidelity with the past. Retaining elements of the FP10 in the assembly ensures a better 'fit' of the new EPS in the wider health care context, both conceptually and practically. The FP10 also endures in a printed form, although without legal status. For example, a printout may support the FP10's traditional role in collecting patients' signed declarations for prescription charge exemptions as well as meeting dispensers' needs for a portable representation of the prescription, a picking list, against which to assemble drugs when dispensing. Similarly, a prescriber may wish to give a patient a paper copy of their drugs to keep, even if the prescription itself is electronically transmitted. And we know that 'handing over the prescription' is a common way that doctors politely terminate a consultation.

In the new electronic world, just as with paper prescribing, an EPS prescription can be composed of multiple prescription messages, each message constrained to a maximum of four prescription items. This constraint, originally imposed by the physical size of the FP10 form, endures in EPS reflecting the need to replicate existing FP10 processes, for example in its role as a dispenser's picking list. This fidelity is

reinforced by the inertia implied in the delivery model used for EPS, in which providers of existing prescribing and dispensing software were invited to integrate relevant functionality into their *existing* software systems. As a result many aspects of EPS software design, in particular interfaces, drew directly on existing processes for FP10 handling in GP practices, Community Pharmacies and NHS Prescription Services.

8.4.2 The Reinvention of Services

EPS is constrained and shaped by the complex and multiple institutional and technical relations in which it is embedded. The confluence of multiple institutional presents place constraints on how and what EPS can do or change, and can conspire to reduce the service functionality and availability. These constraints invite resolution over time through such things as regulatory change (e.g. controlled rugs), workarounds and repurposing of infrastructures. Indeed, work-arounds are a common and an essential part of EPS's ability to respond to challenges and reshape itself over time.

This is also seen in the ways that the NHS Smartcard is repeatedly renegotiated as a part of EPS. The NHS Smartcard implements a Role Based Access Control (RBAC) model in which access to services are associated with specific privileges for individual's roles stored in the Spine's Identity Agent (NHS Connecting for Health 2011). A health professional's NHS Smartcard has to be in an attached reader for the session and a password entered at the start of a session. This is broadly suitable to work practices of prescribers in primary care and such use, for example by doctors preparing prescriptions, predates EPS.

This model was not, however, found appropriate for dispensers in community pharmacy and indeed was never designed to encompass 'non NHS' persons in private organisations – the status of a community pharmacist, either as a permanent or locum staff. The result is that new models of Smartcard use emerged in the form of work-arounds. First, for EPS R1, given access is only to an electronic copy of the patient's prescription, information that the community pharmacy already has, the solution found was simple. Each community pharmacy was issued with an NHS Smartcard that acted as a proxy for the site, and which represented shared rather than a personal roles and privileges. But this 'fix' could not work in EPS R2 where dispensers gained access to Spine services that support inspection and amendment of patient data, which requires an audit trail (NHS Connecting for Health 2010).

For EPS R2, community pharmacies moved to the model used by NHS clinicians. In this model the Spine Identity Agent records the identity of the clinician, the clinician's roles and the sites at which this role is enacted, each site being identified by an ODS code. Locum community pharmacists, moving often from site to site, posed a problem if their ODS mapping requires frequent updates. The solution found was to create a virtual organisation for dispensing staff, initially community pharmacists but later dispensing technicians too, which was given the ODS code FFFFF, the 5-F code (NHS Connecting for Health 2010). This workaround allowed an EPS R2 user access to limited patient data. However, it is now policy that pharmacists have access to the Summary Care Record (SCR) – a national summary of

the individual health record including medicines prescribed, seen as an essential tool to support pharmacists in safe therapeutic drug supply. This created a need to reinvent the process once again to provide a more detailed audit trail. Now locum staff access the SCR by the 'emergency' access button *plus* manually inputting the ODS code for the site where they are working (Royal Pharmaceutical Society 2014).

8.4.3 Ruthless Standardization

> We will improve the leadership and direction given to IT, and combine it with national and local implementation that are based on ruthless standardisation. (Department of Health 2002)

NPfIT, the large national programme within which EPS was initiated, started out with a mantra of 'ruthless standardization'. It took time to dilute and finally wash this idea away. EPS as it has been delivered is very much a child of this policy and the retreat from it. Initially NPfIT proposed that all GP systems would be replaced with just one of two national 'solutions' incorporating EPS. In time there was revolt as GPs realised they would be coerced into giving up systems they knew and trusted. To placate them, in 2006 a new model of GP software procurement was established, GP Systems of Choice (GPSoC). This allowed GP practices theoretically to adopt any software that offered GPSoC functionality including EPS and the Summary Care Record (NHS Connecting for Health 2008).

The GPSoC model of approval based around output-based specifications (OBS) only defined how *electronic* messages would be handled. So controlled drugs initially fell outside of EPS and thus also fell outside of the OBS. Consequently, with no guidance available as to how to manage prescriptions which contained both EPS and non-EPS items, no common model was proposed for managing these situations. Some software suppliers choose to prevent any part of a prescription containing controlled drugs being transmitted electronically, others choose to create an electronic prescription for non-controlled drugs, and in parallel a paper prescription for the out-of-scope controlled drugs. Receiving drugs from GP practices with systems adopting the latter model caused confusion and inconvenience in their own work practices and for patients. This was only resolved when the law on controlled dugs changed.

A more active approach to addressing inertia and limited resources is seen in the structuring of development of pharmacy systems and the lengthy period of software testing required by the Common Assurance Process (NHS Connecting for Health 2008). This stepped assurance process for both dispensing and prescribing systems, moved from safety case analysis through to in-vitro testing with test messages in a sandpit environment through to in-vivo testing in a limited number of sites with a test set of messages, and later, real prescriptions. This detailed programme provided a mechanism through which to focus resources and supplier attention. Deliberate selection of early implementation sites on the basis of their readiness also allowed for the gradual expansion of the service and provided some quarantine for problems arising and unexpected events.

8.5 What Can the Electronic Prescription Service Teach Us?

Looking back over the history of EPS, what stands out is how much of EPS is formed by hybridisation of the digital and the physical/material. EPS was conceived to be new and powerful, embodying policy visions of transformation, but it had also to fit within existing processes and work practices, mimicking existing data flows, and co-opting core artefacts such as the FP10. Thus a flexible and evolving assembly of the digital and the physical was necessary for EPS to come into existence. Further, it is from the institutional environment as much as the installed base of infrastructures that the necessary conditions and resources for EPS are mobilised, assembled and sustained. Of course in this they also create (assemble) the conditions for complications, as we saw with regard to management of prescriptions for controlled drugs in the early implementation of EPS and the multiple reconfigurations of the NHS smartcard RBAC system.

EPS also illustrates how inertia, as represented in the limited capacities of dispensing and prescribing system suppliers to resource change, can be managed through institutional arrangements such as testing and controlled deployment. NPfIT and those managing the deployment used the power to establish specific arrangements to overcome inertia and channel limited resources within the supply network and in the context of use. Even a programme with unprecedented political commitment behind it, as NPfIT had at the outset, had to remain flexible. So our final message drawn form EPS is that the search for new opportunities within and beyond the installed base is driven by a creative search across institutional spaces as much if not more than across technological spaces. The installed base is in this way more diverse, and more pliable than we might at first think, and introduction of innovation rests on the opportunities and routes carved through.

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9 The Challenges of Implementing Packaged Hospital Electronic Prescribing and Medicine Administration Systems in UK Hospitals: Premature Purchase of Immature Solutions?

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9.1 Introduction

This chapter explores the difficulties experienced in recent attempts to implement 'packaged' Hospital Electronic Prescribing and Medicine Administration (HEPMA) systems in NHS England. Though electronic prescribing was originally conceived as a pharmacy technology, it has become the occasion for integrating various other kinds of digital information (e.g. laboratory test results) at the point of care and for sharing this information across the care pathway. HEPMA in the United Kingdom (UK) has thus served as a stepping stone in developing hospital-wide infrastructures that directly support both diagnosis and care delivery. Considerable effort was needed to *integrate* HEPMA modules within the hospital information

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infrastructures and to *interface* them with external systems – and other parts of the health system, notably primary care. The difficulties besetting attempts to implement HEPMA as Commercial Off The Shelf (COTS) packaged software have highlighted the gap between the generic workflow models embedded in standardised COTS solutions (many of which were developed overseas) and the diverse practices of particular UK hospitals. Similar problems arose with previous attempts to implement packaged enterprise systems (ES), but were ameliorated through a protracted social learning (Sørensen 1996) process involving vendors, suppliers and various intermediaries. Comparing HEPMA and ES highlights the current immaturity of the HEPMA market. This is characterised by: the relatively embryonic linkages between HEPMA vendors and their potential market of users; users' lack of understanding of the exigencies of exploiting packaged solutions; vendors' limited understanding of user requirements and poorly elaborated strategies to address diverse user needs in generic solutions.

Stakeholders managing health systems in many countries have invested substantial efforts to implement and deploy electronic or ePrescribing systems (Mozaffar et al. 2014; Cresswell et al. 2013) to support prescribing decisions in health organisations (Aarts and Koppel 2009; Bates et al. 1998). The National Health Service (NHS) in England has similarly invested considerable resources in these systems. It describe these systems as:

> *The utilisation of electronic systems to facilitate and enhance the communication of a prescription or medicine order, aiding the choice, administration and supply of a medicine through knowledge and decision support and providing a robust audit trail for the entire medicines use process. (NHS Connecting for Health, England)*

9.1.1 The UK Context for Hospital Electronic Infrastructures

Health care in the UK is primarily provided through the publicly-funded National Health Service (NHS). With over a million employees, the NHS is an exceptionally large and complex organisation (Hibberd et al. 2016). There are differences between the NHS in each of the devolved administrations (England, Scotland, Wales, Northern Ireland). This chapter focuses on developments within NHS England, which is by far the largest. Hospitals are run by regional health authorities, originally known as Primary Care Trusts, with primary care delivered by multiple independent General Practitioners. Despite a very long history of hospital computerisation stretching over 60 years, the development of hospital electronic infrastructures was seen to be held up, *inter-alia*, by the fragmentation of procurement between hospitals and trusts. Repeated attempts to improve integration culminated in a major national initiative: the National Programme for Information Technology (NPfIT) in which, as well as creating a central transaction processing 'Spine' (Hibberd et al. 2016), selected software applications were to be centrally procured and implemented in NHS hospitals (Sheikh et al. 2011; Robertson et al. 2011). This initiative however encountered numerous problems and, as a result, the Department of Health instituted

a change of direction from a 'centrally driven strategy of replace all' to 'locally chosen and implemented systems' (Robertson et al. 2011; Sheikh et al. 2011).

NHS calls to improve the quality, safety and efficiency of healthcare, coupled with substantial financial support, have provoked widespread interest in the timely implementation of HEPMA systems in UK hospitals (Buntin et al. 2011; Black et al. 2011; McKibbon et al. 2011) and attracted a number of UK and overseas suppliers. Electronic prescribing is already well established in England's primary care (Avery et al. 2007; Fernando et al. 2004; Hibberd et al. 2016). Over the last decade, several attempts have been made to implement HEPMA systems in secondary care. In 2013 only 13% of hospitals had hospital-wide HEPMA systems (Ahmed et al. 2013). This is however expected to rise rapidly as a result of the £500 Million *Safer Hospitals Safer Wards* technology fund launched in 2013 and a policy target of complete implementation across the NHS by 2020 (Carter 2015). The move towards local selection of systems has resulted in hospitals being faced with a range of options, none of which are however currently perceived as fully meeting the needs of the English market (Mozaffar et al. 2014).

Whilst the first generation of HEPMA systems was developed within hospitals, today we see a marked shift away from home-grown solutions towards COTS 'packaged' software (Mozaffar et al. 2014). There are a number of reasons for this move. These include the very substantial costs associated with developing and maintaining bespoke systems (and the stalled progress and anticipated failure of a flagship project to jointly develop an integrated solution within/for English hospitals[1]), the perceived advantages of packaged solutions (in terms of functionality/price, dependability, maintenance) and problems with limited interoperability between providers (Schiff et al. 2003; Westbrook et al. 2012). However, standard COTS solutions, built around generic models of the user organisation, may be far removed from the workflows of particular adopter organisations, necessitating a considerable effort to configure and customise software or to adjust local working practices (Pollock and Williams 2008). Despite these investments, the HEPMA market in England is faced with a great deal of uncertainty and is undergoing rapid change and evolution (Aarts and Koppel 2009; Mozaffar et al. 2014). As well as intense policy pressures and incentives to adopt HEPMA, hospitals are confronted by the lack of maturity of current supplier offerings, their limited tailoring to the English context, the diversity of systems and lack of knowledge about the available options. These factors all contribute to the challenges that hospitals face in procuring, implementing and realizing the benefits of these systems (Wolfstadt et al. 2008; Bates et al. 2003; Cresswell et al. 2013; Mozaffar et al. 2014).

[1] Thus the Lorenzo patient system being collaboratively developed under NPfIT encountered such serious delays that its wide adoption is seen as increasingly unlikely. Tameside Hospital NHS Foundation Trust recently awarded the highest possible risk rating to its Lorenzo project, citing "potential risks to patient safety quality, information governance and performance trajectories" (HSJ 2014).

In this chapter we examine the problems that have arisen in the supply, procurement and implementation of packaged HEPMA solutions. We explore the reasons for this in terms of the state of development of the HEPMA market – encompassing the strategies and capacities of both vendors and adopters. Our analysis brings to bear insights from the Biography of Artefacts and Practices (BoAP) perspective (Pollock and Williams 2008) that emerged from our previous long-term programme of research into the evolution of the Enterprise System market. BoAP draws also upon recent related analytical advances in relation to the conceptualization of information infrastructures and to the formation and maturation of technological fields. As we outline below, this suggests that analysis of the development of information infrastructures (IIs) needs to engage with the exigencies surrounding technology supply and the increasing resort to commercially-supplied solutions. For example (Koch 1997), highlighted the choice between "bricks and clay" when building corporate IIs: between procuring integrated solutions or configuring together large numbers of small infrastructure components. The latter offers greater scope for adopter organisations to exercise choice in the selection of components and (because they tended to be technologically simpler) greater potential influence over their design. Integrated solutions offered less flexibility but transferred the integration challenge to the supplier. They could also operate as a platform onto which other offerings might be erected (Koch 2007). This in turn suggests that theories of the installed base need to go beyond a focus on the evolution of individual IIs and take on board the complex sets of relations linking multiple vendors and their adopter communities. We will explore this conceptual framework in our Discussion.

Methods

This chapter draws upon an extended national research programme investigating the implementation and adoption of HEPMA systems in English hospitals funded by the National Institute for Health Research (NIHR). In this chapter we re-examine these findings in relation to the goals of this book to understand the development of health infrastructures and examine the influence of the installed base.

We draw particularly upon a study of the current status of the English HEPMA market (Mozaffar et al. 2014, 2015; Cresswell et al. 2013; Crowe et al. 2010). We collected qualitative data from both suppliers and adopters of various HEPMA systems in England. Data collection, undertaken over the period October 2012 to October 2014, involved a combination of semi-structured interviews with staff of six English hospitals adopting HEPMA and of four system vendors, ethnographic observations (totalling 21 h) of user groups and hospital practices, a supplier round-table discussion, and collection of publically available documents. Interviews and data analysis were conducted in tandem – research foci and theme emerged inductively over a number of iterations. Table 9.1 summarises the data sources and collection methods.

Table 9.1 Data collection methods

Method	Data source	Focus of enquiry
Semi-structured interviews (ranging from 45 min to 2 h)	Four suppliers	(a) The current status and trajectory of growth of HEPMA systems in England;
	Six hospitals	(b) Strategies in design, development and adaptation (Anglicization) of the system;
		(c) The problems faced during implementation and their possible causes; and
		(d) The supplier-user relationship throughout the project lifecycle
Observations	Two user group meetings	(a) The technological contents of the discussion;
		(b) The supplier-user relationships; and
		(c) Decisions being taken.
Focus group	Supplier round-table discussion	(a) Challenges and opportunities for suppliers from the early stages of project initiation to implementation;
		(b) Suppliers' experiences of go-live and system stabilization; and
		(c) Suppliers' views on system optimization and enhancements

9.2 Understanding the Uneven Success of HEPMA

Overall there had been a relatively low uptake of these products by English hospitals and implementation has been slow (Mozaffar et al. 2014). This market was undergoing rapid cycles of change with many suppliers entering and offering a wide range of products in terms of functionality and architecture. Our analysis suggests a range of explanations for the current uneven growth and variable success of HEPMA systems in England, rooted in suppliers' strategies and adopters' current reactions to the technology and the market.

9.2.1 How HEPMA Systems Are Constituted: Extension of Non-clinical Systems

Our earlier study on the spectrum of available HEPMA systems in England identified a wide range of systems including 13 hospital-wide applications and a range of specialty systems in implementation or use across English hospitals (Mozaffar et al. 2014). Nine of these systems were developed outside England and were introduced into the English market over the past decade.

We studied four HEPMA systems. None were initially designed as HEPMA systems.

One of the products in our sample involved a pharmacy stock control system, which was extended with the addition of HEPMA functionality including what is sometimes described as computerized physician order entry (CPOE) and

computerized decision support (CDS). This medication-focused system offered basic integration between the two modules but it was not a fully integrated hospital information system. This was a standalone application that covered inpatient needs, discharge prescribing, and pharmacy stock control. Interfacing strategies were used to connect this system with other systems used in hospitals. During this the course of this study, plans were made to extend this system by designing and developing the discharge prescribing system.

There were two multi-modular integrated 'systems', which arose through the expansion of insurance or billing systems for U.S. hospitals into integrated hospital-wide systems with the additional modules covering various areas such as inpatient and outpatient prescribing, electronic medical record, clinical imaging and laboratory, linked into an integrated whole with one underlying database. The final system was initially designed as an electronic patient chart system and then expanded over time to include a scheduling system and HEPMA modules (initially only inpatient prescribing, though during the course of this study, plans were made to extend this system by designing and developing the discharge prescribing system). Thus, we saw that the promotion of HEPMA functionalities had pulled in product offerings and component technologies from different sources with different historical paths, which resulted in packages with rather different architectures and configurations.

Members of adopting organisations noted that the two U.S. 'integrated systems' emerged by adding multiple modules to what was originally a billing/insurance management system, formed around calculating the costs of drugs and saw this as an important factor in the problems in implementing and using these systems. They often described these as 'non-clinical systems', to draw attention to the fact that they arose as an extension of an already existing product with a different focus.

> *…over the years they have progressed from the original billing system or pharmacy stock control systems to now be basically sold as EPMA* [ePrescribing and medication administration] *systems …. It's just a billing system… the funding for the hospital was gained raising bills from the patients they treated. So they needed a full audit trail to know what went on with the patient so they can charge the right amount of money. So again they were originally billing systems but they started to tag on clinical functionality on them (Adopter Interview, P1)*

These users questioned the clinical merits of offerings that were not initially designed as clinical systems, but emerged by adding HEPMA functionality to non-clinical systems:

> *…in recent times there has been a lot more influx on the market. The EPMA systems are generally changing to focus on the clinical functionality… but whether you could say that the system is totally designed around the clinical users interface is a debatable question… if you want something to be a clinical tool then it should be clinical enabling and not something like clinical disabling … do we want to collect clinical information to make clinical judgment better or do we want it to manage the process that we are doing when we are trying to treat patients (Adopter Interview, P1)*

The non-clinical origins of these systems were seen as resulting in interface designs and workflows that were not centred around patient care pathways. A clinician,

using the HEPMA system built around a stock control system, felt that system design might usefully take a different starting point:

> *…our starting point is not just prescribing a drug, our starting point is actually saying you come in with this condition therefore your pathway is this. (Adopter Interview, P2)*

We observed a wide range of HEPMA systems shaped by the history through which they were constituted. In general the trend was to add HEPMA functionalities to already existing (non- ePrescribing) systems or to adapt existing systems to accommodate the newly required functions. These systems had inherited some of the characteristics of their source system and this affected their usability. Despite significant technical differences between the solutions, we encountered homologous problems. In particular, in the process of expanding the scope of systems, suppliers seemed to have underestimated the complexity of HEPMA as a clinical system and the particularity of user activities (a failing that closely mirrored criticisms of early ES offerings two decades earlier).

9.2.2 Adoption of Systems That Had Been Developed Outside England

Mozaffar et al. (2014) highlighted that more than half of the systems available in England originated in other countries. Respondents attempting to implement these systems in English hospitals frequently drew our attention to this point which they saw as representing a major problem, as:

> *…their* [US] *way of working is very different to the U.K. based working (Adopter Interview, P2)*

The lack of alignment between 'foreign' supplier offerings and UK hospitals' internal processes and needs was seen as a major barrier to implementing these systems.

> …[Product Name] *is a U.S. system and it works very well for a U.S. hospital, but some things in the U.K. are quite different specially around medicines practices and we are still working with* [Supplier Name] *to see if we can get some of their products changed to better reflect our workflow (Adopter Interview, P4)*

This became clearer when adopters expressed a desire to see England-specific solutions being developed around 'generic' English hospitals' needs.

> *In terms of medicine there are a number of issues we have with* [Product Name] *and most of these are issues that aren't just local to* [Place Name] *they're issues that we think are indicative across other U.K. sites… (Adopter Interview, P4)*
>
> *Well a lot of it is U.S.-based but they have to customize it to the U.K. market because we are different, so I mean that's why we have had a number of meetings with them and with the* [Product Name] *user group to explain, you know, we're different and they know this but we keep having to remind them. (Adopter Interview, P5)*

Overseas suppliers emphasized that they were aware of the differences between the two countries and highlighted that they had particular ways of catering for these needs, in particular by offering England-specific versions of the application.

> *An interface to a formulary vendor for medications is standard in the U.S. but we obviously had to go above and beyond knowing that there are different requirements, there's different information on drugs in the U.K., you know, how they're numbered and tracked is different, you know, DM&D* [Dictionary of Medicines and Devices – unique identifier given by NHS] *number does not exist in our U.S. software (Supplier Interview, P6)*

However, despite pressure from hospitals and end-users, participants in user group meetings complained that many suppliers had been slow to create England-specific solutions.

Some vendors appeared reluctant to invest the significant resources needed to implement these changes, particularly where they only had a small presence in the English market. Other suppliers (and particularly those with a stronger foothold in and expectation of a larger share of the market) were deploying strategies to create England-specific versions of the products. However the challenge seemed to be more substantial than they had anticipated. As they began to implement these systems in English hospitals, they were confronted by growing numbers of requests to adapt the systems to local practices and preferences, which forced them to take on board multiple cycles of modification to their products. However at the time of the study, with only a handful of hospitals having implemented their system, the majority of these systems were in the early stages of being 'anglicized'. Hence, what we observed were products in their infancy with respect to English-specific requirements which arose as a result of differences in national systems and policies (e.g. between private insurance-funded health care in the United States of America [USA] and the public-funded UK NHS) and particular hospital practices (e.g. differences in discharge processes). Some of these overseas suppliers had prior experience and knowledge of the English market. However they tended to develop their English version as an extension of their current non-English HEPMA system. We interviewed one supplier which had had live implementations in England of an older product for over a decade, but which was also offering its new HEPMA product to the English hospitals.

> *…at that point after several hospitals* [in the USA] *were up running live and stable with the software that's pretty much the version that we took as our initial like U.K. kind of starting point… And basically where we started there were certain items that we knew, we knew were going to be different, for example in the U.K. wait lists, 18 week waiting, CDS reporting those are like three kind of big areas that, you know, don't exist in the U.S. [American] software so we literally had to start with some of those areas and we just started from what we knew the requirements were in the* [Old Product Name] *environment and fit those to the, you know, the* [New Product Name] *product, you know, the new version.(Supplier Interview, P7)*

NHS England is seen as a target for many overseas suppliers from Europe and the English-speaking world, though it is only a secondary market for many U.S.A. producers. It is not uncommon for systems to be initially developed for local customers within a national market before being redeveloped for the international markets

(Pollock and Williams 2008). As a result, system architectures may be sub-optimal for the English market. Users who were attracted by the powerful functionalities offered by non-English systems found themselves caught in an unanticipated and slow process of joint system redevelopment with the supplier in a protracted implementation. Suppliers entering the English HEPMA market found themselves needing to address in a compressed timeframe: (1) the NHS policy context and generic English hospital's needs; and (2) the widely differing specific needs of individual adopting hospitals. This in turn called for some way of prioritizing user requirements and selectively developing solutions.

9.2.3 Suppliers' Configuration and Customization Strategies

Suppliers of packaged organisational technology solutions need to develop effective strategies for addressing the diversity of user demands for modifications and new functionality. Experienced suppliers had learnt the need for strategies to cater for increasing diversity as their user-base grew in size. This required them to develop a strategic vision for their software product and its longer-term development, to keep control over the overall architecture of their product as it moved forwards, in the face of the plurality of adopter demands. This allowed them to decide which change requests they would entertain, which changes they would be unable to support, and which changes could only be undertaken by end-users themselves (Pollock and Williams 2008).

In order to retain overall control over architecture in the face of diverse users, software packages are designed around a basic set of organisational functionalities - a 'generic kernel' (Pollock and Williams 2008). Libraries of 'templates' are built upon this kernel, catering for commonly encountered workflows and practices. Such software packages are 'user-configurable', meaning that they incorporate pre-programmed features, which can be selected to meet the needs of various environments through setting up parameters rather than rewriting program codes (Davenport 2000). However if the range of pre-defined configurations is limited and does not meet particular user needs, adopters may be forced to seek to alter the programme. Issues then arise about whether this will be incorporated into the package (with programming and testing imposing a significant effort and expense for the supplier) or whether it will be an *ad-hoc* customization (which the adopter may have to pay/take responsibility for). If too many local customizations are made by an adopter, reliability may suffer and upgrades may become difficult to implement (Fincham et al. 1995).

In the case of HEPMA systems in England, suppliers were pursuing various product development strategies but had made very uneven progress in developing their strategies. Some had rather rudimentary arrangements for incorporating user requirements into the system. Others had begun to develop a more organised approach to assessing change requests, generalizing needs and building system enhancements. Moreover, at this stage, most HEPMA solutions in England seemed to be 'too limited' in terms of the configurability they offered (the range of pre-programmed options that the user could draw upon) in relation to the diversity of adopter practices and requests. In our observation of user group meetings, we

frequently encountered instances where the majority of users asked for a particular configuration that was not offered by the system.

9.2.4 Localized Adopter Practices Versus Generic Systems

The healthcare context is distinctive in terms of the enormous diversity in specific hospital procedures and individual ways of working. Despite the existence of professional NHS policy guidelines, each NHS hospital is a separate legal entity. It has its own local practices and standard operating procedures. So in performing the day-to-day activities, rather than merely complying with a set of professional guidelines, hospital employees are also expected to abide by the localized operating procedures. This was seen as one of the most significant factors leading to the complexity of HEPMA systems uptake in England. Interviews with users indicated that there were no pre-defined best practices in the health sector because there was still no consensus about what is best. Suppliers, though aware of the differences in localized practices, emphasised the need to introduce standards to the sector.

> *…every NHS trust in the country considers themselves to be different… if you give them a standard OBS* [output based specification]*… they make it unique to them… every question* [on the OBS] *has a nuanced, has a little twist in there… (Comment in supplier event)*

The implementation of generic HEPMA systems foregrounded these variations in practices. Operational differences between hospitals became visible, which had not previously been evident. The lack of standard practices became particularly apparent in implementing systems with higher levels of integration and complexity compared to standalone applications. The diversity of practices was not only hospital-specific. Practices varied between departments and specialties, making it difficult for standard applications to cater for the needs of all wards within a hospital.

9.2.5 'Untamed' Adopter Demands?

Adopters emphasized the particularity of hospital procedures and practices. However their responses highlight the lack of adequate awareness amongst users about the exigencies of packaged applications and in particular the trade-off between the costs of customization versus adapting processes to functionality in the package. This resulted in users having what others portrayed as rather unrealistic, indeed 'untamed', expectations of packaged HEPMA solutions. In this respect, users' expectations from packaged solutions were more in line with what might be expected from bespoke (tailored) information systems. Thus many users expressed a desire for local practices to be directly incorporated into the system.

> *…we are all doing the same job but we are managing the processes differently, so when we implement technologies we all want to implement it in our own way (Adopter Interview, P1)*

> *…some of the changes we are asking* [Product_Name] *for are things that individual Trusts* [hospitals] *do… (Adopter Interview, P4)*

Given these expectations, hospitals felt they should have direct links with the vendor company to develop their specific requirements.

> *So companies I've worked for before have always had* […] *a user that partly worked in the Trust* [hospital] *and partly worked for them* [in the vendor company] *so that they are a current user. So they knew the problems so that they could take that back to the* [vendor] *company and already start to look at ways of sorting that out. (Adopter Interview, P2)*

Suppliers referred to escalating adopter expectations as "over-aspirational functional specifications" (Comment in supplier event). They also highlighted the need for early alignment of user expectations and actual system purposes and functions.

> *…aligning expectations if that managed earlier then everyone is on the same page to begin with… (Comment in supplier event)*

A further problem arose from insufficient knowledge about what the actual needs of hospitals were. Both users and vendors expressed concerns about uncertainty surrounding users requirements.

> *…electronic prescribing and medical administrations are quite complex. Until there is kind of more experience or hospitals on these systems it's harder to get some kind of consensus on what are the features and what isn't. (Adopter Interview, P4)*

We further noted a lack of knowledge in English hospitals of both HEPMA solutions and of the implementation and use of packaged applications more generally. One issue that, will be the subject of a future paper, concerns the limited circulation of experience in IT procurement and implementation within the NHS. Many of the staff who played a central role in a particular hospital implementation then went back to their health professional role. Apart from a small number who moved over to work for technology suppliers, there was no ready way of carrying forward and exploiting this expertise within NHS professional structures.

9.3 Discussion

Vendors of HEPMA applications are investing significant effort in expanding their market base internationally. Hospitals in England, in turn, appear keen to implement systems that have the potential to deliver the widely anticipated benefits of such systems. We found that despite this willingness from both sides, for the various reasons considered above, progress with implementing these systems in England is proceeding slowly. To understand the underlying reasons we have developed a broader analytical framework based upon this work and our earlier research into the evolution of Enterprise Systems.

9.3.1 Analysing the Long-Term Evolution of Information Infrastructure

The concept of installed based, which unites the contributions in this volume, was coined to capture tensions arising in the development of electronic *Information Infrastructures* (IIs) – defined as systems of (computer-based) systems that support an increasingly wide range of tasks across an ever-more extensive base of users. Efforts to standardize functions around specific existing users and uses may impede the extension of an infrastructure to new users and uses (Hanseth et al. 1996). This concept has informed various development and implementation strategies to prevent lock-in around existing configurations and provide flexibility to allow new functionality to be taken on board (Grisot et al. 2014). The II discussion, however, has largely been at the level of the 'cultivation' of individual organisational information infrastructures.

Our research into the development and implementation of Enterprise Systems (ES) and other corporate information infrastructures (Pollock and Williams 2008) suggests that we need to analyse these developments not just at the level of particular infrastructures and organisations but also across communities of vendors and their adopters (Koch 2007). We have studied the development and implementation of these kinds of highly complex technologies over three decades (Pollock and Williams 2008). This extended timeframe of enquiry has provided insights into both the evolution of these technologies and the arrangements for their development and implementation. In the 1980s, initial attempts to supply what were then known as Computer Aided Production Management (CAPM) systems as COTS packaged solutions were characterized by sharp mismatches between supplier offerings and user needs. Our subsequent research allowed us to observe how these offerings have 'co-evolved' with their user communities. ES Suppliers have learnt how to develop and exploit close links with their adopter communities to develop generic solutions that can be used and be useful across a wide range of adopter organisations. Our insights derive from extending the scope of empirical research not just laterally, across arrays of vendors and adopters etc., but also along an extended 'longitudinal' timescale (Pollock and Williams 2008).

CAPM refers to the set of technologies that resulted from a UK government initiated program during the 1980s. By adding new functions onto existing Manufacturing Resource Planning (MRP II) technologies, CAPM sought to offer integrated packaged solutions to production control and coordination tasks. It was seen as a stepping stone towards Computer Integrated Manufacture (CIM) (Williams 1997; Webster and Williams 1993). In response to the promotion efforts of government (the Department of Trade and Industry, the Science and Engineering Research Council) and other influential actors such as consultants and vendors, a large number of suppliers from different fields were attracted to offer "CAPM" solutions (Clark et al. 1992; Newell and Clark 1990). The availability of government funds encouraged many vendors of MRP II and related systems to project their products under the name CAPM. This resulted in a swarming of supplier offerings around the concept of CAPM, with functionalities being added to existing products to fulfil the

expectations of policymakers, pundits and adopter organisations (Webster and Williams 1993). However attempts to implement CAPM packages ran into sharp difficulties which resulted in up to 50% of systems being abandoned. The most immediate features were:

1. An acute lack of fit between the presumptions underpinning the packaged solution and the circumstances of particular adopter organisations; and,
2. The CAPM products launched initially were often still-unfinished with various new functionalities added that were poorly integrated (Webster and Williams 1993).

As a result, would-be adopters found themselves drawn in to an unplanned collaboration with suppliers in a struggle to get these standard packages to work in the adopting organisation's particular circumstances. In this process we saw a more or less radical reworking of the solution, with some functionalities being abandoned and new functions emerging.

The immediate result of this accelerated development and diffusion was the launch of products that were often immature and unstable (Webster and Williams 1993). In the subsequent decade however a new generation of ERP and ES systems emerged, building very directly upon these applications. They incorporated the underpinning philosophy and many technical elements of CAPM and its predecessors – in particular the idea of connecting multiple functions across the enterprise with an integrated and interoperable system – and were also heralded as a stepping stone to CIM (Xue et al. 2005; Pollock and Williams 2008). The concept of ERP began gaining momentum through the 1990s, particularly as firms renewed their systems to avoid anticipated 'millennium bug' problems. A range of successful products emerged. Some (e.g. JDEdwards, Peoplesoft) fell by the wayside as the ES product market restructured, leaving global giants such as Oracle and SAP in dominant positions. As a result we find that today SAP's R3 system has been adopted by the majority of FTSE 100 and Fortune 1,000 firms CIM (Pollock and Williams 2008).

The success of ESs built upon several decades of experience with its predecessor technologies (stock control, production control, Material Requirements Planning [MRP], MRP II) (Williams 1997). There are two crucial features underpinning these developments:

i. Successful suppliers of packaged ES solutions had, over time, elaborated sophisticated *generification* strategies, through which they elicited, aligned, sifted and sorted the diverse requirements of their communities of adopters
ii. Permanent linkages were established within the ES community – in particular through user-clubs linking suppliers and adopter communities (Mozaffar 2016).

The subsequent success of ERP/ES was rooted in the mutual adaptation of both adopter organisation practices/processes and packaged features (Hong and Kim 2002; Leonard 2011).

9.3.2 Analysing the State of the Technology Market/Technology Field

These considerations suggest that if we wish to understand difficulties encountered in HEPMA procurement and implementation, it may be helpful to analyse the evolution and current state of development of the HEPMA market in England, drawing parallels and insights from our studies of the ES technology field.

The idea of the maturation of technology fields can be traced back to classic 1970s studies by Abernathy and Utterback who proposed a three stage model (Abernathy and Utterback 1978). In an initial *experimentation phase*, we see the rapid entrance of diverse and changing products into a new market, the ultimate direction of which is still unknown. As the market and the applications of the technology become better appreciated by suppliers and adopters, in the next, *transitional phase,* the market begins to converge around what is known as a 'dominant design' with broadly comparable characteristics. In the *mature phase,* as dominant designs become established, we find concentration of the market around a smaller number of products with higher performance. The focus of supplier efforts shifts from differentiation to enhancing performance and lowering costs within an existing product paradigm. Similar stage models have been advanced to analyse the cyclical evolution of product markets including the software product life cycle (Agarwal and Tripsas 2008; Fincham et al. 1995). 'Institutionalist' organisation theorists have described the homologous processes by which new 'technological fields' (Pollock and Williams 2011; Swanson and Ramiller 1997, 2004) emerge and take shape by establishing consensus amongst communities of vendors, consultants and adopters. The establishment of a technological field greatly reduces uncertainties about the characteristics of a technology both for vendors and customers. They are coupled with the emergence and stabilisation of classifications of technologies and criteria for their assessment. Here we reject simplified (e.g. technology management) approaches which take for granted the formation of technological fields and their progression, once established, to maturation and seek a more dynamic, processual account of the evolution of technological fields which explores how boundaries and names may be recast and maturation may be reversed by the emergence of new technical solutions or business models (Fincham et al. 1995). In the ES field we saw the emergence of new kinds of *knowledge intermediaries* – industry analysts like Gartner Inc. – which capture and collate community experience to advise adopters about available software products and their vendors. By overcoming the asymmetry of access to information between vendor and adopter this provides the 'knowledge infrastructure' needed for the operation of the IT markets for these complex software products whose capacities and fit to the needs of particular adopter organisations cannot be readily established, for example, by inspection (Pollock and Williams 2011, 2016).

9.3.3 Is the HEPMA Market Replicating the Path of ERP?

Our study of the evolving nature of the HEPMA market in England, exhibits some interesting and insightful parallels with the earlier history of integrated systems in the commercial sector: ERP and its predecessor CAPM Systems. This drew our attention to (i) how vendors developed *generification strategies* to create generic solutions that could bridge to a wide-range of adopter contexts, (ii) the development of multiple webs of relations between vendors and adopters through which knowledge about user requirements and vendor offerings could be exchanged, and (iii) how new knowledge intermediaries emerged to advise adopters in their procurements. We were able to assess the extent to which comparable arrangements had emerged in the UK HEPMA market.

9.3.4 The English HEPMA Market Is Still in an Emergence Stage

The comparison with the ES case suggests that the HEPMA market in England is still in an early stage of emergence/growth. Various suppliers have entered the market with each one having a relatively small number of implementations in progress (Mozaffar et al. 2014). The HEPMA market exhibits a high technical variety in development of products with diverse features and forms. These products originate from different geographical and technical backgrounds and are offered in different forms with dissimilar features and functions. This would suggest that their technological features have not yet become de facto standards or 'dominant designs' (Agarwal and Tripsas 2008; Utterback 1974) in the English market. In this market there is still no accepted architecture, established use practice or evaluation criteria to guide and constrain the efforts of suppliers and adopters (Sheikh et al. 2014). This also contributes to diverse supply strategies and use of numerous terminologies and definitions all of which act as barriers to smooth and rapid adoption.

The lack of shared understanding creates a problem for potential adopters in understanding the options available (Helm and Salminen 2010; Jalkala and Salminen 2010). It also creates uncertainty for vendors about customer requirements. End user requests are typically more diverse than anticipated. Suppliers have difficulties in responding systematically to this diversity (Agarwal and Tripsas 2008; Adner and Levinthal 2001) given this lack of clear 'preferences' (Clark 1985). The market remains in the experimental stage with new products and suppliers still emerging.

Suppliers had adopted different approaches to respond to the diverse needs of the English market. On one end of the spectrum were those suppliers which had already grown and stabilized their products in other national markets. Some offered their international products with only minor modifications to cater for the English hospitals' needs. Others had embarked upon concerted attempts to re-design and develop their applications around the particular needs of English hospitals. When we contrast the HEPMA and ES market today, we can see that HEPMA vendors had not

yet developed 'generification strategies' (Pollock and Williams 2008) in relation to establishing mechanisms to decide which of the diverse array of user requirements would be taken on board in their core product but instead tended to respond to requests in an ad-hoc manner. Conversely, since HEPMA systems did not yet incorporate sufficient libraries of common workflows that the user could switch on in configuring the system, rather than by rewriting code, adopter organisations felt compelled to submit customisation requests.

The lack of consensus amongst adopter and vendor communities and domain experts indicates that the technological field is still developing. The field has not yet developed structures and actors to mobilize consensus and set the boundaries of technology (a role carried out in other sectors by industry analysts like Gartner (Pollock and Williams 2011), and by entities such as the Health Information Technology Standards Committee and certifying organisations). These could help reduce procurement uncertainties in various ways: enabling development of generic cases for innovations, creating a space for comparison of different artefacts and suppliers, and helping users come to more realistic and realizable expectations about HEPMA functionalities and its effective use.

9.3.5 Conclusions

We identified several tensions in design and implementation of HEPMA systems in England. The problems can be sorted into six categories: (1) products derived from non-clinical systems proved problematic in England's increasingly patient-centred health system; (2) the process of Anglicization of systems by suppliers from other countries of origin needs to be given sustained attention; (3) the healthcare sector has particularly diverse needs and practices which run counter to the goals of generic applications; (4) current products are limited in configurability in relation to the diversity of adopter requirements which results in escalating customisation requests (5) rather than respond in an ad-hoc manner to proliferating customisation requests vendors need to develop generification strategies (perhaps through user groups) to sift, sort and prioritise these requests to keep control over the strategic development of their product and (6) adopters have little awareness of the exigencies of exploiting COTS solutions resulting in 'untamed' demands from packaged applications.

We conclude that effort to promote HEPMA arguably attracted a range of relatively unfinished solutions into the market prematurely. In this process neither the developers nor the adopting organisation were prepared for the complexities of matching generic products to a diverse adopter context. This echoes elements of previous UK experience with CAPM/ERP systems. We infer that, although policy incentives can be effective in achieving adoption (Aarts and Koppel 2009), they may also have accelerated premature purchase of immature solutions. This suggests a need for a gradual move in the market for such immature technology. So instead of suppliers seeking rapid large-scale implementation of their products, they may need to take a more deliberate and purposeful approach in developing their products for new markets, which will involve partnering with specific institutions until many

of the kinks are worked out. Also adopting hospitals need to be more clear and realistic in expressing their needs in relation to packaged applications. Furthermore, more effective mechanisms are required to bridge the gap between the generic standardized technological solutions and the particularity of national and local needs. In order to achieve this, suppliers must not underestimate user diversity. They need to develop strategies to deal with such diversities in the market. At the same time the adopting organisations need to become pre-aligned to these packages and around views within the Health Service of best practice. In short, what is needed is a co-evolution of organisation and technology together. Public policy might usefully be geared towards promoting – and allowing time for – such extended engagement (though competitive public procurement/tendering arrangements may not facilitate this kind of supplier-user engagement) (Lee et al. 2015).

Finally, we suggest that HEPMA is not the final stage in the process of developing health IIs. Though conceived as a discrete, pharmacy technology, HEPMA systems linked the pharmacy to the ward, and went beyond the point of prescription to the administration of medicine throughout and after their hospital stay. As a result HEPMA systems involved a wide range of stakeholders across the hospital junior doctors, consultants, nurses across different specialities, with their various work practices and requirements (a point which becomes crucial when we consider the difficulties catering for diverse 'end-user' requirements). HEPMA moreover became – at least in the historical trajectory of English hospitals - bound up with the integration of a growing range of digital information services (most immediately laboratory results) at the point of healthcare delivery throughout the hospital. Once introduced, these packaged HEPMA solutions became the starting point for the continued extension of systems and their integration with other systems within the hospital and beyond (for example discharge letters to general practitioners). HEPMA systems are becoming core components of hospital health information infrastructures. We suggest that HEPMA has served as a stepping stone to information integrated health care (in a way that parallels the earlier history of enterprise systems in industrial organisations (Fleck 1988)). Our research has identified a range of immediate problems associated with development, procurement and implementation of HEPMA systems in the English healthcare system. Our comparison with the prior experiences with ES allows us to see these as part of a longer-term social learning process (Sørensen 1996). To overcome these challenges, vendors and adopters must understand their current and potential user-base and develop strategies to address the heterogeneities and multiplicities of adopter requirements and practices. This diagnosis in turn provides important lessons for attempts to build health information infrastructures. England, as one of the leading countries in Europe in adoption of such technologies, can be seen as a site of innovation in which the market and products are being shaped simultaneously. Similar patterns in terms of difficulties of HEPMA adoption have been observed in many countries (Mäkinen et al. 2011; Aarts and Koppel 2009). However England is one of the leading countries with the highest rates of HEPMA adoption (Aarts and Koppel 2009; Van Dijk et al. 2011; Schoen et al. 2006), and other countries may benefit from analysis of UK experiences.

The large scale of the NIHR-funded research programme allowed us, rather exceptionally, to study the implementation of a range of supplier offerings in multiple sites and over an extended period. We identified sharp echoes between these, still emerging, experiences and findings from our own personal research conducted over three decades into the evolution of ES solutions. These highlighted the need to go beyond single site snapshot studies of information infrastructure implementation and also examine the development of the component technologies (in this case discrete and integrated packaged HEPMA solutions) amongst closely coupled communities of developers and adopters of particular products and within evolving technological fields (Pollock and Williams 2008, 2016). The need to understand longer-term evolution of products across a community requires us to go beyond (or radically re-specify) the concept of Installed Base. Here we have drawn upon a long-established tradition of work from organisational studies and related perspectives: notably the institutionalist concept of technology field and related work on product life-cycles. These have provided a helpful framework to guide the extension of our detailed ethnographic study beyond single sites and moments to encompass longer-term developments across vendor/adopter communities. Our work here has focused upon the 'community' of vendors, adopters and consultants linked to a particular technology. This does not however imply a 'flat' approach to community which risks portraying the co-evolution of technologies and their adopters as a simple process of joint learning and consensus building. Instead our studies of both ES and HEPMA highlight the overlapping webs of relationship through which these 'communities' are structured and segmented into a complex topology (Pollock and Williams 2016; Mozaffar 2016). Here we find a contradictory process in which diverse players grapple to accommodate goals in tension – for example supplier efforts to standardize technologies and adopter desires to differentiate systems around their particular (local or disciplinary) methods of working. These play out and need to be analysed over multiple cycles of design and implementation.

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Medication Infrastructure Development in Germany

10

Stefan Klein and Stefan Schellhammer

10.1 Introduction

In principle, the advantages of the digital transformation of the German healthcare system have been recognized by stakeholders and policy-makers. The need to move forward has been emphasized by governmental and representative bodies. Funding has been allocated to finance pilot projects and infrastructure development.

The electronic health card has been and continues to be the flagship of German ehealth initiatives. Its vision is nothing less than to replace most of the manual, paper-based communication processes by secure, digital pathways. Thereby, the initiative aims for providing a nationwide infrastructure on which in the future numerous applications can be build. It is essentially conceived as the entry ticket into the German healthcare system for every health insurance beneficiary.

Yet, so far, the development of the ehealth card in Germany is characterized by delays and significant reductions in the functional scope compared to the original plans. For instance, electronic prescriptions are not any more considered as a priority application. While the government pushes the project further, it remains uncertain when and in what form the first applications will materialize.

Some argue that the "project's sheer size, scale and complexity" is a major cause for its current state (Drews and Schirmer 2015 p. 12). An iterative approach combined with a more balanced economic distribution of costs and benefits is suggested as a more promising way (ibid.). While we do not deny that such arguments are worth to consider, we would like to suggest the notion of "installed base of opposition" in order to make sense of the difficulties plaguing German ehealth initiatives. We have developed and used this concept to trace the development of a rather focused, albeit scalable ehealth project over the last 10 years. The clear focus of the initiative on medication management for

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polypharmacy patients not only implies significantly fewer stakeholders (patients, doctors, nursing homes, pharmacies) but also allows for a tangible definition of economic benefits as well as improvements to quality of care. The initiative aims to improve medication compliance for polypharmacy patients by providing patient specific medication packs functioning as dose administration aids, called automated drug (or dose) dispensing (ADD). The involved work process is not entirely new but close to the existing practice of blistering pharmacies or blister centres. Especially nursing or care homes and polypharmacy home care patients have been targeted as customers. The initiative aims to automate and informate this process to achieve economies of scale and to reduce errors due to manual blistering.

Ideally, the weekly production of individualized medication packs would be built on key components of a general information infrastructure such as e-prescriptions, consolidated medication plans, and electronic communication between doctors, pharmacists, ADD operators and health insurance providers in order to be able to operate most efficiently. Thus, ADD would benefit from and nicely tie into an existing information infrastructure like the one envisioned by the electronic health card, but it may very well function without such a basis.

In this chapter we will show that this well-focused initiative suffered the same fate as the wider electronic prescription in Germany: It does not feature anymore in the discourse of ehealth applications. In our analysis, we were struck by the lack of an open and substantive discourse among the involved stakeholders. Given the cooperatist and consensus oriented governance of the German health care system, a resistance that ranges from a lack of open discourse to outright blockade is disturbing. Therefore, we come to the conclusion that the slow and cumbersome progress of infrastructure development in the German healthcare sector can be explained by the existence of an installed base of opposition. This interpretation does not bode well for the latest attempt by the government to jumpstart the digital transformation of the German health care sector.

Methods

In order to capture the public discourse about medication infrastructure development, research for this paper started with the collection and analysis of newspapers, reports, press releases, position papers, blogs, presentations and studies of the health-care community. These documents have been complemented by legal documents and international academic literature, dealing with medication compliance, ADD etc. Moreover, we have interviewed researchers involved in the study of ADD in Germany and Finland, representatives of Kohl Medical, as well as members of the blister community, pharmacists and doctors. An earlier version of this paper was shared with a representative of Kohl Medical for validation purposes. One of the authors gave an invited talk about the European landscape of ADD at a Blister conference in order to solicit further feedback.

10.2 One Step Forward Two Steps Back: The Situation of eHealth in Germany

In 2003, plans to modernize the German healthcare system by eHealth technology were put in place as part of a law by the federal government. In particular it was envisioned that: "From 1 January 2006 all 72 million customers of the health insurance companies in Germany […] which give access to state health care, should be using a "health card" with a microchip. [This] should make 700 million handwritten prescriptions redundant" (Tuffs 2004, p. 131).

Now, more than 10 years after the envisioned starting date, the system is still far from being operational. In fact, in December 2015 the German parliament passed the so-called "ehealth law" incorporating a roll-out plan to ensure the operation of the electronic health card system by 2018. Although the system has been reduced in its functional scope and now features a step-wise approach including financial incentives to spur adoption, it is still unclear whether the new starting date will be met.

In the following we will briefly revisit the history of the "most extensive e-health communication project in the world" (Tuffs 2004, p. 131).

The initial plans, which passed into law in 2003, listed various functional properties for the electronic health card: Apart from providing data to identify the insured person, it should include data required for the European Health Insurance Card (EHIC) and allow for electronic prescriptions. Furthermore, the card was supposed to support a number of additional applications, such as the use of medical data for emergency treatments, a digital form of communication between physicians and patients (doctor's or referral letters), data necessary for medication safety, an electronic patient record, and information about the donation of organs (§ 291a SGB V).

The initial starting date (of 2006) had to be abandoned in 2005. Instead, a number of field tests were conducted in seven test regions in 2007 and 2008 (Elmer 2014). The introduced solution caused substantial problems partially leading to an extension of the test phase and partly even to the termination of the tests. As a reaction to the failed pilots, the German Medical Association repeatedly positioned itself against the current concept of the eHealth card (Bundesärztekammer 2008).[1] Furthermore, in 2009, the private insurances retracted from the project.

In response to these developments the government decided to put the project on hold for review after the election in 2009 (Neumann 2009). This led to a reorganization and re-start of the project in 2010. In particular, the stakeholders agreed to reduce the initial scope of the card to just three initial applications: (1) basic patient and insurance data (2) introduction of an emergency data set, and (3) secure communication between health care professionals (VFA 2014). Since then, the introduction of electronic prescriptions has largely disappeared from the political agenda. In 2010 a representative survey among physicians showed that e-prescription is perceived as the application of the health card, which is viewed most skeptically (Institut für Demoskopie Allensbach 2010, p. 19)

[1] The German Medical Assembly documented their critical stance also in the memoranda of subsequent years.

Since 1 January 2015 the electronic health card is the exclusive credential to receive medical treatments. About 97% of all insured patients have received the card (GKV Spitzenverband 2015). Yet, so far even the basic functionality is not online. Because of the newly introduced picture of the patient alongside the stored basic patient data it is mostly seen as an expensive way to curb insurance fraud. Also this basic functionality is facing resistance as doctors do not regard cross-checking the identity and insurance of a patient as their genuine task but as an administrative burden that is passed on by health insurance companies (Bundesärztekammer 2015). Even the first field test of the online patient data seems to be delayed again, jeopardizing the subsequent phases (Borchers 2015).

In December 2015 a new law called "law for secure digital communication and applications in healthcare" has passed the German parliament. It essentially sets clear guidelines and deadlines to ensure the implementation of the ehealth card without further delay (Stafford 2015). For instance, until 1 October 2016 a paper-based medication plan has to be made available for patients, who need at least three medications. In 2018 this is supposed to work electronically. As of 2018, emergency health information can be stored on the ehealth card, if the patient wishes. The online verification and updating of patient data is conceived as one of the first applications to be available nationwide. After the implementation, foreseen until mid-2018, the law specifies 1 July 2018 as a deadline after which doctors who do not participate will incur a 1% reduction of their reimbursement (Bundesregierung der Bundesrepublik Deutschland 2015).

The specific deadlines, milestones, and sanctioning mechanisms as well as financial incentives mentioned in the law suggest a clear roadmap capable to overcome the stalled implementation process. Yet, the reactions to the initial draft of the law raise doubts as to whether the optimism of the federal government in regard to the impact of the law is justified (Bundesärztekammer 2015; Schersch 2015).

10.3 Case Background

10.3.1 Medication Management for Polypharmacy Patients

Comprehensive medication management for polypharmacy patients (Lochner et al. 2011) has been recognized as a key area of health care in need of improvement and innovations: it affects a growing number of patients, has huge financial implications and ties into broader issues such as patient health and medication safety, medication records, coordination across different medical specialists, and cooperation between medical doctors and pharmacists.

Medication safety and compliance are major issues in the management of medication for polypharmacy patients. Polypharmacy patients are patients who regularly have to take four or more distinct types of medication. They are typically suffering from diseases such as coronary heart disease, congestive heart failure, hypertension, or diabetes mellitus. Given the sheer number of medication and over-the-counter drugs (OTC) taken, there is a high risk of critical interactions. Adverse drug reactions

and critical interactions among medicines can often be identified and resolved before the actual administration of the drug takes place. However, accurate identification of risks relies on comprehensive information about the current and past medication regime of the patient. Medication safety addresses specifically adverse drug reactions and critical interactions among medicines. Compliance or adherence[2] focuses on the patients' behaviour in particular in long-term medication therapies.

The response to this set of problems varies across different health care systems. Yet, there is a broad consensus about the key components of a solution (Haefeli et al. 2012):

1. A comprehensive patient medication record to document a patient's medication.
2. A control for critical interactions based on the medication record.
3. Monitoring of the medication effects over time.
4. Dose administration aids to support patients and their helpers to follow the medication regime (dosage and timing).

While we will be looking specifically into dose administration aids throughout this chapter, they are only one component of a comprehensive medication management (Royal Pharmaceutical Society 2013) that typically requires components (1–3) as a prerequisite.

10.3.2 Automatic Dose Dispensing (ADD) as a Key Component for Medication Management

Adherence is in particular a problem for chronically ill elderly patients, who constitute the largest segment of polypharmacy patients. The use of dose administration aids, such as the 7×4 pill box or the weekly blister wallet, is regarded as good practice to support compliance (Corlett 1996): the medication plan is translated into separate physical compartments marked with the assigned day, time and filled with the respective medication. So the physical presence of the medication functions like a reminder to take the assigned medication, a materialized logic of compliance. However, from the patients' or caretakers' point of view, filling pill boxes, is a tedious and therefore error-prone process (Lauterbach et al. 2007). Hence, provisioning of dose administration aids is mandated for specific patients in a number of countries including Australia, Austria, Denmark, Switzerland and The Netherlands based on the assumption of enhanced safety, improved medication adherence, reduced cost and time efficiency (Bell et al. 2013).

Automatic dose dispensing (ADD), the industrial production of patient-specific dose administration aids for solid oral medicines, has been introduced in primary

[2] Adherence is the broader concept, which encompasses acceptance (redeeming the prescription), persistence (continuing the medication therapy) and compliance (following the prescriber's instructions) (Düsing 2006, 11). Throughout this chapter we will use adherence and compliance synonymously.

care for home-dwelling elderly patients in a range of countries, such as Denmark, Finland, The Netherlands, Norway and Sweden (Cheung et al. 2014). ADD builds on and extends established practices of arranging medicines in pill boxes, e.g. the widely used 7×4 pill box has twenty eight separate compartments for pills. Each compartment may contain several pills, which are to be taken at the same time during a day (morning, noon, afternoon, evening). Those aids, blisters packs, blister wallets or collections of sachets, also provide information about patient, medication and schedule for administering the medication. From a patient's perspective, ADD replaces the 7×4 pill box by sachets or blister packs, each of which contain the pills of the pill box compartments. These blisters are produced and sealed on an industrial level according to industrial quality standards (GMP – good manufacturing practice). Thus, ADD substitutes the manual administration of medication, dose administration aids filled by patients, their careers or pharmacists, or blisters produced manually or (semi-)automatically by pharmacists or regional blister centres. ADD is typically provided across regions or nationwide, it is a way of scaling up the production and provisioning of blisters for quality and efficiency reasons.

10.3.3 Attempted Infrastructure Innovation

Given the prevalence of national regulation in health care, we have been studying the public discourse about improving medication management in Germany over the course of 10 years. There has been a broad consensus about the need to improve the safety of medication therapy. Since 2007 a series of action plans to improve the safety of medication therapy have been established and executed (AkDÄ 2007), see also (World Alliance for Patient Safety 2008) and specifically to address the risks and costs of non-compliance (ABDA and KBV 2011a; Arzneimittelinitiative Sachsen-Thüringen 2014; Ärztliches Zentrum für Qualität in der Medizin (ÄZQ) 2011; Bierwirth and Paust 2004; Braun and Marstedt 2011).

Pharmacists and operators of blister centres have been lobbying for the official recognition of the advantages of blistering, i.e. the provision of patient specific dose administration aids in form of blister packs, for years. However, their success and impact has been quite limited. Within the Federation of German Associations of Pharmacists (ABDA) they appear to be regarded as a small special interest group of pharmacists focusing on servicing care homes.

We will be investigating specifically the introduction of industrial automatic dose dispensing (ADD) as an infrastructure innovation in the German healthcare system.

10.4 Case Presentation

10.4.1 From Semi-automated Packaging to Industrial Scale ADD

In 2000 the first care homes in Germany started to introduce patient-specific blisters packs to their patients ("Patienten-individuelle Verblisterung in Deutschland – eine Bestandsaufnahme," 2010). Over the next 16 years a number of pharmacies

(28 according to the BlisterBlog (http://verblistern.info/blog/) de facto perhaps two or three times as many) and regional blister centers (29 according to the BlisterBlog (http://verblistern.info/blog/)) has commenced their operation to package pills manually or semi-automatically into blister cards or tubular bags. Two associations (BPAV, BVKA) have been founded to represent the interests of these organizations.

10.4.2 The Design of the ADD Pilot Infrastructure

In 2005, the regulatory preconditions for the industrial production of patient-specific blisters have been established in principal, however, eligibility criteria, rules for reimbursement and the collaboration between doctors and pharmacists in reviewing medication plans had not been included. Subsequently, two industrial ADD operators – 7×4 Pharma and AvidiaMed[3] – have set-up production sites and run trials. The blistering facilities of 7×4 Pharma had been designed to produce weekly blister packs for polypharmacy patients at a national scale, i.e. up to 100.000 patient specific blisters per day. In parallel a number of blister centers have been set-up by pharmacies at a regional level, which produce blisters for a small number of participating pharmacies. Moreover, a number of pharmacies offer the (manual) production of dose administration aids as an additional, usually complimentary service.

While there are numerous options of how to design ADD, 7×4 Pharma had opted for key design features for their pilot: They used blisters instead of sachets, in order to increase the quality of the medication packs. 7×4 Pharma covers a dispensing range or assortment of 400 standard, generic and proprietary substances (Kohl 2010, p. 10). 7×4 Pharma operated as a service provider for pharmacies, in collaboration with general practitioners and specialist doctors instead of direct deliveries to care homes and home care patients. They designed a process flow (Fig. 10.1), which illustrates the direct collaboration with doctors, pharmacists and wholesalers and the indirect involvement of patients and insurance providers. Three components of medication management, specifically medication information management are crucial for the operation of ADD:

- Electronic information exchange akin with *electronic prescription* between ADD operator, physician and pharmacy. ADD assumes up to date comprehensive information about all of patient's prescriptions in order to be able to provide a comprehensive blister of all oral medicines.
- Based on the prescriptions, a consolidated and comprehensive patient *medication plan* is created.
- A *medication list*, typically based on active ingredients identifies standard medication and possible substitutes. The medication list can help to deal with the complexity and multiplicity of medicines.

[3] As 7 × 4 Pharma was the first, most prominent and indeed most controversial attempt to establish ADD in Germany, we have focussed on their case.

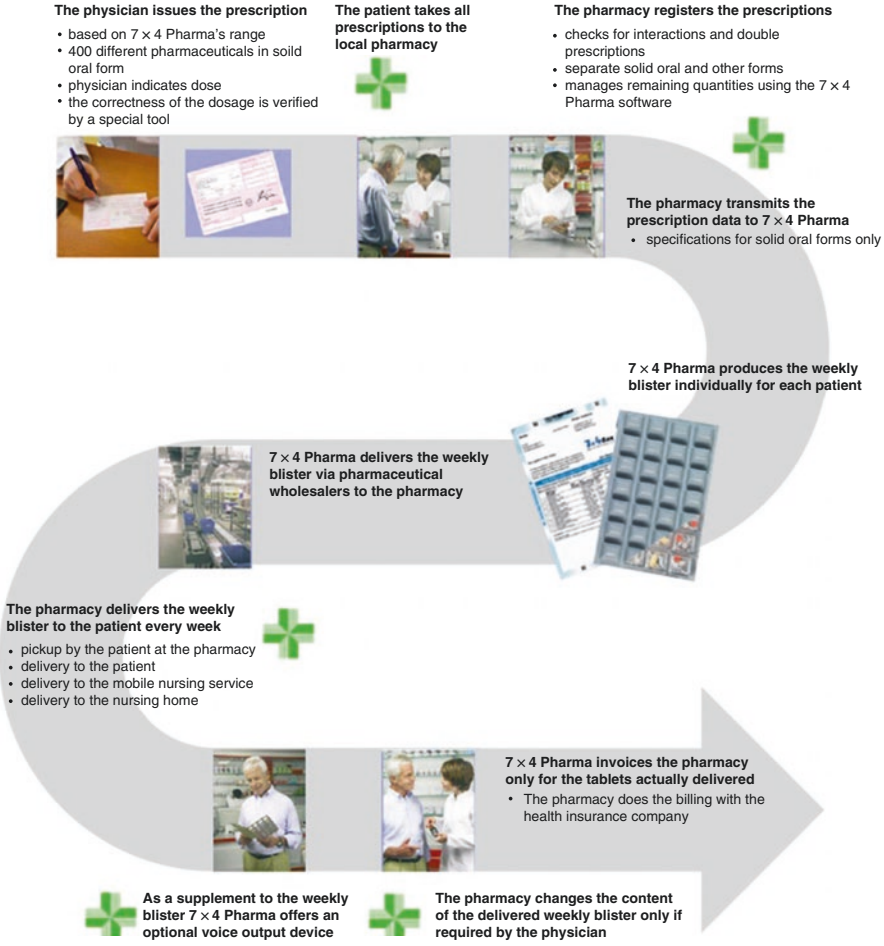

Fig. 10.1 ADD process flow (Kohl 2010, p. 11)

Yet none of these had been formally introduced or regulated in Germany in 2005, and none of these are in place to this day.

The creation and exchange of these documents implies an adjustment of existing practices and involves – apart from the ADD operator – patients, physicians, pharmacies, pharmaceutical wholesalers, caretakers or nursing homes and health insurances as illustrated in Fig. 10.1.

- Physicians use the 7×4 Pharma software to issue prescriptions based on the medication list.
- Patients take all their prescriptions to one pharmacy.
- The pharmacy registers and checks the prescriptions for critical interactions, dosage and double prescriptions, e.g. pain killers prescribes independently by different specialists. The pharmacy passes the consolidated prescriptions to the ADD operator.

- A pharmaceutical wholesaler delivers the blisters to the pharmacy.
- The pharmacy is invoiced by 7×4 Pharma based on the number of tablets delivered.
- The pharmacy charges the insurance providers.

10.4.3 Debates About ADD in Germany

Between 2004 and 2007 a number of studies – commissioned by Kohl Medical AG, 7×4 Pharma's parent company – have been published, which examined different facets of ADD and provided the rationale for industrial ADD at a national level (Glaeske 2007; Lauterbach et al. 2004a, b, 2006, 2007).

In 2006, Wille and Wolf (2006) published a study – commissioned by the association of research active pharmaceutical companies (VfA) – on the costs and benefits of secondary blisters, which contradicted the studies by Glaeske, Lauterbach et al. and concluded that ADD is neither cost efficient nor effective.

Meanwhile, in 2009, the 7×4 Pharma facility went live (Hollstein 2009). Subsequently pilot studies – based on industrial ADD as well as regional blistering – have been conducted in collaboration with health insurance providers in order to assess the effects of ADD in life settings.

At the beginning of 2011, the results of two pilot studies have been published. One was based on industrial ADD (Leker and Kehrel 2011), the other was based on blisters produced by pharmacies (Neubauer 2011; Neubauer and Wick 2011) in cooperation with health insurance providers. The studies provide evidence that ADD contributed to improvements of both medication safety and compliance. Moreover they postulated cost saving of up to 31 € per patient per week (Neubauer and Wick 2011).

In spring 2011, the Federation of German Associations of Pharmacists (ABDA) and the National Association of Statutory Health Insurance Physicians (KBV) published a proposal for improved medication supply in Germany, which addressed the same issues of compliance of polypharmacy patients and medication supply (ABDA and KBV 2011b). While the proposal can be seen as complementary to ADD, it refrains from even mentioning the issue of drug administration.

In August 2011, the association of statutory physicians and the association of pharmacies for the state of Brandenburg (Landesapotheker- und Landesärztekammer Brandenburg 2011) issued a position paper, which assessed and rejected ADD. The association of patient individual blister companies (BPAV 2011) issued a critical and angry rebuttal. The association of pharmacies supplying nursing homes (BVKA Schumbach 2013a) has also articulated critique against ABDA's blockade of ADD.

In November 2011 7×4 Pharma's production of blisters was discontinued. It had become obvious by then that the regulator was not inclined to fill the gap left in the 2005 law due to the coordinated resistance of ABDA and KBV (Schumbach 2013b). Hypothetically speaking, had the regulator provided reasonable rules for eligibility for patient-specific blisters and for reimbursement of the blister production and the requisite medication review, it could have triggered the development and extension of the information infrastructure and thereby making blistering a viable model. The fact that the

ABDA and KBV concept paper (ABDA and KBV 2011b) has been published in 2011 and that 7×4 Pharma was sold during the same year may be more than a coincidence.

In mid 2013, the second industrial provider, AvidiaMed (2013), closed its ADD operation. A pilot study based on the ABDA-KBV proposal (Arzneimittelinitiative Sachsen-Thüringen 2014), initially scheduled to start at the end of 2013, has been delayed by a year (Ziegler 2013).

10.4.4 Status in 2016: Slow Diffusion and Persistent Opposition

About 7,5 Mio patients in Germany take five or more medication regularly (Hillienhof 2015). While the two national ADD initiatives have been terminated, local and regional blister initiatives have continued and are gradually extending their operations. In 2011 about 25% of home care facilities use and pay external blister providers (Rauers 2011). The economic logic for blistering is a combination of quality assurance and outsourcing of preparing the medication for patients: the external production of blisters can usually be done at a lower cost than the preparation of pill boxes in the care homes.

The diffusion of blistering among home care patients is much lower. It is not established as a practice and is rarely recommended by doctors or pharmacists. The daily practices of taking medication is not in scope of a broader debate. Eligibility and reimbursement have not been clarified by the regulator and when pharmacies provide blistering as a free service for their patients, they risk being sued for price dumping (Wessinger 2014).

To this day, there is a strong and outspoken opposition in Germany against blistering by the associations of doctors (KBV), pharmacists (ABDA) and the research active pharmaceutical manufacturers (VfA) industry, and (therefore) not actively pursued by the regulator.

Despite clarifying the legal status of patient specific blisters and the required license for the production in 2005, no subsequent clarification of eligibility, division of responsibilities and reimbursement have been provided by the regulator, which leaves providing blisters for care homes as one of the few economically viable options.

Core ehealth information infrastructure components, notably electronic prescription and electronic patient medication plan, upon which blistering could be more easily extended, have not yet been introduced.

There is neither a public discourse nor research about the benefit and risks of dose administration aids for elderly polypharmacy patients. The official statements against blistering are categorical and do not even leave space for a nuanced reflection of design options.

All this has led to the widespread perception that the issue is “dead” and does not require any further consideration. Notably, even the word “blistering” is largely avoided in the public discourse, except for the dedicated blister community, which seems like a marginalized minority. There are no significant research programs or projects on how to support elderly people in managing their medication. The

discussion what should be covered by medication management is still ongoing (Dartsch 2013).

10.5 Analysis

The field of medication management with the goal to improve medication safety and compliance addresses a complex ensemble of diverse practices, health care governance and regulation as well as technology (codes, standards and artefacts, such as electronic patient health cards). The case underscores that infrastructure evolution is happening over extended periods of time, at a large scale and deeply embedded in practices (Reimers et al. 2012). It highlights not only the role of the installed base, but also the need for aligning the scope of initiatives (from local or regional to national) and the "availability" or state of the installed base at the appropriate level as a prerequisite for infrastructure innovation.

10.5.1 Deficiencies in Installed Base

As an attempted infrastructure innovation, the 7×4 Pharma initiative has been aimed at scaling – from a local or regional level to a national level – and extending existing practices of blistering, building and initiating an evolution of technical components (information infrastructure) and regulatory adjustments. It can be seen as a bold move to create facts that might have engendered a momentum of transformation.

However, it became obvious that neither the necessary supporting practices, such as the compilation, review and sharing of prescriptions and patient medication plan, nor the underlying information infrastructure (electronic prescriptions and digital mediation plans, electronic communication between physicians and pharmacies and software supported review of medication plans), nor the supporting regulation (rules for eligibility and reimbursement) had emerged at a national level.

There is still no mechanism in place to share medication records among health care professionals on a routine basis. Even though each health care professional is in principal obliged to control for critical interactions, there is no clear division of labour between pharmacists and doctors regarding the monitoring of medication effects over time. Both professions regularly rely on the vigilance of patients and their helpers. New routines, roles and linkages between doctors, patients, pharmacists, the blister operator and the health insurance provider were developed during the pilot project, but did not spread beyond the pilot and did not persist once the pilot was terminated. In other words, the installed base of local and regional practices and initiatives, locally deployed information systems and existing regulation of blistering, were not suitable for or not aligned with the goals of building a national infrastructure.

Obviously, 7×4 Pharma had been aware of the situation and has made major efforts throughout the pilot project to initiate a rudimentary information infrastructure development themselves. They provided software for medication review, the exchange

of prescriptions and medication plans to physicians and pharmacists, and suggested ways of collaborating with the clearly articulate goal to improve the quality and efficiency of patient care. The design of the pilot study and the research based on the pilot (Leker and Kehrel 2011) were in line with the principles of benefits assessment as articulated by the G-BA[4] and the regulation about pilot projects in health care (§§ 63–65 SGB V). Still the lack of both, regulatory adjustments and standards has inhibited the proliferation of these practices that have been developed during the pilot.

One might interpret it as a bootstrapping approach, which – however – assumed that it would be sufficient to jumpstart the development dynamics, which would then convince the decision making bodies, the Federal Joint Committee (G-BA) and regulating authorities, to take over.

10.5.2 An "Installed Base of Opposition"

7×4 Pharma encountered what we would describe as an **installed base of opposition.** This opposition is multi-faceted and driven by different rationales. We have identified four key concerns:

1. 7×4 Pharma and its parent company, Kohl Medical AG,[5] have been perceived as a competitor constituting a new entrant into the health care market (Bellartz 2006).
2. The proposal of a mandatory medication list, i.e. the assortment of 400 medicines for blistering, has drawn critique from the doctors association (KBV).
3. The association of research active pharmaceutical manufacturers (VFA) funded research to proof the ineffectiveness of ADD and has been quite outspoken in its critique.
4. Innovations of the IT infrastructure, such as electronic prescriptions and electronic medication plans, and a wider dynamics of innovation have been critically reviewed by KBV.

The 7×4 Pharma design proposal caused predictable concerns or outright resistance across a large set of actors in the health care system:

1. The existing blister community (pharmacies and blister centres) inevitably perceived 7×4 Pharma as competitor and the ADD pilots as potentially disruptive innovation, even though they shared an interest in regulatory amendments in favour of blistering.

As blistering is particularly relevant for pharmacies who deliver to care homes and nursing homes, home care providers and polypharmacy patients, many pharmacies

[4] For more information about the mandate of the G-BA: http://www.english.g-ba.de/legalmandate/procedures/methods/evidence/

[5] Kohl Medical AG also owns kohlpharma, the largest European importer for medication.

see themselves as not really affected by the issue. ABDA as a pharmacy association appears to have decided to speak for the latter group rather than for the former. Even though the 7×4 Pharma proposal goes to great pains to emphasize and indeed strengthen the role of the pharmacists (Kohl 2010), there still may be a concern about potential disintermediation, i.e. direct delivery of blister packs to the patients.

Opponents of blistering aimed to undermine the credibility of 7×4 Pharma's ADD initiative, which provided a prominent and relatively easy target given the specific design proposals, in particular the positive list, and the position of Kohl Medical AG. Speculative concerns, such as the risk of a monopoly of 7×4 Pharma, or even conspiracy theories about the intended vertical control of the medication market by Kohl were two examples of the employed tactics (Bellartz 2006). By aiming at ADD, they indirectly also undermined the credibility of the regional blister centres. The opposition appears to follow distinct tactics of focussing on controversial design issues while not engaging in any dialogue about possible design improvements, and creating their own initiative, which could be regarded as a red herring, while avoiding the issue of blistering, and causing or accepting delays. The official statements about blistering by physician and pharmacist associations (Landesapotheker- und Landesärztekammer Brandenburg 2011) have been criticized as one sided, bloating risks and obstructing blistering, without recognizing the facts of widely established practices of blistering and using dose administration aids in Germany and – more widespread – internationally (BPAV 2011; Schumbach 2013a). We have not found evidence of a willingness of ABDA and KBV to recognize the need for dose administration aids and to engage in a dialogue about improvements of the design of ADD or blistering in general in order to better address patients' needs or to suggest or conduct further research to clarify the contested issues. The benefits of patient specific blisters, if properly administered, have been shown by several studies (Leker and Kehrel 2011; G. Neubauer and Wick 2011), yet these results seem to be "inconvenient truths", which are refused and opposed.

2. Many doctors and their association (KBV) are against, what has been referred to as the positive list, a mandatory list of medication that can be provided by 7×4 Pharma,

Since 2006 insurance companies can and do negotiate discounts with pharmaceutical manufacturers (Bundesministerium für Gesundheit 2006). This could pose a potential conflict with the mandatory list of medication suggested by 7×4 Pharma.

3. The association of research active pharmaceutical manufacturers (VfA), which commissioned an academic study aiming directly at 7×4 Pharma's initiative, had strong reasons for their opposition. If ADD would be introduced in Germany as suggested by 7×4 Pharma, they would have a lot to lose: (a) control over which medication is dispensed to the participating polypharmacy patients, (b) according to the pilot results, less medication would be discarded because of the

provision in weekly blister packs instead of larger retail packages, (c) medication in blisters can be provided at a lower price (Pradel 2015), (d) eventually the ADD operators may be able to procure medication in large packages for the use in blister automats – like in Finland – rather than the current retail packages. The widely cited study (Wille and Wolf 2006), whose content was reiterated by VfA itself (Verband Forschender Arzneimittelhersteller e.V. (VFA) 2009) proved to be very effective in discrediting the efficiency and effectiveness of patient specific blisters based on conceptually derived claims, yet without providing primary empirical evidence. In that way the study would not qualify as evidence according to the standards of the Federal Joint Committee (G-BA).

4. There is widespread reservation or even open resistance against electronic prescription among doctors (Franke 2010; Institut für Demoskopie Allensbach 2010). While the implementation of the medication plan is welcomed in principle, specific concerns still remain (Hillienhof 2015) and the responsibilities regarding compiling and reviewing a comprehensive medication plan are not clear yet (ABDA – Bundesvereinigung Deutscher Apothekerverbände 2015).

We suspect that the concern, the discussion about patient specific blisters might open a pandora's box of subsequent, uncontrollable changes in the health care system, is a key reason for the opposition. In a description of his research on his web site, Neubauer states that based on the insights of the ADD pilot projects, he will be exploring possible improvements of the health care system at large.[6]

Based on the prevalent opposition, the regulator decided not to take any action in favour of blistering (Schumbach 2013b): implementation issues of the 2005 regulation such as eligibility for blistering, reimbursement of costs, roles and responsibilities for aggregating and checking medication plans, let alone the underlying IT infrastructure for e-Prescription and electronic medication plans were left open.

10.6 Discussion

In this section we will be looking at different lenses and interpretations of the notion of installed base as well as the German health care system's propensity to innovation. The case provides different insights on the emergence of infrastructures and the related installed base.

First, it illustrates the various, interconnected facets of the installed base: constellations of practices, specifically of an integrated medication management, health care regulation and governance, and technology: "there is a historicity stemming from the manner sediments of earlier solutions, entrenched routines, prevailing perceptions and social institutions constitute and solidify existing practices." (Aanestad et al. 2005, p.5, see also Aanestad and Jensen 2011, p.162). The introduction of ADD would imply a transformation and extension of practices of medication

[6] See: project description "Patient individual secondary pharmaceutical blister packs in care homes" on http://ifg-muenchen.com/arzneimittel-und-medizinprodukte/

management (consolidation of prescriptions, creating and reviewing the medication plan) and related information sharing practice (between specialist doctors and the GP, GP and pharmacy, pharmacy and ADD operator), practices of distributing medication and practices of invoicing and reimbursing medication. This transformation will create uncertainties as to who – physician or pharmacist – will be in charge, what will be the basis of reimbursement (if any) and how will the coordination between physician or pharmacist be organized. Moreover, the proposals for ADD relate to entrenched opposition of doctors and pharmacists. Doctors fear to lose control over their choice of medication, something which is already happening to some degree as a result of health insurance policies. Pharmacists fear to lose revenue as a result of new business models (Online pharmacies) or new entrants (ADD operators), who might try to bypass community pharmacies.

This illustrates, *second*, the possibly inhibiting role of an installed base of practices, which are not open for discourse, experimentation and innovation, instead seem to focus more on caring for their own economic interests, retaining control and perpetuating the status quo. In particular the national doctors' and pharmacists' associations (KBV and ABDA) appear to be entrenched in politics and lobbying for the majority of their members. The blatant unwillingness even to engage in a dialogue about blistering is striking.

Third, it shows the difficulties of scaling a medication infrastructure before the relevant installed base has been scaled as well or is at least ready for scaling. This includes a momentum of technical innovations and related norms and practices. In this way, the installed base does not only highlight the temporal dynamics of infrastructure development and evolution, but the installed base also becomes a platform and indeed background upon which novel or specialized infrastructures can be built or scaled.

Turned around, this might suggest an expectation that the successful scaling of an infrastructure, specifically ADD, might spur and accelerate the adjustment and adaptation of the underlying installed base and cause a political momentum and reorientation. 7×4 Pharma's goal was to convince the regulator to take action and provide the necessary steps by delivering a proof of concept (pilot installation) with participation of patients, doctors, pharmacists, insurance companies and academics. Insurance companies aided by academics acknowledged the effectiveness of the solution and were meant to provide the necessary credibility.

Conclusion

We have interpreted the ADD initiatives in Germany as attempts to scale scattered local and regional practices of blistering and establish a national infrastructure. The analysis of the failure of these initiatives revealed a lack of an appropriate or even appropriately flexible installed base in terms of established practices of physicians and pharmacists as well as cooperation between them, enabled by regulation and technology, specifically a patient information infrastructure encompassing electronic prescription and patient medication plans.

While both national-level initiatives can also be seen as bootstrapping attempts to foster the development of the bespoke installed base, they encoun-

tered categorical opposition and resistance. While in particular in the case of the association of the pharma manufacturers (VfA), the opposition can be explained by obvious economic interests, the resistance of physician and pharmacy associations is less obvious. Both also represent members who are not only in favour of, but are actually producing and distributing blisters to their patients.

The tactics of opposition seem to suggest a profoundly negative attitude, which is not even open to discourse and reasoning. It is astounding that the international examples of practice, critical discourse and research about dose administration aids as integrated part of medication management dose are not actively considered.

A justification for the resistance to infrastructure innovation might reflect prior experience of government initiated large scale health care infrastructure projects, such as the electronic patient health card. Especially the health card appears as a typical example of a megaproject (Flyvbjerg et al. 2003), which encountered huge resistance, delays, cost overruns and in the end achieved much less then has been promised at the start. Given this experience, an attitude of hesitation becomes understandable.

The governance structure of the German health care system is based on cooperatist consensus building and decision making prior to regulation. The Federal Joint Committee (G-BA) is the decision-making body of the joint governance of physicians, dentists, hospitals and health insurance providers in Germany (www.english.g-ba.de). The G-BA has an innovation fund, which will be available as of 2016 in order to facilitate and study new forms of medical care. Pilot projects for medication safety for multimorbid patients are among the suggested initiatives. This initiative might be read as an admission that innovative forms of care require more attention in Germany.

10.7 Appendix: List of Acronyms

ABDA	Federation of German Associations of Pharmacists
ADD	Automatic dose (or drug) dispensing (ADD), the industrial production of patient-specific dose administration aids, e.g. blister packs, typically for solid oral medicines for a defined period, e.g. 7 days.
AkdÄ	Drug Commission of the German Medical Association
Blistering	The provision of patient specific dose administration aids in form of blister packs.
BPAV	Bundesverband Patientenindividueller Arzneimittelverblisterer e.V. (national association of producers of patient specific blister packs).
BVKA	National Association of Pharmacies supplying care homes or nursing homes.
GB-A	The Federal Joint Committee (G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. [http://www.english.g-ba.de/]
KBV	National Association of Statutory Health Insurance Physicians
VfA	Association of Research Active Pharmaceutical Manufacturers

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