

Digital Infrastructure Innovation and Evolution: The Co-Functioning of Architecture, Governance and Process Strategy

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Case Narrative

1. The Spanish model of pharmacy

The model of pharmacy in Spain constitutes an assemblage that comprises multiple components: pharmacists, pharmacies, Colleges and Councils of pharmacists, trade associations, health services, citizens, public health principles and laws, geographical distribution of pharmacies, ownership regimes, professional practices, medicines, and so on.

At a lower scale, there is the pharmacist; a health agent who exercises its professional practice in community pharmacies or hospital pharmacies. The scope of practice of community pharmacists involves the dispensing of drugs, production of patient-specific preparations, and other pharmaceutical care tasks (e.g. health promotion, tracking patients' medication record, checking drug interactions, etc.).

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 and the pricing of medicines, each of the 17 autonomous regions is competent to organize the planning of the pharmacy system. In the case of the autonomous region of Catalonia, the Catalan Health Service (CHS) is the one in charge of the pharmaceutical planning.

In order to practice pharmacists must be registered in the College of Pharmacy of the province where they practice. In Catalonia there are four Colleges of Pharmacy (corresponding to the four provinces) which coalesce into the Catalan Council of Pharmacists (CCP). 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. Thus professional, commercial and trade interests, health care priorities and legal issues all fall within the ambit of the CCP.

An important stabilizing expressive component of the model of pharmacy is the agreement between the CHS and the CCP for the provision of services. The object of this agreement is to establish and regulate a relational framework between the CHS and the CCP with regard to the conditions by which pharmacists provide pharmaceutical care, invoice according to the contract economic regulations, temporary finance the dispensed drugs and health products.

A core practice of pharmacists is the dispensing of drugs which interacts with other practices (e.g. prescribing, invoicing) and actors (e.g. physicians, patients, CCP, CHS) and involves flows of information, patients, money, and so on. The functioning of the paper-based prescription infrastructure (before its digitalization) was as follows (see Figure 1). Once the physician had decided the drug treatment for a patient the latter was given a paper prescription. Physicians used clinical workstations to generate the prescriptions and print them. The patient took the prescription and her individual medical card 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. 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 CHS, and handled the invoicing for pharmacies. In particular, the CCP submitted a single invoice to the CHS. So, the CCP, not pharmacists, was the one in charge of invoicing the CHS. The CHS reimbursed that invoice to the CCP who checked for errors and finally paid pharmacies according to the signed prescriptions they had previously sent.

In this scenario, the information about patients' treatments (what a patient has been prescribed and dispensed) was fragmented in the systems of multiple health providers and pharmacies either electronically or in paper. That meant that the CHS had only a retrospective view of drug consumption and patients' treatments. It could find out about those issues only when pharmacies invoiced but not when physicians prescribed or pharmacists dispensed. So the CHS had a partial view of patients' treatments and only knew about them retrospectively.

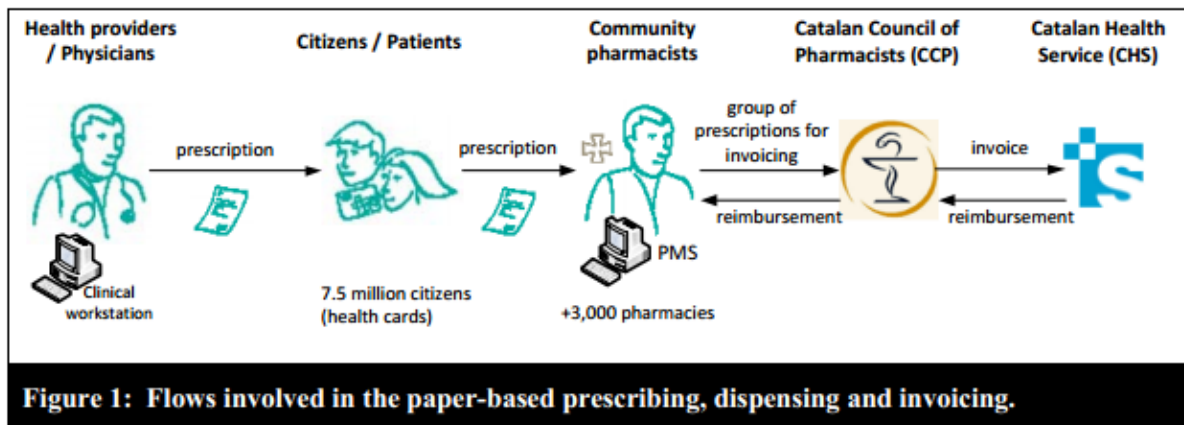


Figure 1: Flows involved in the paper-based prescribing, dispensing and invoicing.

2. Formation of the Electronic Prescription Digital Infrastructure (EPDI) - (2000 – 2005)

In 2000, the Spanish Ministry of Science and Technology in collaboration with several governments of the autonomous regions and the representatives of the diverse professionals involved in prescribing and dispensing –i.e., the Colleges of Physicians and the Spanish Council of Pharmacists– started a project called **PISTA** aiming to set up the foundations for a common Spanish electronic prescription model.

Meanwhile, in 2001 the Catalan Council of Pharmacists (CCP) led a successful pilot of electronic prescription in the private health involving a hundred private physicians and 25 community pharmacies. The CCP tried to extend that pilot to public health, but the Catalan Health Service (CHS) refused so arguing that they were involved in the PISTA project and should wait until that project ended. This fostered the computerization of all the pharmacies in Catalonia, and in turn it standardized some of the pharmacists' practices.

The PISTA project released a first draft of the conceptual model for a common Spanish Electronic Prescription Digital Infrastructure (EPDI) in 2002. That conceptual model, which was very much designed as 'one size fits all', dissatisfied the pharmacists' collective who perceived and argued that

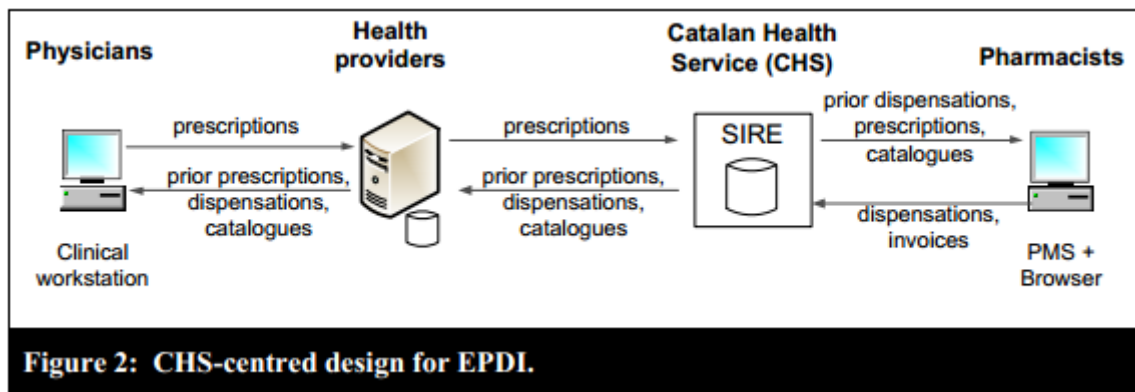
the main goal of the central government was to control their practice and to reduce public expenditure on drugs, rather than the use of IT to develop their professional practice and improve the quality of their services (Cordobés, 2002). Finally, because Spain has a decentralized health care system, the diverse autonomous regions started their own EPDI projects.

In the case of Catalonia, it was in mid-2004 that the CHS set the foundations for the building an EPDI in Catalonia. With the EPDI the CHS 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. To achieve those goals the CHS needed a real-time, holistic view of patients' treatments (i.e., a record of past, present and future prescriptions required for a given patient treatment), and that entailed changing the spatiotemporal scale of certain practices. Pharmacists would remotely access the content of prescriptions thus avoiding misinterpretation of prescriptions; the CHS would have the information about acts of prescribing and dispensing in real-time and would have the capacity to influence both acts for instance by forcing the prescription of generics.

From the outset of the project, the CHS invited all the health agents (e.g. several health providers, the CCP, the College of Physicians, patient associations) to participate. The CHS defined a governance structure consisting of two main committees: a steering committee, and an executive committee later called follow-up committee, in which diverse members of the CHS, CCP, health providers and other stakeholders were present⁴. The CHS was at the centre of the governance structure, and it initially set two central requirements for the EPDI. First, all the data —i.e., prescriptions, dispensations, invoices, patients, drugs, health providers, physicians, pharmacies, pharmacists— should be integrated and accessible online by the diverse stakeholders —physicians, pharmacists and the CHS. Second, the processes of prescribing and dispensing should run in real time; that is, any drug could be dispensed at any community pharmacy in Catalonia immediately after it was prescribed, regardless of the location of the prescribing physician. To fulfil these requirements and in line with the design guidelines defined by the Spanish Ministry of Science and Technology in 2002, the CHS proposed a CHS-centred architecture consisting of a central system owned and managed by the CHS (called **SIRE**) that contained an integrated database with all the data (see Figure 2).

This organizing structure was still running in 2013. 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, communication to population, analysis of legal requirements).

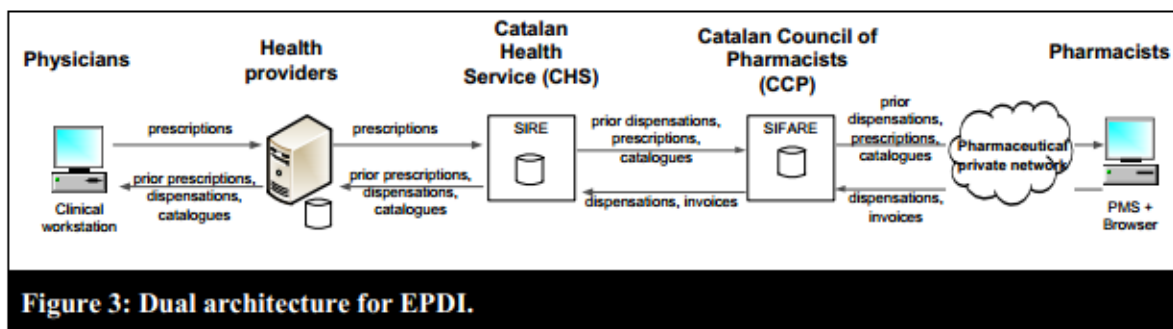
On the one side, the health providers would have to interconnect their systems with the SIRE. On the other side, pharmacists were expected to connect directly to CHS' system —for instance, through a browser— for the dispensing and invoicing processes.



From the perspective of pharmacists however, that architecture disrupted the model of pharmacy in Catalonia. First, it bypassed the traditional central position of the CCP in the invoicing process (Figure 1). That opened the door for the CHS to set bilateral agreements with pharmacists in the future, and that had the potential to weaken the role and position of pharmacists in front of the CHS. That in turn, made the deregulation of the field of pharmacy easier. Deregulation would be a key destabilizing process that would threaten the identity of pharmacists as it would open the door to new entrants (e.g. pharmacy chains) that would not be so much under the influence of the CCP –i.e. the CHS would be detached from the day-to-day practices of pharmacists. Finally, the fact that the architecture excluded the CCP also affected its revenue model. Besides the membership fees from pharmacists, a source of the revenue for CCP was the invoicing process as pharmacies paid for the processing of the paper-based prescriptions.

As a response, the CCP proposed a dual architecture (see Figure 3) consisting of a private network that would interconnect all the pharmacies plus a central server (called **SIFARE**) that replicated the data of the CHS server that was needed for pharmacists –i.e., prescriptions, dispensations and data catalogues. Both the private network and SIFARE would be owned by the CCP. Pharmacies would not have a direct access to SIRE (the CHS system) but instead to SIFARE (the CCP system) through the private network and the SIFARE would synchronize in real time with the SIRE. This dual architecture mirrored the structure of the model of pharmacy (characterized by an agreement between the CHS and the CCP, being the latter the spokesperson of pharmacists in front of the former) and protected the collective bargaining power of pharmacists. That dual architecture also played an expressive role having a strong stabilizing capacity as the CCP created a discourse that linked the dual architecture of the EPDI with the professional development of pharmacists: “Is a pharmacy based on individuality and small holdings viable, or will the future require a proper network of pharmacies with shared values, strategies and services?” (Excerpt from the speech of a member of the CCP at a Spanish pharmaceutical convention in 2005).

Moreover, the new architecture (figure 3) fulfilled the interests of both the CCP and the same CHS. On the one hand, the data would remain centralized residing in the servers of both the CHS and the CCP thus conferring real-time visibility over the data to the CHS. On the other hand, the software code for the dispensing and invoicing practices would be executed partially in the central servers of the CHS and the CCP, and partially in the pharmacists’ applications (PMS) as had happened until then (thus respecting the installed base of pharmacists and giving space for innovation).

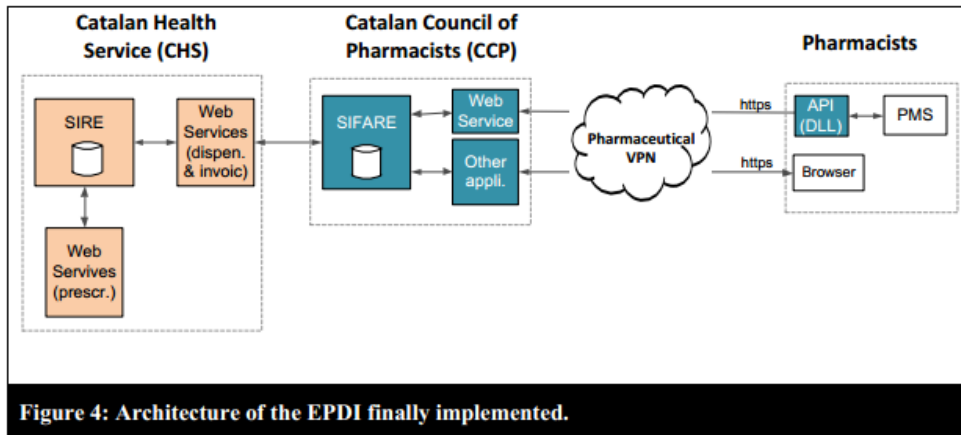


The new architecture slightly changed the distribution of rights over the project. It bestowed the CCP rights over the design, implementation and operation of EPDI. The CCP would be in charge of building the private network for pharmacies; developing the SIFARE and APIs; coordinating PMS vendors; promoting the use of the EPDI among pharmacists; re-scaling the technological infrastructure (e.g. bandwidth of the network, processing capacity) as the EPDI grew with new services. Because the CCP would mobilize resources, material (e.g. money) and expressive ones (e.g. legitimacy) for pharmacists, the CHS perceived it as a catalyst for the success of the EPDI. Hence, the dual architecture and the new associated role of the CCP minimized the organizational complexity of the project for the CHS.

On September 2005 the CHS and the CCP signed an appendix to the pharmaceutical agreement which established the clauses for the development of the pilot for the EPDI, and made explicit the role of the CCP (ANNEX, 2005). That is, the appendix to the pharmaceutical agreement reified and consolidated the material components and roles of actors previously defined.

On the side of pharmacists, the CCP decided that SIFARE should be as transparent as possible for community pharmacies such that they would not be forced to use an additional system for dispensing (as would have happened with the initial design proposed by the CHS, see Figure 2). This meant that pharmacy management systems (PMS) vendors should be able to integrate their solutions with SIFARE in a way that minimized the changes to the practices of pharmacists.

In 2005, the CCP created an advisory committee for technology and communications which brought together the CCP and the PMS vendors. Under this governance structure the CCP revamped a recognition program for PMS vendors. The program, which defined a minimum set of functional and technical requirements that PMS should fulfil, homogenized the behaviour of PMS vendors and of pharmacists in terms of access and use of the EPDI. The CCP developed a set of web services for SIFARE and an API (application program interface) (see Figure 4). Those vendors who passed the recognition program got the API from the CCP to interconnect their PMS solutions with SIFARE. The members of advisory committee met every quarter to discuss about the status of the EPDI and agree on its evolution –e.g. agree on the new requirements and services, on the pace for implementing those services. For instance, as a result of those meetings the CCP decided that the SIFARE API would be developed in C++, exposed in a DLL, and made calls to other Windows 2000 APIs. The reason for developing such a kind of API exposed in DLL was for the convenience of PMS vendors. Since all the PMS were running on Windows operating system, that kind of API minimized the disruption among PMS vendors. Moreover, the API enabled the dispensing and invoicing practices to run partially at the pharmacies and at the CCP. In particular, the API kept some degree of freedom for pharmacists about how they should perform their work while at the same time all the pharmacies sent the same information to the CCP's server for checking purposes.



Overall, the EPDI architecture and the governance structure created dependencies between the CHS, the CCP, PMS vendors and pharmacies. According to EPDI architecture (see Figure 4), the CHS would develop a set of SIRE web services to be used by the CCP for dispensing and invoicing. Then the CCP would create a SIFARE web service and an API for PMS vendors (see Appendix 2 for more details). With that API, PMS vendors would adapt their solutions for electronic prescription, and install and configure the new version of the PMS in pharmacies. Those dependencies conferred the CCP the capacity to set the pace of evolution. For instance, the CHS constantly released new versions of SIRE web services reflecting changes to the existing functionalities (e.g. the inclusion of new filters, the prescription by active ingredient), and developed new web services reflecting new functionalities (e.g. consult generic alerts). Yet when a new feature included in a new web service was not mandatory (not required by law), the CCP might consider that it 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 it, and might decide to skip the new feature. Accordingly, the CCP accommodated those changes to its own development resources, the capacity of PMS vendors to update their products, and the needs of pharmacists (Appendix 3 illustrates this idea).

IT Governance Arrangement Matrix

	IT Principles		IT Architecture		IT Infrastructure		Business Application Needs		IT Investment & Prioritization	
	Input	Output	Input	Output	Input	Output	Input	Output	Input	Output
Business Monarchy										
IT Monarchy										
Feudal										
Federal										
Duopoly										