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Tying the policy knot: the Case of an Ongoing Digital Archiving Project for Patient Records

Léonord Rolland-Blin, Khuloud Abou Amsha, Matthieu Tixier
Université de Technologie de Troyes, LIST3N
{firstname.lastname}@utt.fr

Abstract. Our study delves into the pivotal role of policies in the success of digital transformation initiatives, focusing on a case study of digitizing patient records at a general hospital. We aim to bridge the research gap on how policies are interpreted and applied in such projects, using a qualitative approach to understand the motivations and actions of the involved parties. By transitioning from paper to digital formats for clinical letters and test results, the project sought to optimize space and improve document access. Our findings, drawn from field notes and observations, highlight the diverse interests in digitization, from space management to policy compliance. We conclude with insights on the importance of policies in digital transformations, offering valuable lessons for future projects and digital archiving efforts.

Introduction

Computer-Supported Cooperative Work (CSCW) researchers have significantly contributed to understanding the collaborative nature of healthcare work, primarily through detailed workplace studies (Symon et al., 1996; Munkvold et al., 2007; Bardram & Bossen, 2005). However, the application of CSCW research in healthcare has primarily focused on the level of practices, leaving in the background considerations for the context of policy and regulatory compliance within healthcare environments. Fitzpatrick and Ellingsen (2013) emphasized this gap, pointing out the lack of specific examples of CSCW research addressing conformity with policy and regulations in healthcare settings, especially regarding privacy-related issues in hospitals and collaborative practices.

Accordingly, to truly transform CSCW findings into practical solutions for Electronic Health Records (EHRs) design and deployment, researchers must consider the broader picture encompassing legal and policy-related challenges (Jackson et al., 2014; Centivany, 2016). We need to develop a better understanding of the roles policies play in ongoing digital transformation projects. Current retrospective accounts are missing how the actors interpret and mobilize policies to achieve their project and agenda. This raises interesting and important questions about the possible roles of policies in ongoing digital transformation projects. Do policies support cooperation in digital transformation projects? Do they define a simple set of constraints and non-functional requirements (Sommerville, 2009) stated once and for all for a project? Can we understand policies as boundary objects (Star & Griesemer, 1989), setting up a shared and partially aligned context for the involved actors?

After introducing relevant related work about EHR projects in CSCW and previous analysis of the role of policies, we present our fieldwork and study approach in a digitization project at a general hospital. We present our study site in the Urology department, the work with patients' records, and the organization of the digitization project. The findings of our thematic analysis highlight the project's stakes from the different stakeholders' perspectives. We discuss the current status of this ongoing project and characterize the cooperation between the actors we have followed, the role of policies in the progress of the project and possible learning for future work.

Related Work

Beyond the complexity of integrating digital records into healthcare practices, limited attention has been paid to the policies that impact practices. The policies related to patients' records pose challenges and limits to practices, for instance in relation to the use of records as legal evidence. Research in CSCW has begun to

further the analysis of policies in technology development and appropriation. Our study aims to contribute to this emerging corpus of research about the role of policies in ongoing digital transformation projects.

Electronic Health Records for Cooperative Work

Medical documents such as clinical letters, reports, and discharge referral letters are vital information sources heavily relied on by care actors within the healthcare ecosystem (Lovis et al., 2000). They account for a significant part of the medical information stored within EHRs, offering a comprehensive and expressive depiction of the patient's medical history and current condition (Sultanum et al., 2018). The importance of these documents is multi-faceted.

Firstly, medical documents are essential for care actors to gather valuable information about the patient's trajectory, documenting the various steps and milestones in their healthcare journey (Mønsted et al., 2011). They facilitate a comprehensive understanding of the patient's condition, aiding in delivering personalized and supporting coordination for effective care (Bardram & Bossen, 2005; Cabitza et al., 2009).

Secondly, these documents play a crucial role in the legal aspect of medical work. Unlike structured data, which can change over time as the patient's condition evolves, these text-based documents serve as a constant and unchanged record of facts that help to accurately trace the patient's medical history (Lovis et al., 2000). This role is essential for legal compliance and safeguarding the patient's and care providers' rights and interests.

Furthermore, medical documents are integral to billing, auditing, research, and administrative actions within the healthcare setting (Almeida et al., 2012). They serve as a vital resource for the various stakeholders involved in healthcare delivery, including healthcare professionals, administrators, and researchers, enabling them to carry out their respective roles efficiently.

Lastly, these documents foster communication and collaboration among the different care actors, facilitating a seamless exchange of information and insights that can significantly enhance patient care (Winthereik & Vikkelsø 2005; Marref et al., 2022).

While the importance of these documents is well-recognized, it is crucial to note that the design and deployment of technologies such as EHRs often focus on one specific role of the medical document, sometimes at the expense of its other equally important functions. Research in CSCW has significantly contributed to our understanding of the collaborative nature of healthcare work, primarily through detailed workplace studies. These studies have highlighted the importance of coordination across diverse healthcare settings (Symon et al., 1996; Munkvold et al., 2007), the role of collaborative artefacts (Bardram & Bossen, 2005; Cabitza et al., 2009), and the unique challenges posed by large-scale Information and

Communication Technology (ICT) initiatives in healthcare (Ellingsen & Røed, 2010). Such findings are invaluable for designing and deploying technologies that support health professionals and care providers in delivering patient care.

Fitzpatrick and Ellingsen (2013) noted the scarcity of CSCW work at the policy level, essential for significantly impacting larger-scale health IT projects. Addressing these gaps is vital for a comprehensive understanding of the complex nature of healthcare systems and for creating compelling and holistic technologies that support health professionals in delivering patient care.

Digital Archives in Healthcare

Paper-based health records are related to several policy compliance issues; the same goes for EHRs. In a digitization project, a key consideration often revolves around the legal validity of records, which is frequently associated with digital signatures.

Each country has its particularities, like specific documents that still must be created on paper or the level of identity trust required for e-signatures. In the European Union, Iceland, Norway, and the United Kingdom, this question is one of the objects of the Electronic Identification, Authentication, and Trust Services regulation (eIDAS). The regulation defines three levels (simple, advanced, and qualified) corresponding to three degrees of confidence in the author's identity. All levels have legal validity, but only the qualified level is considered equal to handwritten signatures, as detailed in the EU regulation 910/2014. In the USA, this question is addressed by the Electronic Signatures in Global National Commerce Act (eSIGN) described in the public law 106–229. They aim to ensure cross-border validity to facilitate commercial exchanges and specify the conditions for e-signatures to be legally valid.

As the study is conducted in a hospital in France, we will consider the French legal framework in more detail. Since 2000, French legislation (Loi n° 2000-230) has recognized the probative value of digital signatures and digital documents (Wack et al., 2002). This position was confirmed in a 2016 order affirming that digital records are equivalent to paper records, provided their authorship is clear and they are preserved to prevent integrity loss (Article 1366 du Code civil). French law defines “*archives*” as all the documents produced or received by a person while practicing an activity (Article L. 211-1 du Code du patrimoine), which encompasses the English categories “*archives*” and “*records*”. Under certain circumstances, the archives' status implies a designated document management procedure. For example, French laws indicate mandatory preservation periods for health records (Article R. 1112-7 du Code de la santé publique) that impact the creation and update of the documents and their meta-data. In addition, control of the preservation must be realized for public archives, a procedure often managed by territorial archives. Most healthcare organizations are in this situation, either being public organizations themselves or associated with public services because

of their public health missions (Cornu, 2016). Besides an internal management process, they must communicate with territorial archives to transfer them a sample for long-term preservation and obtain authorization to eliminate records after the mandatory preservation periods (Leroy et al., 2017).

CSCW and Policies

While often set as a background element in the study of technology-mediated cooperative practices, the crucial role of policies in the initiation and deployment of technology is better acknowledged (Jackson et al., 2014; Centivany, 2016), and more studies have called for understanding the impact of policies on appropriation and design in CSCW. Fitzpatrick and Ellingsen (2013) especially call for a better understanding at this level in healthcare technology, where an essential part of technology changes and implementation are initiated on behalf of local or national policies aimed at improving healthcare organizations for the benefit of patients (Cormi et al., 2020).

Jackson et al. (2014) propose to look at technology, practices, and policy as interdependent elements of a policy knot. On the ground of two cases of technology-mediated social practices that have been compromised by policymakers, namely *GirlsAroundMe* and *Google Buzz*, they eloquently highlight how policy can shut down a potentially harmful platform as an aftermath or counter the top-down development of a product unduly imposed by a significant firm.

Centivany (2016) supplements this corpus of case studies with a study about a digital library agreement about document sharing. The authors emphasize how, over the long term, initial choices made while policy-making can have a major impact on the spaces opened or closed for technology and social practices later in related project implementation.

These studies clearly show that policies can critically impact socio-technical practices and their technology support. However, the studies so far dealt more with retrospective accounts, and little has been said about the role policies are playing in ongoing digital transformation projects. The precise nature of the relationship between policies, practices, and technology in the “policy knot” is considered open (Jackson et al., 2014) and calls for generating more hypotheses. This raises interesting and important questions about the possible roles of policy in ongoing digital transformation projects.

Fieldwork and Methods

We conducted our fieldwork in a public hospital (Hospital A) for six months, from March to August 2023. The hospital representatives, namely the head of the medical information department (HMInfo) and the head of the archives service (HArch), presented the digitization project in Urology at the first meeting. They

presented their objective to suppress all paper-based exchanges of medical records between the archives and urology and replace them with digital exchanges. The HArch then led a tour of the archives.

We participated in eight meetings related to the project and two observations at the urology secretary's office (one three-day observation and another lasting two and a half hours). The aim was to understand the practices surrounding patients' records and the objectives behind digitization for the various stakeholders (Table 1). Notes were taken during the meetings and then summarized in reports. These field notes reports were then used to conduct a collaborative corpus analysis with the Cassandre software (Lejeune, 2010), designed to support a qualitative analysis approach inspired by grounded theory (Strauss & Corbin, 1990; Lejeune, 2019).

Three of the eight meetings were steering committees, occurring every two months throughout the study period. They were held in the office of the HMInfo and attended by the same people as the first presentation meeting.

A **meeting with the chief secretary** has been arranged by the HArch in her office. Discussions focused on the necessary information for finding documents and the practices of secretaries.

The **first observation in the Urology secretariat** was conducted briefly afterward. We followed the tasks the four medical secretaries (MSec) carried out for three days. The aim was to gain an understanding of their work practices and organization.

The HArch's contacts enable an **exchange with another public hospital** (Hospital B). This hospital initiated the digitization of all patients' records a few years ago and reached the end of the project phase. The videoconference occurred in the medical information office and included significant members from Hospital B's digitization project team: three archives personnel and a computer engineer. In Troyes, in addition to the HMInfo and HArch, the Director of the Hospital IT department (ITD) was also present. The digitization project team of Hospital B provided a brief history of their project, guidance on necessary regulations, and feedback regarding their software service provider.

A **meeting with the departmental archives** (DepArch) was arranged due to the hospital's affiliation with public services. The DepArch oversee the scientific evaluation of Hospital A archives. An appointment with a specialist in digital archives has been organized in the HArch office.

A **proposal for an electronic document and records management system (EDRMS)** was presented to the HArch. The software provider initiated the meeting and held a video conference. The DepArch had previously confirmed the need for such specialized software to manage digital records properly.

Following our request for an interview with the head doctor of the urology service (HDUro), a **global meeting** was organized in May 2023 in the staff room on the Urology floor. It brought together representatives of some of the leading project's stakeholders: the HDUro, two MSec, the chief secretary, two nurses, the

HMInfo, and the HArch. During this meeting, the HDUro proposed a new process to reduce the transfer of paper patients' records between archives and his service.

One month after the proposal by the HDUro, a **second observation** was conducted with the MSec. The goal was to observe the new organization, the eventual changes and problems that occurred, and the secretaries' first feedback on the restructuring.

These meetings have allowed us to understand the practices and concerns of the main stakeholders. The table below summarizes their roles and the scope of their concern for digitization.

Table I. Overview of the digitization study involved stakeholders

Stakeholder	Number of Informants	Role	Scope of digitization
Head of the Medical Information Department (HMInfo)	1	Medical information management; Communication with direction	All new medical records
Head of the Archives Service (HArch)	1	In charge of the project's documentation redaction; Resource person for archives regulations	Overall
Head doctor of the urology service (HDUro)	1	End-users of information in medical records	External documents only (exams and letters)
Medical secretaries (MSec)	4	Preparation of the records before consultations and operations; Exchanges of records with the archives and the medical staff; Checking and sorting medical records	External documents only (exams and letters)
Nurses	3	Final users of information in medical records; Transfer of medical records to doctors during consultations	Overall
Information Technology Director (ITD)	1	Medical information and systems security; Software selection, implementation, and maintenance	Overall
Departmental archives (DepArch)	1	Evaluation of the hospital's archives; Guidance and expertise in document preservation	Overall

The Digitization Project Context

In what follows, we present an overall view of the work of the Urology department secretariat. Then, we introduce the key stakes and steps of the archives' digitization project as understood by HArch, who has the project leadership. Both provide essential background information for understanding our analysis.

Document Work at the Urology Department Secretariat

In urology, the four medical secretaries are divided into three positions that are exchanged weekly. One is responsible for preparing hospitalizations, one for preparing consultations, and two are typing assistants.

The preparation role in the Urology Department's secretariat is vital for coordinating patients' admissions for surgeries, treatments, and consultations. The MSec organizes documentation and logistics for a smooth process, including collecting and verifying patients' records, finalizing treatment plans with medical staff, and meeting pre-hospitalization requirements. Their tasks also encompass scheduling surgeries, stays, and patients' transport while considering resource availability, which requires meticulous attention to detail and strong organizational skills.

At Hospital A, patients' records are shared by all departments and contain medical information collected since the patients' first hospitalization. In addition, the services manage the records for patients who have only come for regular consultations with their doctors. As soon as a patient is admitted to hospitalization for the first time, their complete records, including consultations, fall under the hospital's responsibility and are then preserved by the archives service.

Managing paper patients' records for hospitalization and consultation in the Urology department is systematic and crucial. MSec starts by identifying upcoming admissions and consultations and requesting necessary records from the archives. Then, the archives department delivers these files, which MSec inspects, ensuring all relevant data is ready for use. To this end, they add documents recently received and sort them by date. Then, patients' files are sorted by physician, day, and consultation time before being transmitted to the relevant medical personnel.

For hospitalizations, French law specifies that the clinical letter must be sent to the concerned doctors on the day of the patient's discharge (Décret n° 2016-995). In Hospital A, the interns write the letter, which the MSec then edits. A clinical letter also exists for consultations but can be sent the week following the appointment. The two secretaries in charge of the typing task use the physicians' audio recording to type the consultation letters, and a copy is added to the patient's records.

To complete the cycle, MSec returns records to the archives after reordering their content if necessary. The records are placed in a designated office area, where the archives team picks them up on their daily shuttle.

This cycle of requesting, updating, and returning paper records is critical in the secretariat, supporting the hospitalization and consultation processes with comprehensive and current medical information crucial for the hospital's healthcare delivery.

Since HDUro reorganized the secretarial process in May 2023, the number of records requested from archives has significantly decreased. As most urologists agreed to base their decisions solely on recent documents rather than complete

patients' files, the records are only ordered for specific situations, such as first urology consultations or cross-cases with the oncology service. In return, the MSec can spend more time typing letters and returning documents to the archives. However, the preparation of hospitalizations has remained unchanged because of the necessary records exchanges with the nurses and the surgical unit.

A Health Records Digitization Project

Launching a digital archiving project within a general hospital has many prerequisites. One central requirement is the production of documents to present the project to the hospital management and, in a way, give it an administrative existence: a project file. This file also acts as a guide throughout the project. In our case, the HArch oversees this aspect. The project file outlines the project's stages and objectives, the stakeholders involved, the existing processes and resources or those that need to be acquired or implemented, and the designation of a steering committee. This last task is crucial, as it will affect the available resources.

As the project file describes the hospital's current resources and processes, such information must be gathered from different stakeholders. In our situation, the HArch knew paper archiving practices and their legal requirements but needed to learn about secretarial practices, digital archiving, and the hospital's IT architecture. For instance, a naming convention for digital documents must be defined with MSec to benefit from a consistent convention when digitizing patient records. The project file must also comply with the hospital's archiving policy, a document that sets out an organization's archiving goals and processes and must be validated by the hospital management. While the Hospital's A archiving policy is only in its drafting stage, it still must be in line with the project file. The HArch is the most suitable person to verify it since she also writes this archiving policy.

This project significantly impacts the hospital's archives and requires exchanges with the DepArch. As previously mentioned, hospital archives are covered by public archives laws. Consequently, their preservation must satisfy the preservation requirements of public archives. Replacing paper records with their digital version in managing the patient situation is allowed. Still, the approval of the DepArch is mandatory to eliminate the paper versions as the hospital wishes. Their veto would be disastrous for the project.

Findings

Our thematic analysis highlights the stakeholders' perspectives about the potential benefits of saving space and time, gaining access and sovereignty on hospital health records, and how tradeoffs about the project scope are achieved considering the issue of conformity to policies.

Digitizing for Saving Space

One of the cross-cutting issues of several hospital stakeholders is space management. During our observations, this concern was more visible in the secretariat and archives and affected medical practices.

For the HArch, space management is an essential task. She must constantly keep under control the space occupied by paper archives at the scale of the hospital. She manages the patients' files and the entire hospital archives, including, for instance, the HR and purchase department, with their legal constraints. It represents about 400 linear kilometers of paper archives split in different rooms across the hospital, and medical records represent 12 linear kilometers. The records' volume is already slightly higher than it should be, leading to storing new files on the highest shelves and causing handling problems.

“Many [patients' records] are on the highest shelves of the archives. This accessibility problem makes the handling more difficult as they must bring a stepladder to reach them.” Field note based on MSec comments.

The archives service aims to reduce the volume of preserved archives, but for now, active work only enables maintaining the current size.

The digitization project for the Urology department is of crucial interest to the HArch as it could prevent the service from producing new paper-based patient files, which brings the promise of free space as old enough patients' files can be progressively destroyed or transmitted to the DepArch. She sees the project as a potential pilot project that can serve as a model for other services.

In the Urology secretariat, the space is mainly used to store medical records prepared for consultations or waiting to be archived (figure 1). As the service has a high activity level, many files are exchanged daily with the archives and kept in the secretariat. At the beginning of the observation, the shelves were insufficient to hold all the documents.

“[In the Urology secretariat] There are shelves for storing patients' records all along the wall on the corridor side. One of them (further than the others) has been added because of the quantity of records on the floor. They were obstructing movements within the secretariat. Transport trolleys are also used to store them.” Field note based on MSec comments.

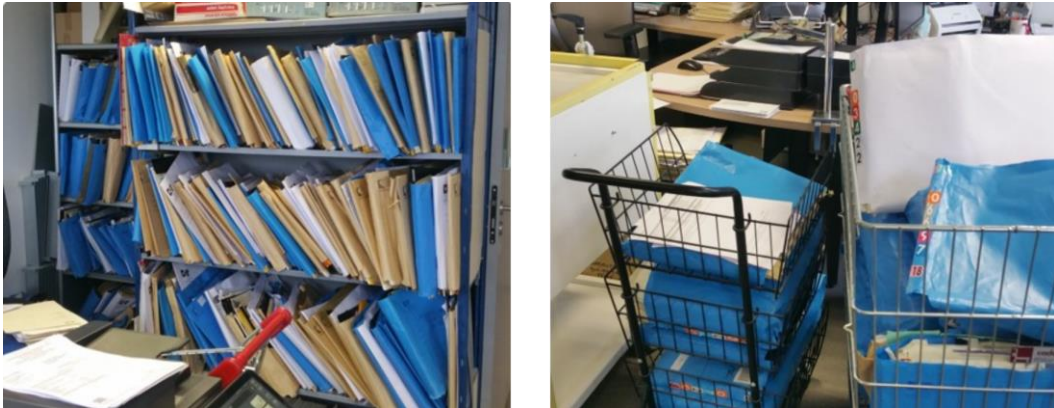


Figure 1. On the left is a view of shelves in the secretariat; the additional shelf is the central one; on the right, there are trolleys filled with patients' records.

In addition to the hospital records exchanged with archives, the urology secretariat also contains medical files for patients who have only seen a urologist for consultation, as they are not under the hospital's responsibility.

"These files are stored in the secretariat in drawer cabinets and, as there is not enough space in them, in boxes near the desks and in the patients' records shelves." Field note based on MSec comments.

The new process, defined in May 2023, improves this situation as fewer files are requested to the archives and stored in the secretariat.

"Shelves are much less crowded, and the central area of the secretariat clearer. [...] Eventually, secretaries hope to remove the additional shelf that obstructs the movements of one of them and her visibility of the rest of the secretariat and to reclassify the remaining records." Field notes based on MSec comments.

Physicians have already agreed to limit themselves to fewer documents during consultations in some other medical services. In urology, this practice shift partially happens by applying the process proposed by the HDUro. Moreover, patients' records are kept in the secretariat for much longer than the consultation time to complete them with received documents. In this context, their digitization, or at least of specifically selected papers, was seen as a solution to reduce the flow of records between the archives and the secretariat. It means fewer medical records in the secretariat, thinner files in the archives, and less time spent searching specific files in the secretariat.

The hospital's management, including the HMInfo, the HDUro, and the HArch, has safety concerns with many patients' files in the secretary's office. A few years before the beginning of our research, there was a work hazard in another service where a hospital employee fell due to paper files on the floor.

Nurses and doctors of the Urology department find the paper-based files cumbersome but are not concerned with the lack of space as they scarcely come to the secretaries' offices to pick up patients' files. Most of the time, the secretaries bring the patients' files.

Digitizing for Saving Time

As mentioned earlier, two secretaries are responsible for preparing patients' records, one for the hospitalization journey and one for day consultation. The other role is typing assistant for preparing reports and mail that will end in the patients' files and be posted to the relevant healthcare professionals.

At the beginning of our study, ordering all the patients' files before patients' visits was a regular and required activity. It involves preparing a list of patients to come from the doctors and hospital schedules and checking the location of patients' files, which can already be in the MSec office. After ordering patients' files to the archive, the secretaries in charge manage the reception of the complete files and their consistent ordering in piles according to the day of the visits (half-day for consultation). Fax and mail documents will arrive throughout the days for inclusion in the patients' files, for instance, biology exam results. This preparation activity takes a lot of time daily.

The other secretaries are responsible for typing reports and letters from doctors' audio recordings. The reports and copies of the letters must be printed and included in the patient's files. The secretaries suffered from the increased number of patients' files in the office, which also increased the time needed to find precise information. While cleverly organized by the secretaries as different piles, there is a tradeoff as this organization requires space to save time in looking for patient information.

The secretaries expect that digitizing patients' documents would relieve them from retrieving files from the archives department and the complex management of paper files in their office. To a certain extent, this was achieved with the reorganization decided after the global meeting in May 2023 as, apart from hospitalization cases, the MSecs no longer order patients' files and instead bring the new documents to the archives, where they should sort them back in the corresponding files.

As a mirror, managing patients' files for the Urology department is also heavily time-consuming for the archives department. The archives handle around 100 patients' files daily, and the Urology service is the biggest request provider. The archives staff must process the patients' records requests on one dedicated software, check for their location in another software, get each file in the archives rooms, put and sort in the trolley, and perform a daily shuttle delivery. For the staff, the operation takes the entire morning. The HArch has identified the potential relief from replacing patients' records movements through digitization from the project's onset, especially as other specialized departments work well with far fewer record requests. Another issue comes from the patients' files tending to stay in the Urology department secretary's office long before returning.

From the perspective of the HDUro, one of the main motivations for engaging in the digitization project lies in his search for a better organization for recovering reasonable typing delay. According to his estimates, agreed by the secretaries, a

clinical letter might take ninety days to reach its recipient. This considerable delay in typing put the department far out of the legal delay of 7 days for clinical letters to the GP or other hospital services. Thus, the primary expectation from the digitization project is to reduce the time spent ordering and organizing complete patient records in the secretarial office to save time for other jobs.

The HDUro and the HMInfo are expected to improve the organization and save time by digitizing at least part of the patient's files. They hope searching from digital files will be easier and faster than accessing paper records through the multiple mediations of human work.

Digitizing in Compliance with Legislation

The digitization project was initiated to reduce paper circulation between the Urology and Archival departments. However, this project will also affect the work practice of medical document management in both departments, highlighting some challenges related to conforming to the legislation.

For the Archival department, the digital version of the health records must meet certain conditions to have "probative value" in the event of legal disputes as well as set clear delays for elimination.

Moreover, in such digitization projects, the hospital must secure approval from DepArch to transition from paper to digital records, which also involves destroying paper documents post-digitization.

The digitization process should provide the Archival department with information such as the date of the patient's last hospital visit, which is crucial to destroying the medical records, whether in paper or digital form, according to the law.

Hospital A adheres to a specific regulatory framework for retaining medical records. The standard retention period for these records is 20 years following the patient's last visit (with several exceptions). The hospital faces challenges in meeting these retention deadlines, often due to insufficient information and issues with regulatory compliance.

"Generally speaking, currently, we lack the information needed to apply deadlines and are not compliant with regulations, so we overkeep the documents for safety." Field note based on HArch comments.

The HDUro put forward concerns about delays in document processing exceeding legal limits due to the overload of the secretaries. For the Urology department, the digitization project is one way to free the secretaries and thus make them able to type and send clinical letters within the legal delay.

This project highlights the interdepartmental dynamics and challenges between the Archival and Urology departments. These challenges stem mainly from differing perspectives on document management and digitization. For instance, a proposal from the Urology department suggested that as the digitization project is not taking off soon, the secretaries scan the medical documents by date and put

them in boxes. Then, the Archival department employees should classify these documents in patients' records. However, this was declined by the HArch primarily due to confidentiality concerns.

Gaining Access and Sovereignty on Hospital Health Records

Hospital A encounters several challenges in data management and archiving systems. HMInfo has explained difficulties with the existing electronic health records software, particularly concerning data ownership and compliance with the General Data Protection Regulation (GDPR).

“With our electronic health records software, we don't own our data and must pay to get it back. The publisher refuses to delete the data [according to the legal duration], which also poses a problem regarding the GDPR.” Field note based on HMInfo comments.

The hospital is actively exploring neutral archiving options for EHR to address these issues. These alternatives enhance data control and facilitate better integration with other information systems.

“Neutral archiving gives us total control over our data, independence from publishers, and automated connection with other information systems.” Field note based on HMInfo comments.

Hospital A efforts to transition to a “paperless” environment are ongoing, although various regulatory limitations impede them. Developing digital archives that meet the legal requirements is highly complex.

An exploration of electronic signature systems is underway. However, these systems have yet to align with existing regulations fully, indicating a need for further development to ensure compliance. When discussing the implementation of electronic signatures at Hospital A, the HArch mentioned being aware of a system purportedly functioning as an electronic signature in some of the hospital departments. However, upon closer examination, this system did not align with the expectations set by eIDAS regulation. This discrepancy highlights a significant gap between the operational reality within the hospital's departments and the stringent standards required by eIDAS for digital archival, underscoring the challenges in achieving regulatory compliance in digital authentication processes.

The quest for an archiving solution at the hospital reflects the intricate challenge of finding a system that meets the hospital's specific needs and rigorously adheres to regulatory standards. For instance, one EDRMS system vendor presented its software to the project team; the solution revealed significant discrepancies upon closer inspection of the French digital archiving norms (NF Z42-013 of 2020 on digital archival systems and NF Z42-026 of 2023 on document digitization). Initially, though marketed as an EDRMS system, the vendor's software bore more resemblance to a legacy document management system. Key issues included the tracing of operations and the protection of stored data and documents. In the case of Hospital B, the involvement in refining an off-the-shelf brought it up to standard after several years of adjustments. These adjustments included the implementation of server stamps, log caches, chain-of-evidence, and specific storage features. This

case underscores the complexity of deploying a digital archiving solution that aligns with legal requirements while also fitting the unique operational context of a hospital.

Discussion

In what follows, we discuss the status of the digitization project and characterize the cooperation between the actors we have followed, in particular, the role of policies in the progress of the project and possible learning for supporting such a digital transformation project.

The Current Statu Quo of the Digitization Project

The archives and the Urology secretariat share the need to save time and space when dealing with patients' records. However, the legal concerns are quite different for each stakeholder. The Urology department aims to meet the minimal legal requirements. Their concerns are, for example, medical responsibility, the accessibility of medical information, and their transmission between health professionals. Meanwhile, the HArch tends to support relatively complete conformity with legislation to guarantee the probative value of the hospital's records. Improvement of the hospital's control over its data brings together the HArch, the HMInfo, and the ITD. However, their main interests differ slightly, as the HArch focuses more on assuring the probative value. In contrast, the HMInfo and the ITD mostly search for interoperability and improve access and sovereignty on the hospital data.

All these topics are highly intertwined; the approach of each stakeholder depends on their perspective on the patient's records. This overview highlights that although each stakeholder's objectives are generally aligned, they are not entirely convergent. As the issues are all related to the hospital's records, the HArch remains crucial in the digitization project. Her expertise and professional relationships are essential in meeting the legal requirements of public records management. HArch is recognized as such and is therefore consulted to verify the validity of the different proposals.

During the study, several tasks were conducted to prepare the digitization project. The HArch initiated writing sections dedicated to the digital records in the archiving policy and the project file, which will be presented to the management. She also organized the first discussions with the DepArch. Furthermore, the chief of the secretaries and the HArch exchanged upon secretaries' practices to create the first naming convention, which specify the naming of the future digitized files.

However, the stakeholders involved do not have enough information about the hospital's IT systems and the capabilities of its current software to complete these

tasks. As the project also requires new software able to manage digital records, precise budgetary information and software expertise are needed to pursue it.

Finally, the aim to align the hospital with digital archives and health records policies is still valid. The project is not discarded but suspended until better conditions allow access to the missing information, support, and resources.

Tying Knots and the Role of Policies

In our study, a space and time constraint within the Urology department initiated a project, unfolding complexities in aligning with regulations and necessitating diverse expertise from different stakeholders. Our case study exemplifies the intricacies Jackson et al. (2014) described in the “policy knot” concept, a framework illustrating the entwined nature of design, practice, and policy.

On the side of the relations between policies and technology, we observe how digital archives and health records policies challenge the identification of a software component that matches the requirements at Hospital A. We even see the embedded generativity of policies (Centivany, 2016) at play in the digitization project of Hospital B, where the chosen system has been changed several times to fit the policies and hospital practices.

On the side of the relations between policies and practices, we identify influences at two levels. On the one hand, the requirements of conformity to digital archives and health records policies led the HDUro to escape the complexity of digitization by choosing a new organization for the Urology secretariat work. On the other hand, the digital archives and health records policies are clearly not offering an adaptable and robust scheme of shared categories, a boundary object (Star & Griesemer, 1989), for supporting the cooperation between the involved stakeholders. While we have seen the authority and legitimacy of these policies are not challenged, only HArch and DepArch understand their content. We observe that digital archives and health records policies are rather providing HArch with a roadmap and a set of suggested boundary objects that she has to build and negotiate case by case to secure the alignment of each stakeholder. We identify instances of this work in the project file for cooperation and agreement with the hospital management and DepArch, or in the naming convention for digital records negotiated with MSec.

In our case, the project’s advancement resembles what Engeström and colleagues (1999) call “knotworking”, a dynamic collaboration process transcending conventional boundaries. It involves forming adaptable “knots” of professionals and clients focused on a shared goal, capable of evolving with the project’s needs (Abou Amsha et al., 2021). The global meeting with the urology service gives a good illustration of this knotworking. Due to the presence of health professionals, discussions revolved around concrete medical practices and specific legal constraints such as delays for sending clinical letters. The HArch and the

HMIInfo were also present, and were able to guide the choice of the new secretarial process based on its compliance with legal requirements for medical document and data (practices and policy). For example one proposition of the HDUro implied to destroy biological exams results when they can not be used for medical decision anymore but was rejected after the HArch pointed out that they were proof to support medical decisions and so needed to be preserved in patient's files. However, the IT department was not represented, so topics such as the capabilities of the hospital's software were not discussed further

Our study reflects the continuous adaptation and compromise made by the actors. This approach underscores the project's continuity over the individual participants, allowing for changing involvement as the project progresses. While occasionally paused, the project is ongoing, driven by persistent challenges or evolving regulations. Our study highlights the importance of supporting this continuous process of collaboration, underscoring the dynamic nature of policy implementation and technological adaptation.

Learnings for digital transformation project

The statu quo of the project at the end of our study highlights different practical concerns related to healthcare records policies in a digital transformation project. Observing the project progress dynamic, we can hardly expect implementation and release to be an ideal one-shot go live. As lessons from the field this highlights three important learnings for digital transformation projects in policy-dense environments.

Achieve stepwise project through artefacts: Implementing a digital archives project at a hospital is complex. We have highlighted how policies suggest a roadmap and boundary objects for progressing along knotworking episodes. As illustrated by HArch's work on the hospital archiving policy that is still in the draft stage, she is aware of and expert in dealing with such a dynamic. HArch knows that digital archives projects are a long run. While the project may be paused, she is taking benefit of the progress made at one step to anticipate progress for the next. Here the production of documents and artefacts that can act as boundary objects with part of the stakeholders is especially useful to keep track of the project progress and capitalize advance despite recurrent restart.

Aim at progressive compliance of digital records: Given the importance of the requirements for the digitization of patients' records (i.e., file naming, storage, changes log, signature, and authorization structure), it is hardly expected that digital documents can meet the expectations in one time within such a lively organization as a hospital. A wise option lies probably in progressively increasing the compliance of the records with the policies at each step in the long run of the project (Tosi & Bénel, 2016; Zacklad, 2006). For instance, defining and releasing a naming convention for digitized documents is a passage point in the direction of

compliance with digital and health records policies. Such a strategy can mitigate the issue of restarting the digitization from scratch.

Do not neglect relation work: The relation work (Bjørn & Christensen, 2011) involved in tying knots and advancing such complex project appear of special importance. For instance, completing the project file has involved a lot of work from HArch to gather information and get support from different stakeholders. In our situation, HArch knew paper archiving practices and their legal requirements but needed to contact different resource people regarding MSec practices, the hospital's IT architecture, or the departmental archives. Meeting these different stakeholders is essential so that they agree to concur to the project progress.

Conclusion

Our qualitative study highlighted the role policies play in ongoing digital transformation projects. Our analysis highlights the different perspectives of the involved actors concerning compliance with patients' digital records policies and the challenge for their cooperation in the project.

We hope to continue and follow up the hospital digital archiving project for patient records in the coming years and further our analysis of the next steps in tying knots between policies, technology, and practices.

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