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Beyond Organizational Boundaries: The Role of Techno-Legal Configurations

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Beyond Organizational Boundaries: The Role of Techno-Legal Configurations

Completed Research Paper

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Abstract

In this paper, we explore how techno-legal configurations shape the evolution of an information infrastructure (II) by focusing on data as its critical components. We define techno-legal configurations as assemblages, which are technologically determined by the functionalities for data storage, processing, sharing and usage, and legally determined by the basis for data processing, such as consent, data-processing agreements or laws. To study II's evolution we conduct an 11-year study of a regional II in Norway as electronic patient record data and patient-generated healthcare data were shared within and across hospital organizations. We show how the considerations of data as internal and external to organizations are continuously renegotiated across techno-legal configurations, which we define as harmonized space and disparate space. We contribute to the II literature by raising the importance of the law in shaping the boundaries across which data can be produced, shared and used.

Keywords: techno-legal configurations, information infrastructures, patient (generated) health data

Introduction

Health data and the information infrastructures (IIs) across which they are produced, shared and used are facing a changing landscape. An increasing number of healthcare services are provided beyond clinical environments, relying on remote care monitoring (RCM) technologies used by patients at home. The new types of technologies (sensor- and wearable-based, as well as patient reporting forms) are based on new types of data, which differ from the data commonly stored in electronic patient record (EPR) systems. These patient-generated health data (PGHD) are produced by patients at home using medical equipment, inclining less trust in the precision and data quality from clinicians' side, and posing novel security

concerns. PGHD, consisting of real-time and continuous data streams, related to patients' symptoms, treatment, lifestyle choices, have proven to be particularly valuable for treating and monitoring chronically ill patients (Bardhan et al., 2020). However, as of now, PGHD remain an underutilized, but valuable resource for preventing, predicting, and following-up on diseases.

Our research aim with this paper is to delve into the challenges of utilizing health data, shared across organizational boundaries and produced by multiple sources, including bringing together EPR and PGHD data. Researchers have pointed towards the regulatory complexities of producing, sharing and using sensitive, personal health data (Winter & Davidson, 2019), and the importance of harmonizing regulatory, technical and organizational spheres around PGHD as a novel, unregulated category of data originating from consumer-centric devices. In this paper, we investigate the interplay of technology and law related to EPR and PGHD, by adopting an II perspective. The II research stream is well suited for studies on health data, as it takes real-life complexity as a premise, addressing the interplays between multiple organizations with different interests, a heterogeneous technical system landscape and complex, overlapping regulatory regimes. We argue how studies on data as critical components of IIs could go beyond the utility perspective (i.e., the understanding of data as valuable assets and resources, primarily focused on data's intended usage) (Grisot et al., 2019; Vassilakopoulou et al., 2019; Vassilakopoulou & Aanestad, 2019) and acknowledge the importance of the underlying organizational, technological, legal structures conditioning how health data can be produced, shared and used.

The research question we seek to answer is: *"how does the interplay of technology and law condition the sharing of data in information infrastructures in healthcare?"*. For that purpose, we empirically follow the 11-year evolution of a regional information infrastructure in the specialist healthcare sector in the South-East region of Norway, encompassing both, EPR data and PGHD. By building on assemblage theory as a theoretical lens (DeLanda, 2006, 2013, 2016), we regard the interplay of technology and law as techno-legal configurations. We define techno-legal configurations as assemblages which are determined by the technological functionalities for data storage, sharing and usage, and by the legal basis for data processing, such as consent, data-processing agreements or laws.

Overall, this paper contributes to the literature on IIs and data by showing how the production, sharing and usage of data is not necessarily internal to organizations' managerial authority. Instead, the boundaries determining how data are produced, shared and used are continuously negotiated beyond single organizations and across techno-legal configurations. With this, we do not indicate how organizations (particularly those operating in highly regulated settings) only seek legal compliance and lack agency. Instead, various forms of producing, sharing and using data can take place enabled and constrained by legal and technical provisions.

This paper is structured as follows. Next, we review the literature on IIs in healthcare, and particularly IIs and health data. In section three, we present assemblage theory and unpack the concepts of assemblages and territoriality and show how we utilize them in our particular case. In section four, we describe the research approach and our case background. Section five presents our findings formulated around four techno-legal configurations from our empirical settings as data were shared within and across the regional infrastructure. In section five, we analyze the findings and define two spaces across which technology and law got configured related to the nature of data – in our case, EPR or PGHD. In section six, we discuss the main contributions of the paper.

Related Research: Information Infrastructures and (Health) Data

Our research paper is positioned within studies on information infrastructures, which have been increasingly focused on how data are collected, recirculated, processed by different IT systems, contributed and distributed across organizations and used for various purposes (Jarvenpaa & Essén, 2023; Tempini, 2017). In this paper, we organize this literature around two central aspects. First, the core assumptions underlying the nature of data as moving beyond organizations' unilateral control, requiring an inter-organizational approach, such as that of information infrastructures. Second, the studies on data in IIs in healthcare, suggesting how the existing work practices, institutional arrangements, organizational structures, technological capabilities enable and constrain how data can be produced, shared and used.

A core assumption underlying the rising literature on data in information systems (IS) is how data are distinct assets or resources than digital technologies (Alaimo et al., 2020; Vial, 2023), despite being

mediated by digital artifacts (e.g. software) and different devices. Data can be stored, accessed, copied across various organizations simultaneously without depleting in value, and edited, recombined and used for purposes beyond their original intent (Vial, 2023; Yoo et al., 2012). Data's mobility and ability to be recirculated, while increasing rather than depleting in value have been central in studies of inter-organizational nature. Davidson et al. (2023) raise how "many data resources are situated outside a single organization's boundaries and beyond its unilateral control" (p. 03) and commonly nested across societal levels. Moreover, Jarvenpaa and Essén (2023) argue how data should span technological and human generations, as data resources which were previously pushed aside, could have potential future use value. Overall, these works argue that the nature of data challenges organizations' managerial control and instead requires "new, distributed organizational forms enacted by individuals, technology vendors, data-holding (or using) organizations, and regulatory agencies" (Davidson et al., 2023, p. 04).

Furthermore, scholars have raised how the distributed nature of data triggers changes in the social, economic, technical space organizations operate in. (Alaimo & Kallinikos, 2021, p. 3) have referred to this phenomenon as the "decentering of organizations". As they state, the production of data objects (e.g., users, customers, products) "loosen the tight grip of domain knowledge over the production and use of data, [and] reorder the relative significance of internal versus external references". Beyond data objects, other have also argued how organizational work does not inherit value, meaning, purpose from organizations as "containers" but can be encapsulated by various organizations across which meaning, purpose and value are negotiated (Winter et al., 2014). As illustrated by developments in personalized medicine and home monitoring services, healthcare is a good example of this organizational unboundedness and decentering (Alaimo & Kallinikos, 2021).

In the area of data work practices, Vassilakopoulou et al. (2019) illustrate how clinicians worked across an II for genetic data sequencing, based on data stored across multiple repositories, prone to heterogeneous terminologies, quality assurance and control mechanisms. This study, while showing the complexity of making sense of distributed data sources, brings attention to the specific characteristics of the users, their interests, prior knowledge and the context within which they make sense of data. Within a municipal healthcare context, (Grisot et al., 2019) also show how data produced by patients at home, originating from external (outside of hospital) sources enabled novel work practices in personalizing care through remote care monitoring for chronic patients. As the authors conclude "personalization is achieved by working with selecting which data are relevant and meaningful to nurses (e.g. by deciding for each patient the type and frequency of data collection), working on data by interpreting and cross-analyzing data from different sources (e.g. from the devices and the questions) and working on enriching device-generated data by collecting additional data on specific issues (e.g. by asking specific follow-up questions to each patient)." (p. 615). This distribution of data sources beyond clinical and hospital environments clearly shapes the social, economic and technological healthcare organizations operate in, as argued by these works.

In the area of remote care monitoring and patient-generated healthcare data (PGHD), the changed organizational landscape has also led to discussions related to barriers in adopting these services (Simblett et al., 2018), data quality, security and privacy (Azodo et al., 2020), and their integration with electronic patient record systems (Dinh-Le et al., 2019). It has also been argued how PGHD require new considerations for harmonizing technology, laws, and organizations (Winter & Davidson, 2020), and how their relying on cloud solutions can collide with national laws and regulations (Kempton et al., 2020). However, in information systems, longitudinal studies discussing the challenges of the nature of PGHD against the underlying installed base of IT systems, organizations, institutional arrangements, are still lacking.

A second line of research in IIs can be identified around how the production, sharing and usage of data is shaped by the II, and shapes the II in return. This builds on traditional II studies highlighting the importance of the existing set of technological capabilities, organizational practices, user communities, institutional resources enabling and constraining the evolution of the II (Aanestad & Jensen, 2011; Hanseth et al., 1996; Sahay et al., 2009). For instance, in his study on an online patient community, (Tempini, 2017) shows how architectural components which were initially glued together had to be unbundled to leverage the value potential of data as central components in the II (e.g., in his case, the conditions, or diagnosis shared by many patients), in contrast to the previous architectural arrangement which tightly coupled functionalities to the individual patient. Therefore, data were shared by the II, and were shaping the II in return.

Overall, studies in IIs have predominantly focused on health information systems as central components and (Currie, 2012; Klecun et al., 2019), but have not specifically discussed the role of data as central components. Empirical insights show how the involvement of sensitive and personal data brings in specific dynamics to the evolution of IIs. For instance, when studying the information infrastructure for data sharing of the National Health Service in UK, Pouloudi et al., (2016) show how various issues were raised on gaining access to sensitive patient data among the public-private network, including compliance with national regulations, security and confidentiality, the mingling of EPR data with other data sources, the potential for commercial firms getting access to these data. Seddon and Currie (2022) also discuss challenges in the trans-border data flows in the context of cloud computing in healthcare, highlighting the need for harmonizing regulations, compliance and defining roles and responsibilities. However, while the involvement of personal and sensitive health data clearly brings the need for considering the role of law, the law has not been studied as having a central role in shaping the II, and being shaped by the II in return.

Assemblage Theory as a Theoretical Lens

Assemblage theory (DeLanda, 2006, 2013, 2016) is an ontology of processes and structures, arguing how there are different degrees of order and chaos, heterogeneity and homogeneity, in the dynamic, social world (Rutzou & Elder-Vass, 2019). Assemblages, as its central concept, refer to the process of fitting together a set of heterogeneous components that form larger wholes, but keep on changing. As processes, assemblages are formed by relating heterogeneous components; as structures, the heterogeneous components stabilize and form larger wholes. Therefore, assemblages simultaneously form cohesive larger wholes, while keeping on changing.

Due to the interplay of process and structure, assemblage have certain degree of *(de)territorialization*. The territorialization of assemblages can be determined by two parameters: 1) the *sharpness of boundaries* defining what is internal and what is external to the assemblage; and 2) the *homogeneity of components*, as in the components that are included or excluded from assemblage's internal territory. Overall, the degree of territorialization helps the assemblage keep its identity over time. However, assemblages, due to their heterogeneity keep on relating and therefore, are simultaneously deterritorialized. The more *blurred* the boundaries between the internal and external territory, and the more *heterogeneous* the *components* – the more deterritorialized an assemblage is. Therefore, assemblages have a certain degree of dynamism and recurrence, heterogeneity and homogeneity, territorialization and deterritorialization, but dynamism, heterogeneity and deterritorialization always have the upper hand.

In this paper, we consider organizations as assemblages of data, technologies, laws, organizational work practices, institutional resources which are continuously in the process of change. We refer to territories, as spaces defined by technology and law determining the data flow across organizations. The law sets the boundaries to what data are considered internal and external to organizations. The technology sets the boundaries over the architectural components across which data are produced, used and shared.

Research Approach

Case Background

Our empirical study was conducted in the South-East Health Region in Norway which offers specialist health services to 57% of the total population in Norway. The Regional Health Trust (Health South-eEast, hereafter referred to as HSE) is the administrative body overseeing 11 public hospital trusts, 5 private, non-commercial hospital trusts and its own IT company (HospitalPartner) that works together with the vendors and hospitals in implementing the necessary digital technologies. Moving services outside of the hospital was emphasized in the HSE's Strategic Development Plan towards 2035. This comprises both temporary home-based cases using connected medical equipment (so-called home hospital services), long-term monitoring with sensor technologies (called digital home follow-up), and more episodic communication services such as video and chat. In this paper, we regard all these services as remote care monitoring (RCM). The strategic emphasis on moving services to the home aligns with national policy as well as general trends. Going back to 2011, national strategy documents called for provision of digitally mediated care in the patients' homes. A national implementation program for so-called welfare technologies (also known as ambient assisted living or telecare) saw many municipalities implement technologies in patients' homes.

Some of the municipalities also implemented digital home follow-up services for patients with chronic diseases such as diabetes, heart failures or chronic-obstructive lung disease.

The technologies in use included sensor devices, patient-reporting of data, and digital consultations. Several of the hospital trusts in the South-East health region had already initiated various home hospital projects (e.g., to allow patients with cancer or on long-term antibiotics treatment to stay at home) and digital home follow up services (e.g., to support early discharge of newborns). Some of these were in pilot phase and others had been implemented in routine service. There was, however, no dedicated II in place that could support the deployment of RCM at scale, and each initiative had conducted their own procurement and service design process. In the autumn of 2020, the HSE started work to consolidate the fragmented portfolio of IT systems. This was connected to a larger initiative which aimed to provide a shared infrastructure that would enable the HSE to scale up RCM beyond the stand-alone projects, through implementing a new process platform. We aligned our study with this process platform initiative, starting the study in October 2020 when the project was in its initial concept phase, up until the purchasing and implementation of the platform as of 2023.

Gathering of Empirical Material

We conducted a qualitative study and primarily relied on interviews as a data gathering method (Alvesson & Sköldbberg, 2010). We conducted 14 semi-structured interviews with key actors from the regional authority (some participants were interviewed twice), hospitals and private vendors. The sources are summarized in Table 1.

Data gathering	Amount	Duration	Description
Regional authority	6	1-2 hours	Participants: regional project leaders and IT architects
Hospitals	5	Approximately 1h	Participants: hospital managers/innovation directors
Private vendors	3	Approximately 1h	Participants: Chief Technology officers and IT architects
Document analysis	21	/	<ul style="list-style-type: none"> • 4 concept phase documents for process platform, API platform and digital home follow-up • 4 internal regional documents on process platform, API platform and digital home follow-up • 2 tender documents for process platform • 5 documents on national data sharing architectures, including message exchange, document sharing and structured data exchange • 4 documents on changing the Health Register Act and Health Record Act • PGHD report from Health Directorate • 1 document on structuring the electronic patient health record across regions
Presentations	5	/	2 presentations for steering group meetings and 3 individual presentations
Meeting observations	2	/	Steering group meeting and innovation network event
Video presentations	1	/	Hospital presentations on remote care monitoring
Webpages/press releases	7	/	RCM – ongoing initiatives nationally and in regional hospitals

Table 1. Summary of the Data Gathering Process

The interviews included core project members from the regional authority (5 persons), innovation and technology experts from the regional hospitals with pre-existing services in the area of RCM (7 persons), as well as vendor companies (4 persons). The interviews with the project team were group interviews, containing two, or three participants at the same time. The interviews with hospitals and private vendors were either group (containing two participants) or individual. Including more than one participant was either suggested by us (such as with the project team), but most often the participants we contacted would suggest that another person from their organization takes part. It was common that the interviews would include both technical and management people from the same organization. We could thus get an overview of both, the technical and organizational implications of the regional initiative for the stakeholders involved.

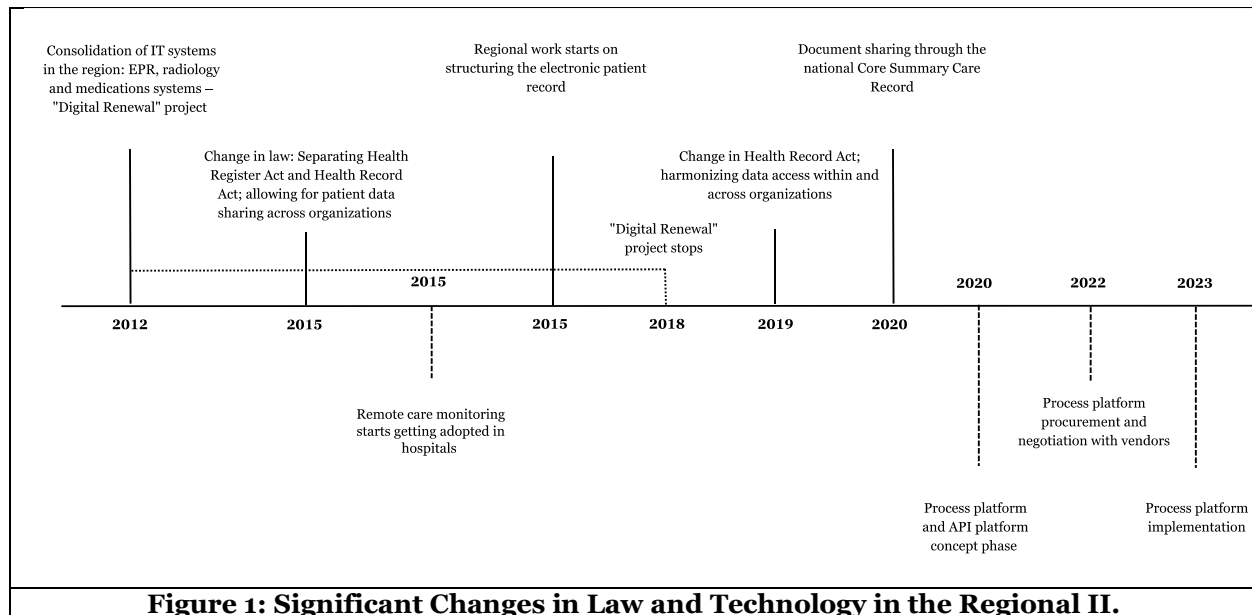
Through these interviews, we elicited the interviewees' accounts of the rationale for the process platform project, its progress, challenges, and achievements. We started the data gathering by interviewing informants from the regional authority, which shared their project vision, planned scope, and expectations. As the project moved into the procurement phase in December 2021, we shifted to interviewing informants from the regional hospitals, as well as vendor companies that offered DHF services and had active installations in the region. Our study included three hospitals that were involved in the concept phase and two other hospitals that were assigned pilot user status.

However, the interviews were focused on the process platform as an upcoming large-scale infrastructural project; empirically we were puzzled by remote care monitoring (RCM), and particularly, patient-generated health data (PGHD). We realized that RCM as a use case was posing new challenges for the installed base of data, IT applications, users, institutions. For that purpose, we decided to collect documents which do not only justify the rationale around the process platform project, but also encompass the historical evolution of the II over time. We also analyzed presentations commonly shared with us by participants, and observed events of importance such as steering group meeting and regional innovation events.

Analysis of Empirical Material

We conducted an abductive (Dubois & Gadde, 2002), process analysis (Berends & Deken, 2021). Our starting point was empirical, as we were puzzled by the nature of PGHD, as heterogeneous, unregulated and novel types of data sources and their interaction with the pre-existing conditions across healthcare organizations. However, the real-time process platform initiative was motivated by larger architectural concerns on updating the regional application programming interface (API) services. Therefore, we started analyzing documents encompassing the main regional architectural projects. The documents revealed how the regional aims for data sharing also posed legal challenges and were followed by changes in law. This made us interested in studying the interplay of technology and law in the regional II. We created a timeline of 10 key events of significant technological and legal changes which led to the current state of the II – the process platform initiative (as represented in Figure 1). The events encompass the large-scale IT initiatives in the region in the past the years and changes in the law which had implications for the regional data sharing.

At this point we consulted the literature on IIs to help us understand the interplay of technology and law across these events. However, we realized that the current literature is predominantly focused on architectural arrangements for IT consolidation or data sharing, but does not fully account for the role of law, except for considerations regarding users' rights and privacy. For that reason, we decided to consult assemblage theory and the concepts of assemblages and territorialization to make sense of the empirical material. We used the concept of territorialization to understand the data flow space which is considered internal and external to organizations, and defined it by two parameters – technology and law. The law was determining the boundaries of which data production, sharing and usage is considered internal and external to organizations. The technology was determining the architectural arrangement across which data production, sharing and usage can take place. This helped us define four overlapping phases in the empirical findings across which technology and law were configured as EPR and PGHD were shared across the regional infrastructure. At last, we defined two techno-legal configurations related to the data type in question, namely EPR or PGHD, resulting in two techno-legal configurations: harmonized space and disparate space.



Findings

Sharing Electronic Patient Record Data Within Organizational Boundaries

As of 2012, HSE was facing a heterogeneous portfolio of siloed IT systems purchased to cover specific needs, which were not able to share data with each other. Internally within hospitals, the communication between systems was predominantly based on message exchange. *"When a patient is admitted to a hospital, the admitted message goes to the systems. And when the patient is an inpatient, given a bed, you will have a message for a bed assignment. You will have a message for a transfer from one part of the hospital to another. It's a transfer message. If it goes from medical department to surgery, you will get a message when the transfer applies."* (Informant, Private vendor).

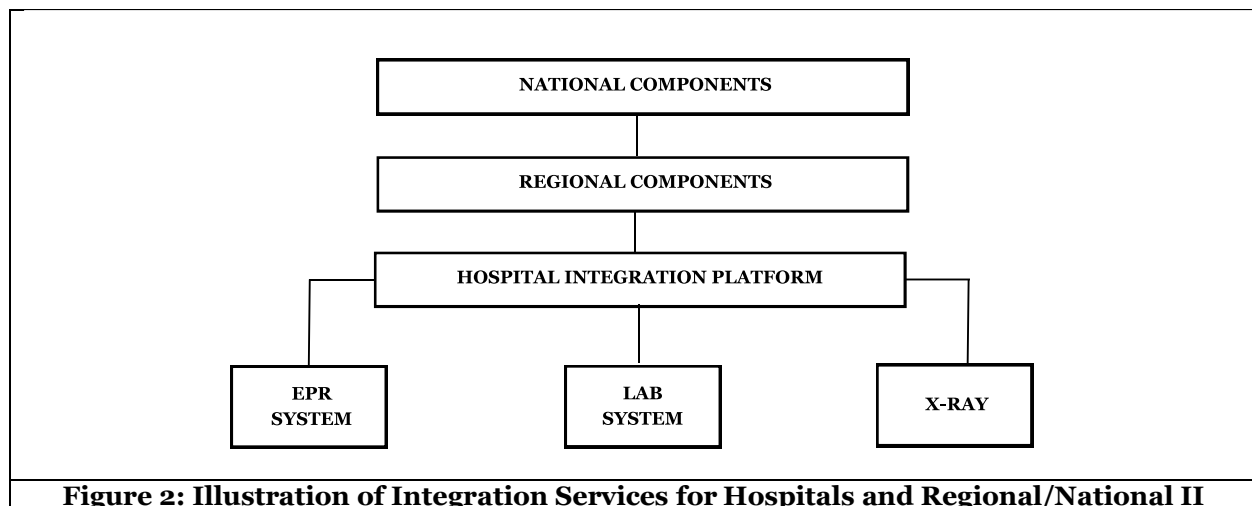
Message exchange also allowed for some external sharing of patients' data, such as when referring a patient from the GP to the hospital. *"When you do a referral from a GP to a hospital, it's possible to add documents to the referral. You can add documents that describe the underlying situation or some broad work or all the type of information. You transfer that in the process where you refer the patient to the hospital. The feedback loop to the referral party is the epicrisis. Epicrisis is a message when the patient has received a certain treatment. They [the hospitals] send an epicrisis to the GP and the patient. The patient receives it at HealthNorway and the GP receives the epicrisis, or the discharge summary, in his inbox."* (Informant, Private vendor). However, by attaching documents in the referral, data about patients were duplicated across various organizations and only data directly related to the referral could be exchanged.

In 2012, the Parliament released a white paper "One citizen – one record" suggesting that patient information should follow the patients along the course of treatment, with the rationale that this would support patient-oriented healthcare services. After the white paper, there was an increased focus on sharing health information using forms of interaction other than message exchange. Various regional projects were initiated aiming to consolidate the IT portfolio and build the necessary application programming interfaces (APIs) for accessing data across organizations and systems.

However, the hospitals did not only have different systems, but also different installments and configurations of the same systems. HSE initiated various projects aimed at standardizing the regional IT portfolio, so that the same EPR, laboratory, radiology, or medications systems would be used across hospitals. Moreover, HSE started updating the regional integration services to develop the necessary APIs for exchanging data across system. In order to keep data across the hospitals legally separate, HSE decided to develop separate integration platforms for each Hospital Trust; including 1) local APIs for sharing data within hospitals, for example from the EPR system towards lab and radiology systems, allowing healthcare

personnel to order tests and view results from the EPR system; 2) regional integration services allowing for data sharing across hospitals in the region; and 3) regional integration services towards the national solutions, other regions, or primary healthcare services. The integration services are illustrated in Figure 2.

However, sharing patient data was challenging, not solely technically, but also due to legal reasons. As of 2012, storing, processing, and using patient records data was regulated by the Health Register Act, which regulated both patient records, but also secondary uses of data. The Act allowed accessing data from patient record systems only to healthcare personnel that were employed by the organization providing such access. The rationale was that data processor authority and managerial authority of employees had to overlap in order to ensure the necessary information security levels. Health personnel, therefore, could not access data from patient records in external organizations, even if they were treating the same patients.



Despite the regional efforts, the technical landscape remained heterogeneous. Across the region, there were three different technical platforms and nine installations and databases of the EPR system across the different Hospital Trusts, in addition to several thousands of other systems used. The various systems were integrated through a mix of proprietary and open APIs, with strong one-on-one interdependencies. Moreover, except for some patient administrative areas, the EPR record was based on free text and patients' records were lacking structure to be represented in the APIs.

Sharing Electronic Patient Record Data Across Organizational Boundaries

In 2014, various healthcare actors, the Ministry of Health and Care and the government started discussions on changing the Health Register Act to allow for various forms of data sharing across organizational boundaries. The rationale for changing the Act was to support the flow of patient data across healthcare personnel and provide better diagnostics, treatment and follow-up of patients. The changes were in effect starting 1 July 2015, and the Health Register Act was split, regulating two separate areas; 1) Health Register Act, regulating health registers, and the processing of health information related to health analysis, population health management, and other types of secondary use of data; and 2) Health Record Act, regulating the processing of health information in treatment-oriented health registries, i.e., electronic patient records.

The Health Record Act in principle opened possibilities for healthcare personnel to *access* and search for patient data stored in external EPR systems. Such access could be granted based on healthcare personnel's official need. The possibility for patients consenting to the data sharing was assessed as time consuming, and instead, it was decided that patients should have the right to object to the data sharing. The Health Record Act opened a possibility for healthcare personnel employed in different organizations to establish formal organizational collaborations that involved data sharing: 1) organizations could establishing a joint patient record; or 2) organizations could use the national solutions to document information, such as the Core Summary Care Record. The joint or national records were not intended to work as a substitution, but as complementary records to the existing patient records used within organizations.

As of 2019, the Health Records Act was updated again to simplify access to patient information to healthcare personnel. With this change, the rules for accessing data internally and externally across healthcare organizations were harmonized. According to these changes, health data could be made available to healthcare personnel for the purposes of providing healthcare, but also for quality assurance, self-recording and training. According to previous practice, access to healthcare personnel was controller-based on, among other things, their connection to organizations and departments, professional IT systems, connection to patients, professional roles, task and responsibilities. As per the new law, data controllers could provide automatic access on an organizational level which did not need to cover one patient at a time. This did not mean that access could be given to whole organizations or departments, as the law only allowed for accessing as much information as necessary to provide health and care. Instead, legally the rules for distinguishing between internal access and external were removed, but it was still up to the organizations to determine what requirements they place when access is requested and determine the specific data responsibilities according to the legal provisions. However, it was also pointed out that due to challenges with integration between systems between GPs, psychologists, municipalities and health organizations alike, access would still need to take place manually.

The changes in the law allowed for various forms of data sharing, but it was to a large degree up to the individual organizations to determine how to preserve security and privacy in their IT solutions, determine the technical and organizational means under which access can be granted and establish the necessary data-sharing agreements. For instance, as of 2020, HSE collaborated with the national Core Summary Care Record to facilitate access to selected documents from the hospital EPR systems. Such access was partitioned across four categories: 1) all users of the Core Summary Care Record; 2) doctors and psychologists; 3) patients' GPs; and 4) selective access to e.g., doctors from emergency rooms in municipalities or private hospitals. Accessing documents through the national components allowed healthcare personnel to re-use patient data for various purposes beyond the organizations they were employed in, but within the provisions defined by law. The changes in law thus shifted the burden over to the technology component in the techno-legal configuration; if the hospital wanted to share data with external organizations they could do it as long as their IT was technically able to facilitate this data sharing within the legal constraints.

Extending Organizational Boundaries Through Patient-Generated Healthcare Data

As far back as 2015, hospitals in the region started adopting RCM services, based on data generated by patients at home, such as temperature, blood pressure, oxygen. These services were commonly provided to chronically ill patients, such as patients with chronic obstructive pulmonary disease, diabetes, or cancer. For instance, in 2017, HospitalEast, together with a private vendor, the HospitalPartner, the Cancer Association, and other hospitals, started a collaborative project on developing a patient-facing app supporting patients with cancer. The following vignette describes how the app worked to facilitate following up a patient at home.

Healthcare personnel log into the app with their EPR login details. In the app, nurses can see an overview over all her/his patients and click on each patient to see the specific measurements. If there is a discrepancy in the measurements, it is colored red, and a smaller discrepancy is colored yellow. The nurse can use the app to get statistics on the reported data, define the thresholds on when to be notified about a patient, schedule the repetition of digital forms sent to patients, and set reminders for the patients. The nurse can also chat with the patients. The information is stored in the EPR system as a dynamic document which is updated in real-time. In the app, the nurse can set up chat groups with other healthcare personnel, e.g., create groups around the same patient. Patients log in using BankID and generate data from their homes. (source: video presentation by HospitalEast)

RCM services brought in various technical and legal challenges to the underlying infrastructure of EPR data. First, RCM solutions were architecturally separate from the EPR systems. Healthcare personnel had to login in different systems, using multiple user identities and passwords, as illustrated in Figure 3. To document care in the EPR system (which is a legal obligation), data from the RCM system had to be transferred manually and healthcare personnel were not able to see RCM data in context with other data about patients in the other hospital IT systems. Moreover, the data generated through RCM were commonly structured data reported using digital forms, while EPR data were often free text and unstructured. This made it

architecturally challenging to transfer patient-generated healthcare data (PGHD) to the EPR systems in the structure they were generated in, and store them there. Instead, vendors were storing data in the cloud, and at best, could transfer limited data as a PDF summary document that can be stored in the ERP systems; in other circumstances, data would be transferred manually through copying some of the measurements or event descriptions into the EPR system.

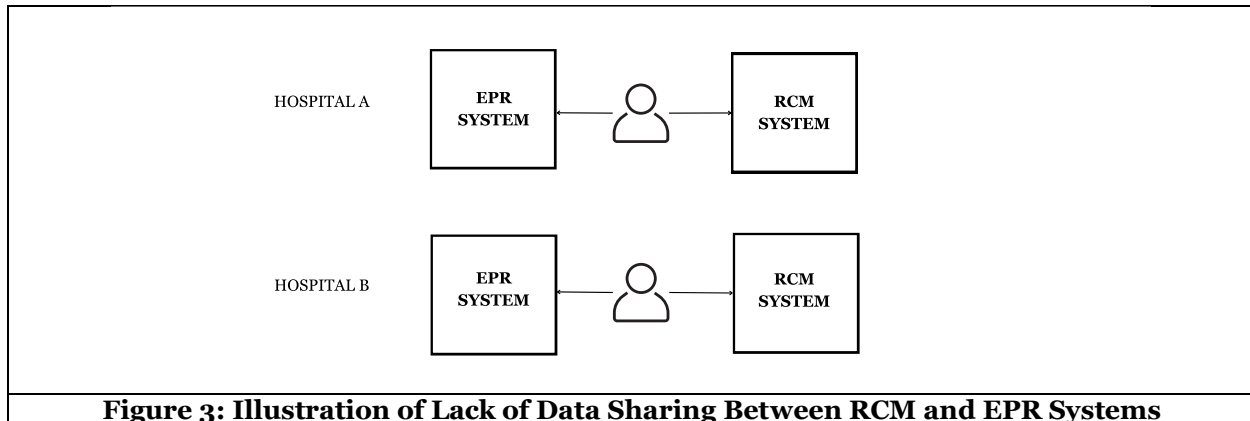


Figure 3: Illustration of Lack of Data Sharing Between RCM and EPR Systems

“We have more than 1,300 different questionnaires, which means that there are more than 1,300 different data structures. And providing a storage for that requires quite a lot of effort on the customer side, unless you want to kind of generalize it, but then you lose a lot of the benefits of having this structured. And as of now, that is stored where the structured data is, – in the customer's installations, and we host them as software-as-a-service in the private cloud.” (Informant, private vendor)

The EPR systems also did not consider remote care monitoring as a service which is internal to hospitals. The patients were not formally admitted to the hospital, and creating a novel category in the EPR system for home-based patients was not trivial. An informant from the HospitalPartner gave an example: *“You have a contact between the hospital and the patient, but it is not inpatient, it is not outpatient – it is homecare. If they [the EPR vendor] have picked a database where you can reconfigure a lot of different types of contacts, then it would be relatively easy to do, but this contact information and the values may exist in 20 integrations in [EPR vendor] already. So, putting all in contact which is called ‘homecare’, then you have to do quality check on all these 20 integrations with the other systems – do they still function.” (Informant, HospitalPartner).*

Second, beyond the technical challenges, there was legal uncertainty as to whether RCM were to be regarded as treatment-oriented health registers, or as extended components of the EPR system and what requirements the law places on the management of data in these solutions. The patient data generated through the RCM solution were also not directly regulated by the Health Record Act.

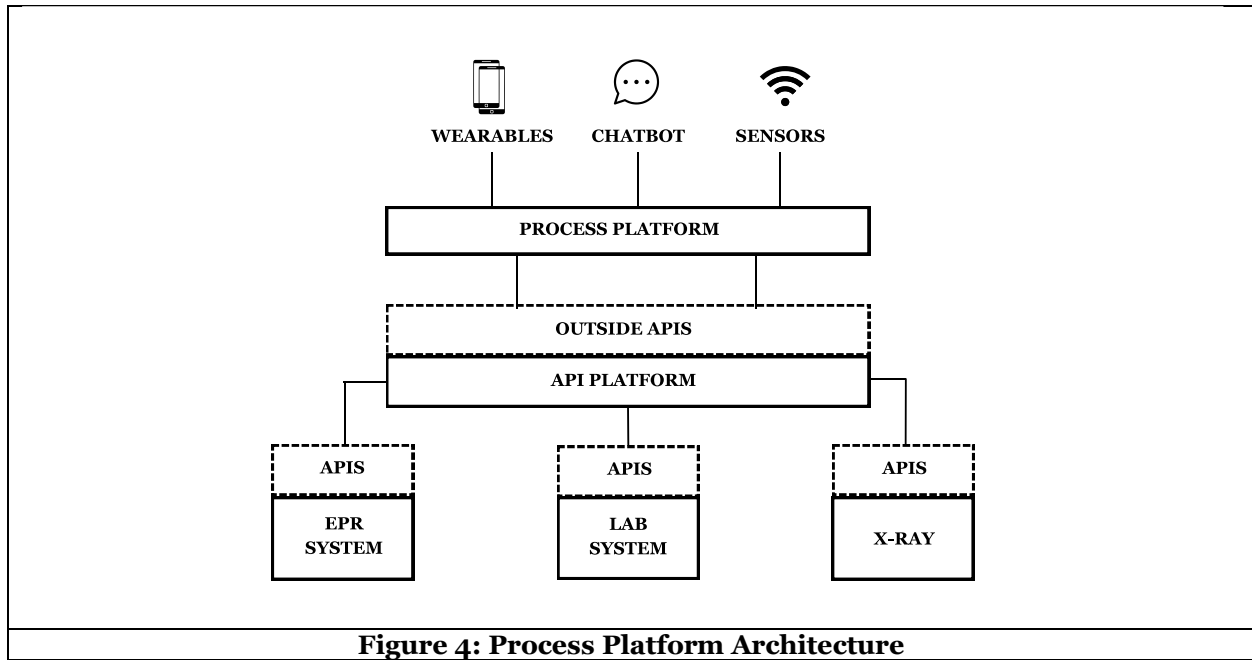
“We do not see ourselves as a patient journal system because we deliver the reports that need to be stored in the journal system. So, we are like an x-ray system, a special tool to allow the dialogue with the patient, but everything that should be stored as part of the patient's journal belongs in another system. (...) We are not considered part of the Health Record Act, but all the other laws that are related to storing sensitive data – because we do store sensitive data. But, from our customers, we are not considered a journal system. We are considered what they name as ‘Subject application with sensitive data’ (...). They do treat us as kind of a separate system that is an input to or an extension to the journal system. And technically, you could delete our system and you would not lose any decision data from the patient records, because all of this is stored in the patient record system.” (Informant, Private vendor)

To establish a legal basis for accessing the data stored in RCM, hospitals (or in some cases, the regional authority) entered separate data-processing agreements with the individual vendors they were using. The data-processing agreements regulated how the RCM vendor processed data on behalf of the healthcare organizations, and the vendors could not use these data for their own purposes. In some cases, the private vendors were data processors on behalf of the hospitals or regional authorities as data controllers, in other circumstances they had the status of suppliers, but not of data processors.

These individual data-processing agreements again moved healthcare personnel's user rights to access, edit, write data under the managerial authority of the organizations they were employed by. In some instances, healthcare personnel had to get "zero percent employment positions" in another hospital to be able to have a user account and authenticate themselves in connection to the RCM services. Although there was regional coordination on the data-processing agreements, but for each agreement the routines for deleting data, transferring data from RCM to ERP systems, or transferring data if the vendor system is discontinued, had to be determined independently. Therefore, the necessary risk assessments, vendor negotiations, and information security requirements, were conducted for each hospital separately, although competence was scarce.

Towards Techno-Legal Amendments for Sharing Patient-Generated Healthcare Data

The situation was perceived as sub-optimal, and in the autumn of 2020, HSE started working on a new regional initiative aimed at standardizing the existing portfolio of IT systems provided by private vendors, including RCM. Previous attempts to consolidate the application landscape through standardization had shown limited success. The current initiative aimed to take a different approach and install a process platform above the existing siloed systems. The process platform was presented as a necessary enabler and a precondition for the novel and patient-oriented forms to succeed. The justification for the procurement was multifaceted, mentioning aspects such as supporting more agility, ability for faster rates of change, flexibility to accommodate new technologies. The area of RCM was early seen to fit well as a use case for the (initially parallel) project of the process platform. However, the larger process platform project was motivated by more general concerns that went beyond supporting RCM, also including a renewal of the regional API integration platform.



An informant explained: *"The process platform will be consuming integration services, so the integration services will be delivered on top of the current IT portfolio and by HospitalPartner. The new services we will require in a homecare setting are a number of APIs that encapsulate existing systems and national services"* (Informant, HSE project team). The introduction of the process platform would require private vendors to develop the necessary integrations to the regional APIs. Architecturally, the process platform aimed to work as a mediator between the EPR systems and RCM, where data could be shared by accessing data from EPR through the RCM, and copying data from RCM into the EPR systems. This would eliminate the need to develop costly point-to-point integrations between RCM and EPR systems. The process platform architecture is illustrated in Figure 4.

RCM was chosen as a central use case supporting the argumentation for the process platform. E.g., it was argued that the process platform architecture will help the health care providers shift from today's model of follow-up and care which is calendar-governed, to becoming needs- and events-driven. Moreover, the process platform promised easy process design functionality, was expected to allow reuse of already existing service models and resources and thus support the efficient scaling up of RCM services across the region. The individual hospital departments who offered RCM services at the time, catered for well-defined patient groups and operated through local procurement agreements with different commercial vendors of RCM and did not consider re-using IT solutions and service models, or sharing data for primary or secondary purposes.

Another effect of moving the RCM services onto a joint infrastructure, was this it would allow for standardizing the terminologies used across hospitals for specific diseases, as well as have central coordination of best practices when defining treatment plans using structured data forms. Not the least, a centralized architecture would offload hospitals of the work of vendor negotiations and risk assessment to ensure that information security concerns were met. While the process platform did promise capabilities that can homogenize the portfolio of RCM systems, overall, it was perceived as one more application introduced in the regional IT.

However, despite the technical capabilities, the process platform did not resolve the legal challenges related to RCM. It was indicated that RCM data should be kept in their initial source (currently being the cloud and in some cases, the regional infrastructure), and a centralized data storage for sensitive personal data could be made available. This would allow contractors and subcontractors to be compliant with the regulatory requirements, and segregate personal sensitive data in a local data center, managed by HospitalPartner, if necessary. The data controller responsibility for personal sensitive data was either to be held by the HSE or by the hospital trusts, but no clear decisions were made on who would take what responsibility in the specific data sharing situations.

In the spring of 2023, the process platform was procured; meanwhile, two hospitals were chosen for the pilot implementation. The focus areas that were prioritized were video consultations and patient-reported outcome measures; the prioritized diseases were chronic obstructive pulmonary disease, children with diabetes and cancer patients. The work processes and treatment plans established in the pilot hospitals were later to be expanded across other hospitals in the region.

Analysis

Our findings show how the production, sharing and usage of data was not solely defined by managerial authority, but continuously re-negotiated across techno-legal configurations. We define techno-legal configurations as assemblages, which are technologically determined by the functionalities for data storage, processing, sharing and usage, and legally determined by the basis for data processing, such as consent, data-processing agreements or laws. Our findings show how the sharing of EPR data and PGHD required different techno-legal configurations, which we define as *harmonized space* and *disparate space*. By using the term space, we do not refer to the organizations' boundaries, but the boundaries defined by technology and law. The findings and analysis are summarized in Table 2.

We regard techno-legal configurations as *harmonized space* when they technically and legally align the space across which organizations produce, share and use data. In our case, the techno-legal configurations for sharing EPR data were harmonized. Legally, the Health Record Act harmonized the rules for internal and external EPR data sharing across hospital organizations. Technically, the EPR systems across hospitals in the region were consolidated and the regional integration services facilitated larger data sharing (to a degree). The changes in law opened possibilities for various forms of sharing patient data beyond message exchange. However, the degree to which data were actually shared was still determined by organizational and technical means.

We regard techno-legal configurations as *disparate space* when the technical and legal arrangements across which data are produced, shared and used are heterogeneous and separate. In our case, the techno-legal configurations around PGHD were defined across disparate space. Legally, regional authorities or hospital trusts entered individual data-processing agreements with RCM vendors. This created a complex landscape of legal arrangements regulating overlapping areas; RCM were at times regarded as extended components of organizational EPR systems, in other circumstances as suppliers. Technically, RCM solutions were

producing structured data, which was architecturally difficult to accommodate within the existing infrastructure. These heterogeneous arrangements allowed for some forms of data sharing, such as sharing summary PDF documents from RCM to EPR. However, while process platform was expected to standardize the technical heterogeneity, the legal arrangements for sharing PGHD remained unresolved.

Techno-legal configurations	Description	Findings	Technical arrangements	Legal arrangements
Harmonized space	Technical and legal alignment for sharing EPR data	Sharing electronic-patient record data within organizational boundaries	Access to data within hospitals; Message exchange across hospitals.	Health Register Act limits EPR data sharing beyond healthcare organizations
		Sharing electronic-patient record data across organizational boundaries	Accessing data across hospitals; Sharing data through national solutions	Health Record Act harmonizing rules for EPR data sharing across healthcare organizations
Disparate space	Separate technical and legal arrangements for sharing patient-generated healthcare data	Extending organizational boundaries through patient-generated healthcare data	No data sharing; log into a separate solution	Data-processing agreements regulating patient-generated healthcare data
		Towards techno-legal amendments for sharing patient-generated healthcare data	Possible data sharing through a process platform	Various overlapping laws, data-processing agreements and consent regulating patient-generated healthcare data

Table 2: Summary of Findings and Analysis of Empirical Material

Discussion and Conclusion

This paper seeks to answer the following research question: *"how does the interplay of technology and law condition the sharing of data in information infrastructures in healthcare?"*. We explore this research question by conducting an empirical study of an II in the highly regulated Norwegian healthcare context dealing with personal and sensitive data. We answer this research question in the following ways.

First, we show how due to the nature of data resources – in our case, personal and sensitive health data – the boundaries across which data were shared across organizations were continuously re-negotiated across techno-legal configurations. We define these configurations as harmonized space – aligning technology and law; and disparate space – separating technology and law. In their work on neo socio-technical systems, Winter et al. (2014) state: "[e]ven in cases where research went beyond the organizational container, such as studies of inter-organizational systems, organizational boundaries were essentially treated as given" (p. 258). We contribute to this work by showing how the spaces in which data can flow are not simply given by organizational boundaries but determined by the interplay of technology and law. Our case shows how data did not solely inherit purpose, meaning and value from organizations, but data's production, sharing and usage was re-negotiated across spaces shared by multiple organizations and based on techno-legal configurations.

This argument builds on other works suggesting how data resources are commonly situated outside of single organizations' boundaries and their unilateral control (Davidson et al., 2023; Jarvenpaa & Essén, 2023; Vial, 2023). As stated by Vial (2023), in contrast to IT systems "data have no such fixed boundaries. Once they are obtained, they can be easily copied, altered, falsified, and used for a purpose that is vastly different from their original intent.". Therefore, data are not encapsulated by databases, the IT systems that process them, or the organizations that produce, share or use them. Instead, data can be "here" and "there", simultaneously existing at both places, challenging the view that it is organizational boundaries that give data their fixed and finished forms. Our case also supports the argument raised by Alaimo and Kallinikos (2021) on the "decentering of organizations" through a longitudinal study. We show how in our case, the sharing of EPR data was not necessarily a decision internal to organizations' managerial authority. Although organizations could determine the technical means for sharing data, the law – as an actor in its own right – was defining what data can be considered as internal and external to organizations. For instance, the law could oblige hospitals to provide access to data from their EPR systems to external healthcare personnel for the purposes of providing health and care, but organizations could determine the technical means under which data sharing or access is provided.

Second, we also contribute to II studies in healthcare (Kempton et al., 2020; Mekonnen & Sahay, 2008) and II studies on data (Jarvenpaa & Essén, 2023; Tempini, 2017) by raising the importance of the law in the evolution of the information infrastructures. Researchers have raised how "[i]ncompatible health IT systems and data standards, barriers to data sharing across organizations including regulations intended to protect health data privacy, and organizational reticence to sharing valuable data all present substantial barriers to mobilizing health data resources to address societal concerns" (Davidson et al. 2023, p. 04). In II studies on healthcare, researchers have focused on related pressing issues, such as institutional pressures (Seddon & Currie, 2022; Mekonnen & Sahay, 2008) and complex IT landscapes (Currie, 2012), but there has been much less attention to the role of data entities and the techno-legal interplay across which they can be recirculated across IIs. Beyond acknowledging how sensitive and personal health data are prone to privacy and security concerns (Winter and Davidson 2019). particularly in public-private intersections (Kempton et al., 2020; Pouloudi et al., 2016), up to our knowledge, empirical studies have not followed the evolution of an II through the interplay of technology and law.

With this, we move beyond a utility perspective on data as valuable assets in IIs studies (e.g., Grisot et al. 2019; Vassilakopoulou et al. 2019; Vassilakopoulou and Aanestad 2019). In our case, the focus was not on how health data are used across IIs (Barrett et al., 2016; Tempini, 2017), but on the underlying legal and technical conditions that enabled and constrained the production, sharing and usage of health data. Considering the role of techno-legal configurations in shaping IIs evolution allows for studying data not solely around their use potential for organizational value creation (Aaltonen et al., 2021; Alaimo et al., 2020) but also focusing on the constraints imposed on organizations in exploiting data's use potential. This should not indicate how organizations in highly regulated settings only seek legal compliance and lack agency; instead, various forms of data sharing and innovation can take place conditioned by legal and technical provisions. In our case, PGHD were more prone to organizations' managerial authority due to their less clearly regulated legal nature.

Third, our paper also raises the significance of patient-generated healthcare data as new data types and resources with a vast, but currently underutilized innovation potential, as others have done before (Azodo et al., 2020; Turner et al., 2021). Our paper, as previous research (Grisot et al., 2019; Winter & Davidson, 2020), shows how PGHD differ from traditional EPR data. We build on these works by highlighting the technical and legal complexities in scaling up the usage of PGHD in routine healthcare delivery. Technically, PGHD are more granular (including data streams of elements such as temperature, oxygen saturation) and structured, in contrast to EPR data which are commonly free text. This makes it technically challenging to integrate them with the installed base of EPR systems. Legally, PGHD are unstable and heterogeneous. Traditionally, patient data had a stable location – being stored in EPR systems and by healthcare professionals. PGHD, instead, do not have such a stable location. At times they stored in the cloud, in other circumstances can be copied in regional infrastructures, and at times (up to a limited degree) available as PDF in EPR systems. PGHD also require higher mobility, as they are generated by patients, and should be accessed by various stakeholders (e.g., municipalities, GPs and hospitals). In conclusion, our case shows how PGHD are not simply technically heterogeneous, but also legally unstable, as they are encapsulated by overlapping legal provisions. These insights build on previous research arguing how patients data in general

(Winter & Davidson, 2019) and PGHD in particular require a harmonization of organizational, technological and regulatory spheres (Winter & Davidson, 2020).

Our paper also contributes to practice by showing how the sharing of patient data, particularly personal and sensitive data, is not necessarily a managerial decision, but requires complex configurations of technology and law. We also show how the law is not necessarily imposing rules and constraints but can also open up possibilities for creating value from data in various ways. This paper also comes with limitations. The case takes place in the highly regulated Norwegian healthcare sector dealing with sensitive, personal healthcare data. In other sectors or industries, different aspects of the underlying structures could be more significant, such as industrial actor structures or organizational contracts, instead of technology and law.

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