Regulatory Complexities for Patient-Oriented e-Services in Norwegian Healthcare

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Abstract. The paper explores regulatory insolvencies and gaps (complexities) in the present-day Norwegian legislation around patient-oriented information systems in healthcare. Complexities characterize “problematic” institutions in the current Norwegian law, which evolves in dynamic together with patient-oriented concept of e-services. This paper is a grounding piece for the subsequent work, which shall show how the four cases of patient-oriented services emerge and develop in the challenging regulatory environment. However, the technologies correspond to laws and policies by their practices and emerging organizational forms. This work is aimed at mapping of regulatory complexities for the purpose to study interaction between the case study technologies and the current regulatory environment.

Keywords: regulatory environment, patient-oriented e-services, law, policy, information systems, complexities, Norway

1 Introduction

The work investigates the regulatory environment (laws and policies) around existing patient-oriented information systems in healthcare in Norway. My purpose is to determine and map the main regulatory complexities (insolvencies, gaps, collisions, ethical issues, etc.) as “nodes” of potential responses to them in practice by technologies with a patient-oriented approach in healthcare. As Lanzara claims (2009:37), in the process of design, the technology has to be “enclosed within a normative shell” or be “normatively assisted”, otherwise it cannot be established in normative sense or enacted within the existing framework. However, the regulatory environment is not perfect, since it is developing in the ongoing process of interaction with the object of regulation by encompassing its general characteristics (Seipel 2004). In other words, laws and policies as regulatory environment “learn” from the technologies and evolve with them simultaneously in the process of interaction.

The Norwegian Government expects the emergence of a common national e-health infrastructure in several years. The approximate picture of such infrastructure is preliminary described in Communication to the Parliament number 9 “One resident – one journal” (i.e. Melding til Stortinget “Én innbygger - én journal: Digitale tjenester i helse- og omsorgssektoren”, 2012 - 2013, further – Meld. St. 9 “One resident – one journal”), which is issued on November 30th, 2012. This policy document indicates
problems, challenges, aims and principles for establishment of a well-organized coordinated patient-oriented information infrastructure in healthcare, which shall interconnect local information systems of health institutions, heath databases and other IT-solutions in the sector for the sake of patient-oriented approach. According to the view expressed by the Government in Meld. St. 9 “One resident – one journal”, such a coordinated infrastructure shall result in better treatment and improvement of social welfare. However, the aims of the policy explicitly imply the increasing complexity of norms, practices, values, organizational forms, etc. in the due course of the development of the national e-health infrastructure. This complexity of technological and practical coordination is challenging for the evolving legal environment. The legal environment, besides the expected need to evolve, embeds internal problems and inconsistencies. However, technologies also undergo sophisticated challenges to develop means and solutions to users’ needs in the healthcare domain. Technology and law are two regimes, which both have regulatory power. In their mutual relation they generate number of problems in accountability, efficacy, authority, legitimacy, fairness, etc. (Contini and Lanzara, 2009).

My major interest in the research project is to understand how the interaction between laws and technologies happen, i.e. how the space between the Norwegian laws relevant to the healthcare sector and emerging information technologies with patient-oriented approach look like, why and what patterns of their dynamic interaction are observed. The interest of this paper, however, is to take a close look at the regulatory environment of laws and policies towards information systems with patient-oriented approach, the insolvencies, dilemmas, vagueness, gaps or collisions of the current relevant laws as environment for technologies, which are to develop in accordance with expectations to them found in policies by the Government. The public sector influence to the technologies is significant, because the Government claims the principle of centralization and coordination as grounding for e-health.

However, patient-oriented approach is the aim, which both regulatory environment and technologies are supposed to co-evolve to. This approach in healthcare might be understood e.g. as empowerment of individual user by providing him/her with more choices, ensuring the feeling of respect and human dignity, specifying tools for participation in decision-making and exercising the rights (Fisher et al. 2005:106). However, as of year 2013, the old provider-oriented approach in information technologies in the Norwegian healthcare is dominating over the patient-oriented approach. The old one implies high participation of the healthcare providers in the decision-making about the patient health. The new approach shifts significant piece of such decision-making power to the patient. This shift raises the issue of patient rights and forms of information management under the patient-oriented information systems approach.

Subsequent research will show up how the regulatory complexities are dealt by the emerging and existing patient-oriented information systems as case studies. The case studies are the official public portal Helsenorge.no (further – Helsenorge.no), a web-based portal for patient-hospital communication My Health Records (further – MHR), an emerging IT-solution for better organization and sharing of the essential patient data (such as drug use and severe allergies) among the treating healthcare personnel with a limited set of patient-oriented functions - the National Core Journal (Nasjonal Kjernejournal), and a private IT-solution for easy and fast uploading and sharing of
personal health data My Health Book. In this paper the case studies are introduced in the framework of the regulatory complexities.

2 Literature

As it was mentioned in the section above, technologies and law represent two huge regulatory regimes, which generate varied problems in accountability, efficacy, authority, legitimacy, fairness, etc. (Contini and Lanzara, 2009). Kallinikos (2009) defines regulative regime as “a technical, social, institutional system of forces that shape human agency both in the direct way of embodying functionalities that engrave particular courses of action and in the rather unobtrusive fashion of shaping perceptions and preferences, forming skills and professional rules.” In other words, in the clash of the regulatory regimes of law and technology we expect to observe emerging functionalities, perceptions and preferences shaped by numerous human agencies involved in the regulatory regimes, conducted actions and negotiation processes. As Koops, Lips, Prins and Schellekens (2006) claim, technologies demand to be regulated. In literature, regulation is understood in different ways depending on the chosen perspective. Lessig (1999) states that a new technological creation may lead to elaboration of a completely new institutional order, and by such a technology he means Internet. Later on, Lessig (2004) develops the model of code, which is “regulation” of technologies shaped by practice and ethical norms, legislation, market demands and needs, and technological architectures. This concept of regulation can be used for the analysis of information systems’ shaping towards the whole complexity of environment and national contexts.

Since my focus in the general research is aimed at case studies and is limited in the framework of techno-legal shaping, I am looking primarily at the “micro-world”, the level of teams and groups developing the technologies in the case studies. As Barry (2001) notices, the “micro-worlds” consist of specific work practices, institutional principles and techniques, which are capable to re-configure the space of government. The regulatory complexities discussed in this paper belong to this “space of government”. Thus, I am interested in figuring out the connections between the regulatory complexities and the emerging/developing patient-oriented technologies, since these connections determine the field of their bilateral shaping and co-evolution. In between technologies and law we expect to find new institutional capabilities, which Lanzara (2009:36) calls communication channels among authorities and agencies in the framework of the gradual loss of bureaucratic control and spread of “administrative disorder”. Patient-oriented approach in information systems seems to be emergent from such disorder. However, this is a new object for law to react to. Seipel (2004) claims that in the due course interaction with technologies, law encompasses the general characteristics of information technology such as automation element, logic, organization, activities, etc. In order to correspond to emerging technologies, law needs this interaction. Seipel (2004) states also that law shall not aim at regulation of technologies, because that is likely to be a hinder than a help. Instead, law shall focus on regulation of the use of technology. As Kallinikos (2009) fairy notices, design and use of technologies are interrelated in varied complex ways. These ways have to be disentangled conceptually and studied empirically.
3 Research method

In order to determine and explain complexities in law, I read relevant legal acts\(^1\) and conduct textual analysis. The basic idea with the textual analysis is to understand the meanings behind the text and assumptions of the data in case if the authentic resource is of high importance (Lacity, Janson 1994). In this paper the authentic resource is very important, because I try to find and reveal the content of the regulatory complexities found in the current legislation in Norway. The regulatory character of the studied environment implies our reference to the authorized public structures such as Parliament issuing laws and Government issuing policies.

Besides laws, I use the policy material issued by the Norwegian Government and addressed to the Parliament as guiding documents with the general principles of what the information systems in e-health shall strive for. A preliminary comparative analysis of the case studies of the four patient-oriented information systems shall show what paths to unveil the complexities the subsequent case study research will likely to take. This strategy is applied to study how technologies are capable to influence law and corresponding regulations by creation of new institutional order Lessig (1999). It will be possible to develop in the subsequent research aimed to understand the interaction between law and case studies separately.

4 Cases and regulatory complexities

Even though the idea of a common patient-oriented e-health information infrastructure is already not new, its practical development raises many questions in the regulatory domain. The document Meld. St. 9 “One resident – one journal” states the principle that the existing and emerging IT-solutions for health shall operate in coordination fruitful for the common national e-health infrastructure. This infrastructure is expected to be visible by 2017. Even though I do realize that the development of such an ambition project will take decades and might not necessarily resemble the vision, which is found in 2013, but the idea of the corresponding policy material is an attempt to “synchronize” the regulatory (especially legal) environment with the increased technological development and users’ needs. Therefore, policy documents are worth attention to reflect on laws and vision of the technological collaboration. Below I introduce the cases and their basic differences to show the

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\(^1\) In this paper I use the English translation to the Norwegian laws and regulations. The English translation comes from the short title of the laws and regulation as it is stated by the Parliament. Full titles of the legal documents are given in the list of references, which I begin with the English translation. These are: the Act on Health and Care Services (Helse- og omsorgstjenesteloven, i.e. Lov om kommunale helse- og omsorgstjenester m.m.), the Act on Patient and User Rights (Pasient- og brukerrettighetsloven), the Act on Health Personnel (Helsepersonelloven), the Act on Specialist Health Service (Speisialshelsetjenesteloven), the Act on Personal Data (Personopplysningsloven), the Act on Health Registries (Helseregisterloven), the Bylaw on Journals (Journalforskriften), the Bylaw on Cross-Area Patient Journal (Forskrift om virksomhetsovergripende pasientjournal) and the Bylaw on the National Core Journal (Kjernejournalforskriften).
contrasts in their approaches to the patient-oriented concept at the background of the existing regulatory environment. As it was mentioned above, among the case studies there are three as the IT-solutions developed by the public sector (Helsenorge.no, MHR and the National Core Journal) and one private initiative (My Health Book).

4.1 The official public portal Helsenorge.no vs. user rights

Helsenorge.no has been designed to exercise the right of individual user and patient to information on health issues in accordance with § 3-2 of the Act on Patient and User Rights. However, this portal resembles general electronic “encyclopedia” about diseases and treatment, seasonal health vulnerabilities and basic rights of patients. The information found at the portal is checked by professional experts to be reliable enough for self-consultative purposes. As professionals at Helsenorge.no ensure, the information provided by the portal is better in quality than descriptions of health issues found by “googling” at forums and blogs.

By use of Helsenorge.no the individual user exercises the right to “choice between the available and appropriate investigation and treatment” grated in § 3-1 of the Act on Patient and User Rights, since the individual user may be get aware of what disease he/she is likely to have on reading information from the portal and compare it with the own feelings. However, the right to information about the own health condition and sufficient insight in the health service due to found risks and side-effects of treatment (as of the clause 6 of § 3-2 of the Act on Patient and User Rights) is not exercised by use of Helsenorge.no. This right requires the data analysis behind the given information to the individual user for subsequent decision-making. In terms of gaining and managing the personal health data by individual users, Helsenorge.no has only six e-services: “Order health insurance card” (“Bestill helsetrygdkort”), “Report side-effects” (“Meld bivirkninger”), “My deductibles” (“Mine egenandeler”), “My general practitioner” (“Min fastlege”), “My receipts” (“Mine resepter”) and “My vaccines” (“Mine vaksiner”). Moreover, many important healthcare databases containing patient data at healthcare institutions are not yet under coordination over Helsenorge.no. The back side of the portal is Helsenorgebeta.net, where there is a blog for feedback from individual users and patients, and updated information on IT-innovation in the sector. This function is designed for getting any feedbacks on technologies and health services, which are parts or prospective pieces of Helsenorge.no.

4.2 Patient-hospital contact solution MHR vs. patient as user & the legal relation with the policy domain

The second case, MHR, is a web-based portal for patient-hospital communication. It is developed on the initiative of a small team from the IT department of a large hospital in Norway. This IT-solution is designed to speed up the communication process in the processes of treatment, which may be a crucial factor for providing sufficient medical help. I would claim that MHR exercises to some extent § 3-1 of the Act on Patient and User Rights, where patients and individual users have a right to
actively participate in choosing between available and appropriate methods of examination and treatment, and cooperate actively in the treatment. Moreover, MHR exercises partly the provision § 5-1 of the Act on Patient and User Rights on the right to insight into journal, so that patients may get discharge summaries and laboratory results. However, in that case the individual user shall be a patient and be registered at a healthcare institution. Thus, MHR is designed predominantly for patients, registered sick persons, but not for usual healthy individual users.

One more interesting aspect in the case of MHR is that this IT-solution belongs to Norsk Helsenett SF, a state-owned association, which has an internal document of a legally-binding power for its members known as “Norms for information security: health, care and social sectors” (“Norm for informasjonssikkerhet: helse-, omsorgs- og sosialsektoren”, or “Normen”; further – “Normen”). This internal document provides a binding power to the flexible policy guidelines of “Framework for authentication and security in electronic communication in the public sector” (“Rammeverk for autentisering og uavviselighet i elektronisk kommunikasjon med og i offentlig sektor”) on information security level 4. Thus, MHR is regulated not only within the legal framework, but also within regulations of Norsk Helsenett SF, what allocates MHR into the double control.

4.3 The Core National Journal vs. essential data and the data controller

The third case, the National Core Journal, shall compile core records and make available essential information on patients across boundaries of health institutions and administrative levels. According to Meld. St. 9 “One resident – one journal”, the National Core Journal shall become a core technology of essential (critical) health data of the Norwegian residents. It won’t be a piece of Helsenorge.no, but the access to the National Core Journal will be provided through the official public portal Helsenorge.no. However, the National Core Journal shall first deal with an interesting legal challenge: according to the newest Bylaw on the National Core Journal, § 4, this information system is going to treat the following health data about the Norwegian residents without their consent: their name and ID-numbers; contact information to them and their representatives; the lists of drugs; critical information about allergies, implants, provided healthcare, etc.; data about all the contacts with healthcare institutions; references to varied health data including patient journals, test results, images; patient notes in free form; administrative information on reservations to access to health records, given consents, gained denials, log-in data of the third persons; and, if the patient wishes so, the data about ongoing treatment. This information is the most essential for exercise healthcare to a person, and according to § 2 of the Bylaw on the Core National Journal, the Norwegian Directorate of Health is a data controller, who determines the purpose of the processing of health information and the tools to be used (see reference to the clause 8 of § 2 of the Act on Health Registries).

Such an empowerment of the big public structure over essential health data of each and one in the country may be the reason for individual users to exercise the right to deny the creation of the Core Journal about them according to paragraph 3 of § 4 of the Bylaw on the National Core Journal, where only the name and ID are given and the
reason for reservation against the Core Journal. How this complexity will develop in practice is one of my key concerns to research about in the framework of separate case study work. The testing version of the National Core Journal will be launched in autumn 2013.

### 4.4 My Health Book vs. private purposes with the personal health data

In contrast to the mentioned three cases, My Health Book is a private initiative. It is designed for easy sharing of health data between residents of Norway (not necessarily sick) and health personnel registered in accordance with the Act on Health Personnel. My Health Book is an application-based IT-solution providing data sharing between individual users and authorized health personnel via mobile devices and PCs. The case of this technology implies that the shared health data is in private property of the individual user, and the user treats it for the private purposes. Then such data is not considered as sensitive in accordance with paragraph 2 of § 3 of the Act on Personal Data. This norm states that the Act does not extend its power to personal data carried out by merely personal or other private purposes.

The problem is that there is a gap in the Norwegian law, which does not define the content of the right to property, such as right to own, enjoy and dispose the item, as it is found in international practice. Thus, as a regulatory environment of the files shared by My Health Book the regulation of immaterial property may be applied and the Act on Certain Aspects of Electronic Commerce and Other Information Services, which is an alternative and challenging domain for emerging e-services for healthcare in Norway. My Health Book, being such an alternative technology for data sharing, provides respective security level and user-friendliness as a main principle. The forms of interconnectivity of this solution with the cases above in future are under discussion by the designers.

These four cases, as it is shown, are also not unproblematic at the moment. The design of the technologies in the case studies and the direction of their evolution in the changing legal environment is of my research interest. The solutions of their governance structures may shape up functionalities and architecture of the common infrastructure in future. Thus, any problem of the case studies in the framework of the general regulatory imperfection is very important for my research to investigate how technology adapts and what feedbacks gives to the regulatory environment.

### 5 Other complexities in the regulatory environment

Below I would like to highlight and discuss some challenging issues, which I found in laws and is concerned to follow up in the due course of my work in researching about patient-oriented approach. Kjønstad (1999) claims that all rights of patients may be divided into the following categories: rights to become a patient (such as getting urgent medical help); rights that person gains on getting a status of patient (such as the right to choose a hospital); and procedural rights (such as the right to appeal in case of violation of granted patient’s rights). Winblad and Ringard (2010) add the
fourth “dimension”, i.e. time periods for the treatment of patients, which is very important for health condition and the choice of other rights. All these four categories appear in the subsequent search of regulatory complexities related to usual users/patients, electronic form of data, access issues, etc., which the chosen case studies can potentially meet and unveil in their development.

5.1 Becoming a patient & being a resident (“en innbygger”)

The right to urgent help is provided to individual user and patient by a commune, which exercises a standard service (verdig tjenestetilbud) under § 2-1a of the Act on Patient and User Rights and § 4-1 first paragraph b) of the Act on Health and Care Services. The latter provision duplicates the former and does not give a definition of “standard service”. That gap contests the nature of local IT-systems involved, which is important in the process of building interconnectivity as the main aim in Meld. St. 9. The second questionable issue is the right of residents to be in the list of a general practitioner in a Norwegian commune, including asylum seekers and their families being members of the National Insurance Scheme under § 2-1c of the Act on Patient and User Rights. Asylums shall have an access to “My therapist” (“Min fastlege”) at Helsenorge.no. According to Meld. St. 9, on having logged in the individual user will have access to all own health data stored at all systems containing them. However, no regulation so far determines such an access model and specific material and procedural norms in terms of such a user group, whereas the right to be in the list of a general practitioner is too general for them. Thus, no possible differences in journal options for IT are wherever described so far. I believe, the answers on how the technology is going to manage this challenge may be found in the technical architectural models of the evolving Helsenorge.no for the subsequent research.

Moreover, the status of patient is conditional in terms of the right to specialist medical help (spesialisthelsetjeneste) from the regional health authority, including immediate help, § 2-1a of the Act on Specialist Health Services. The person shall reside permanently or thereabout in a region. Thus, some categories of users without the permanent residence permit fall out this right. This provision is, however, to reduce cost burden on the Welfare State and prioritize long-term residents, who may become Norwegian citizens. However, the rights to become patient existing at the moment may be a factor for user-stratification in virtual reality of the emerging infrastructure within its basic concept “one resident – one journal” and lead to vertical user-profile fragmentation. This complexity may get a practical technological solution within a case study technology in a while. I will be able to discuss it in several months. This is a user-profile regulatory complexity. The directions of information infrastructure development may depend on legal status of users.

5.2 Patient journal, electronic patient journal (“en journal”) & data sharing

According to paragraph 1 of § 3-2 of the Act on Specialist Health Service, health care institutions, which exercise specialist healthcare, shall take into account the need for effective electronic communication by acquiring and developing their medical
records and information systems. The Act on Health Registries allows the electronic
treatment of health data in § 5 with respect to all conditions towards processing
sensitive data stated in § 9 of the Act on Personal Data, and the need of approval of
such a treatment from the Data Inspectorate (Datatilsynet) stated in § 33 of the Act on
Personal Data. However, the very definition of “electronic patient journal”
(elektronisk pasientjournal) is missing in the Norwegian legislation. According to § 3
of the Bylaw on Journals, a journal is a collection of registered health information
about a patient. One more definition, proposed by the Norwegian Directorate of
Health (Helsedirektoratet), is given at Helsenorge.no. A journal is understood as a
collection of information in electronic or paper form, which contains data on patient’s
contact with health services on i.e. diagnosis, the course of disease, the treatment and
information on other factors, which may be relevant (italics are mine) to the ongoing
treatment or any subsequent treatment (Pasientjournal, http://helsenorge.no).
Electronic patient journal might be defined in analogic way. However, according to
paragraph 2 of § 6a of the Act on Health Registries, cross-institutional health
registries (virksomhetsovergripende behandlingsrettede helseregistre) shall be kept
electronically, and contain only specific health data in a limited scope (italics are mine)
that is necessary and relevant to collaborative medical personnel to provide
proper healthcare services to the patient or individual user.

The norm-definition of the in-hospital patient journal is “inclusive”, i.e. it norm
includes varied types of health data. The norm on cross-institutional health registries
is “exclusive”, i.e. it excludes “unnecessary” data. However, despite the fixed
“exclusive” norm there is also the provision of the paragraph 2 of § 39 of the Act on
Health Personnel, which states that in healthcare institutions there shall be appointed a
person who has an overall responsibility for each record and for deciding what
information shall be in the patient record. Thus, the structure of health data is in hands
of local practices of health workers. Therefore, definition of electronic journal, which
is deduced from the paragraph 2 of § 6a of the Act on Health Registries, § 3 of the
Bylaw on Journals and from the proposal by Helsenorge.no need revision with the
paragraph 2 of § 39 of the Act on Health Personnel. It may also be one of the factors
for problems in developing IT-standards to health data for the technologies.

At the same time, § 2-4 of the Act on Patient and User Rights contains the right of
patient to choose a healthcare institution, which may provide the necessary help. It
means that the patient may not necessarily be treated at one healthcare institution.
However, in case of cross-institutional (virksomhetsovergripende) treatment it is only
the data controller (databehandlingsansvarlige) or health professionals, who have
documented the data, have the right to share the data with another health institution at
the given consent of the patient (see paragraph 2 of § 45 of the Act on Health
Personnel; § 13 of the Act on Health Registries). The law does not provide any
requirement to the form of the shared data in cross-institutional treatment. It may be
in hard paper copies or be communicated orally, or sent by usual post, or
electronically if possible. This is the complexity of health data sharing.

In sense how the electronic form of the patient data and the sharing process is
exercised the case studies demonstrate, how the complexity may be unveiled. The
purpose of the National Core Journal is to provide electronic sharing of the necessary
health data to exercise the required healthcare, and not to stimulate paper-duplicates,
since then the requirement to information security by § 13 of the Act on Personal Data
might not be guaranteed (Etablere av Nasjonal kjernejournal, Høringsnotat, http://www.regjeringen.no). The second case, My Health Book, is a private patient-oriented IT-solution specifically aimed at health data sharing in electronic form. It is stored in the technical architecture of My Health Book, but not in the mobile devices of individual users, which are used for sharing. A unique code is generated by the technology as soon as the individual user chooses the option to share the data with a health worker. For the security reason the code may be communicated to the medical doctor orally. In order to get access to the shared health data, the medical worker uses the own user-profile with included HRP-number, which all healthcare workers have. The shared data is encrypted. The security level is high, but the health data has a status of the property of the individual user in accordance with the paragraph 2 of § 3 of the Act on Personal Data. This possibility though emerge from the right to copy granted by the paragraph 1of § 5-1 of the Act on Patient and User Rights, which still implies the hard paper form of the health data issued to the patient at the request from his/her patient journal.

The security aspect of the health data sharing is one of the most principal differences between My Health Book and MHR. The latter follows the requirements of the highest level of security for the health data as sensitive information in accordance with the paragraph 1, 8), c) of § 2 of the Act on Personal Data and “Normen”, an obligatory document for MHR to follow as a member of Norsk Helsesett SF. The sharing capacity of MHR is lower in terms of types of the health data, but the security level is the highest and all corresponding laws on health data in the Public Law are applicable to MHR. These are possible technological paths to deal with the complexity of sharing. I think that their technological background may serve for elaboration of electronic patient journal concept as a collective concept.

5.3 The right to insight & processes

According to Meld. St. 9 “One resident – one journal”, the modern e-health instruments shall work on how to provide improved functionalities for decision-making in healthcare processes. Patient safety will be enhanced if healthcare workers will be granted better grounds for decision-making; information security will be enhanced by better management and monitoring of access to medical records. Here we see the triangle: patient safety, decision-making by healthcare workers, and healthcare processes. By empowering individual users to manage their own health (Fisher et al. 2005) there may take place the high risk of shifting responsibility for healthcare decisions onto sick persons, i.e. patients. However, at the moment we can already foresee the approximate path of the legislative development, which shall prevent such a dangerous scenario.

Meld. St. 9 “One resident – one journal” puts emphasis on the right to insight (innsynsrett) into electronic journal, which shall be improved for both individual users and healthcare workers. Users will be empowered to control the possibility by someone else to get insight into the patient journal (see p. 26 of Meld. St. 9), which I would call “negative consent” by user. At the moment, the insight to health data by the patient into the journal shall be approved by the health personnel, who exercises medical help (see paragraph 1 of § 41 of the Act on Health Personnel). The consent
for sharing the health data is not required until the data circulates within one healthcare institution. However, the data may be shared cross-institutionally by the data controller (databehandlingsansvarlige) or health professionals who have documented the data (see paragraph 2 of § 45 of the Act on Health Personnel). Then the patient consent is required. Subsequently created metadata on events of electronic shaping might be included into the list of sensitive data to complement the data on health. However, this is just an assumption, which needs empirical verification or disprove at example of MHR and Helsenorge.no.

According to Meld. St. 9 “One resident – one journal”, patients and individual users shall be actively involved in the process of their treatment. The right to insight into the journal, guaranteed in § 5-1 of the Act on Patient and User Rights, might be denied in case the competitive medical worker considers that the insight into the health data may worsen up the health condition of the patient. According to § 5-2 of the Act on Patients and User Rights, the patient or usual individual, whom the data is applied to, has the right to require the correction of the health data if the data is incorrect or wrong. However, if the decision to deny the insight to journal is based on the incorrect or wrong data, the patient or individual user is in vicious circle. This is obviously a legal problem, which raises a value dilemma whether the health personnel may decide on the denial of the insight. This is a difficult, unsolved regulatory complexity, which is in need of empirical investigation at examples of my case studies.

6 Conclusion

In the framework of this paper I have found the following challenges in the regulatory environment for the emerging and developing patient-oriented information systems in healthcare: complexities with exercising of the rights of individuals to the information about their health condition (requiring active assistance by the information systems in the data treatment to insure better decision-making, which is different from the usual “encyclopedic” approach to information), complexities with the right to insight into health data (relevant to the status of the resident; the health condition of the patient; professional skills of the health personnel authorizing patient for this right), complexities with the right to copy (hard paper versions of patient journals as grounds for photo-sharing within an electronic information system). Moreover, there are also complexities with the understanding of the patient journal (and hence, the character and use of the data there, and the forms of data sharing), complexities with regulation of the existing information systems (pure legal norms and legalized policy documents due to organizational forms in the management), complexities with the required level of security to sensitive health data (still allowing varieties of technical architectures of information systems), complexities with the data controlling procedures (monopoly of the public sector to essential health data of the Norwegian residents; patient consent issues preventing data flow; status of metadata) and complexities with the legal status of the health data (which is not considered as sensitive if shared for private purposes).
The complexities are not necessarily problems, even though the complexities may potentially contain them. Meanings with them vary. One of such meanings may be to provide involved “micro-worlds” of specific work practices, institutional principles and techniques (Barry 2001) with a fruitful environment for technological solution the space of possible technological trajectories of the best solutions in the framework of a case. The design of technology may contain an answer on how to deal with regulatory complexities assisting the ideas. The technology may become a precedent of a solution, just like My Health Book and the jurisdiction of the Civil Law to treat the health data for private concern.

However, the cases of bigger IT-solutions coming from the public sector, since they may face several complexities as it is in case of Helsenorge.no founding itself in between two regulatory regimes – legal and technological. The technical architecture of Helsenorge.no shall be capable to process and treat huge amount of data in a secure way and the patient-oriented strategy with the guaranteed execution of the patients’ rights by finding out really smart paths veiled in the involved complexities as “nodes” for possible solutions. It may take much more time than it was planned, but then we will witness the emergence of the regulatory regime in between legal requirements and pure technical model of a national e-health platform. This solution is likely to show unique organization of functionalities and perceptions shaped by varied human agencies involved in the overlapping regimes in performance of actions and ongoing negotiation processes (Kallinikos 2009). Some of the found complexities may be dissolved by themselves by practices and improved law, since law also “learns” from practices (Seipel 2004). However, new regulatory complexities may emerge. I do not exclude the emerging complex challenges coming to meet both the technologies and law from the improved medical practices.

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