

The Right to Insight (*Innsynsrett*) and Information Flow for User-Oriented e-Health Infrastructure in Norway

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Abstract. The research focuses on investigation of problems found in the 'right to insight' (*innsynsrett*) into health data in patient journal. The urgency of the topic is caused by the fact that the Norwegian government and the public sector consider user-oriented approach as priority for the development of information systems in healthcare. For instance, in Norway the right to insight is not formulated specifically for electronic systems. Moreover, the right to insight still contains problems defined in research in 1980-s. This right, however, provides persons with particular capacities to become aware of information on the own health condition stated in the patient journal. This awareness is basic for decision-making by patients/individual users about the treatment and, therefore, for the user-oriented approach of the emerging national e-health infrastructure. The flow of health data under such approach is the purpose of high-quality healthcare services.

Background to this research and my general interest

As an introduction to this work, I find it necessary to comment first on the bigger scope and interests of my project. Then I will narrow down the focus to the focus of this paper. This strategy is necessary to deliver my present message.

Technological and legal worlds represent two complex realities with their own history, norms, standards, values, practices, paths, actors, interests, etc. In designing an information technology, the IT-developers do not always have law

as their main concern, but the actual needs or challenges of the society and practices, which the technology aims to solve (Kiran 2011). In the course of legislative processes, for example, the expertise of IT-world might not always be the strongest voice as well. Moreover, in general, new laws tend to appear as soon as there is a need to regulate relations, which contain in themselves a degree of conflict. The contemporary reality shows, however, that both the technological and legal realities experience interplay with each other, especially when a new idea is about to be introduced. This tendency has led to some changes in the legal philosophy: it has witnessed the shift in regulatory reaction from *ex post* to *ex ante*, i.e. we may observe the emergence of laws anticipating the actual needs of regulation, but this takes place in order to prevent possible subsequent harm of non-regulation in the future (Seipel 2004).

The outcomes and performance from both legal and technologic sides is what determines my interest, and, I believe, IT-designers and lawmakers for the evolving e-health sector. However, the research in IS in this topic seems to be underrepresented, especially in the Scandinavian region, which is known for high participation of public sector institutions in delivering services to the residents. Research around techno-legal interrelations is found in the e-Governance field, i.e. on rebuilding public sector processes for better e-services (Andersen 2004), priorities and values formation in regulatory domains for e-Governance (Goldkuhl 2009) and models for e-Governance development (Goldkuhl 2008). However, the sounding models of techno-legal interrelations for information systems are lacking there. Another overlapping field, Legal Informatics, provides reasonable critics to the contemporary legal thinking towards technologies, suggests new conceptual frameworks and claims the interdisciplinary demand to study techno-legal interrelation for both practice and research (Seipel 2004). The IS field is a fruitful area for such studies, especially if we take into consideration the discussion on techno-legal shaping by Lessig (2006) and the Anglo-Saxon school in general. I can contribute here from the Scandinavian perspective.

The focus of the research is the Norwegian e-health sector, its emerging common e-health infrastructure under the user-oriented approach. The focus of this paper falls on the right to insight (*innsynsrett*) into patient journal as the basic right empowering users and as a solid factor for the health data flow, and on understanding the old problems of the right to insight, which the law still keeps. In the final version of this paper, I will be able to trace the evolutionary path of the right to insight into patient journal, and assess it critically on its way to support the technological idea of the user-oriented approach in the Norwegian e-health.

User-oriented approach in e-health and the right to insight (*innsynsrett*)

Having been discussed in research since 1980-s, user-oriented information systems have finally become one of the top priorities for the Norwegian Government in the healthcare domain. In Communication to the Parliament number 9 “One resident – one journal” (Melding til Stortinget “Én innbygger - én journal: Digitale tjenester i helse- og omsorgssektoren”, 2012 - 2013, further – Meld. St. 9) the need of new regulation for the national user-oriented e-health infrastructure is declared. By year 2017, the public health portal Helsenorge.no is supposed to become such an infrastructure different from the former provider-oriented information systems. The contrast between the user- and provider-oriented approaches is sharp. Provider-oriented systems are managed by providers of the health services (i.e. hospitals), which register and share medical health records under supervision of data controllers, or labs, which store medical analyses. Patients/individual users do not actively participate in data management under the provider-oriented approach.

User-oriented approach, as Toleva–Stoimenova (2010) suggests, has the ability to satisfy the end-user. For instance, this is the ability to cover relevant data, to response accordingly in a time lag to search-requests by the user, to present the output to users in a particular form, to answer requests in a comprehensive way, to recall the search requests and to be precise regards the retrieved material, which is relevant to the user. According to Meld. St. 9, in several years the public health portal Helsenorge.no will provide Norwegian residents with decision-making opportunity regards their own health, grant them easier access to health-data, become effective for treatment, lead to better healthcare results, provide contacts support between residents and health workers, patients and any other users.¹ The Norwegian policies state also that all these issues are possible to reach in case of effectively regulated fluidity of personal health data.

However, to claim that the law is capable to provide the society with such an expectation is a big question. The key right to criticize and elaborate on is the right to insight (*innsynsrett*) into patient journal, as the basic authorization of users to be aware of the health data stated about them in the medical records. The right to insight includes also the right to ask for a copy of the data stated there with subsequent explanations of medical terminology, to ask for correction or deletion of the health data and to reject the transfer or loan of the own health data to other healthcare institutions (Chapter 5 of the Act on Patient and User Rights). The right to insight shall not be mixed up with the right to get information about

¹ As of March 2013, Helsenorge.no provides following user-friendly e-services: “Bestill helsetrygdkort” (“Order health insurance card”), “Meld bivirkninger” (“Report side-effects”), “Mine egenandeler” (“My deductibles”), “Min fastlege” (“My general practitioner”), “Mine resepter” (“My receipts”) and “Mine vaksiner” (“My vaccines”).

own health condition and the content of the healthcare and possible risks to health (§ 3-2 of the Act on Patient and User Rights). In contrast to the right to insight, which implies *knowledge* by the patient/individual user on what is stated in the records, the right to information (*informasjon*) implies cooperation between the patient/individual user and medical personnel for better treatment (Høringsnotat: Lov om pasientrettigheter, Regeringen.no). The right to insight in the Norwegian law shall not be translated as the right to access, since access is “*tilgang*”. This concept implies a broader category of subjects possessing the right to access: these are not only patients/individual users, but also authorities to exercise their rights and work duties (See: § 1-1 of the Act on Patient and User Rights, §§ 6 and § 44 of the Act on Personal Data). In other words, the right to insight provides the first step for the health data to start flowing by the initiative of patient/individual user since the moment he/she has become *aware of* what is stated in the patient journal about him/her. User-oriented approach, as it comes from its definition above, has to ensure the patients knowledge on health, which the right to insight provides, and the general meaning of this knowledge, i.e. provision of the high-quality healthcare services.

New demands versus old problems: the right to insight on information flow for the new user-oriented infrastructure

The right to insight as it is now is problematic for the development of user-oriented national e-health infrastructure. Surprisingly, but at the moment the right to insight still contains the problems found in 1983 by J. K. M. Gevers, when he analyzed European legislation on insight and access to patient records. Besides this, the right to insight has its own, national regulatory challenges in Norway, which I mention below.

Gevers (1983) claims that the European law needs improvement in the issue of health data confidentiality, controlled by the patient’s consent, which is required when the health records are shared across healthcare institutions. Gevers (1983) believes that such norm has a high price in case the complex treatment is needed and the patient has a serious illness. High-quality healthcare service may be provided by many healthcare professionals sitting at different healthcare institutions, and the patient may not always know who they are and how they can use his/her data. The healthcare service provision has become a kind of “teamwork”. The right to insight in Norway implies the right by patient/individual user to reject sharing of the medical records with health personnel other than ones assigned for the treatment (§ 5-3 of the Act on Patient and User Rights). However, this norm applies in general, i.e. without specificity to electronic form of data. Electronic form of the health data sharing in cross-

institutional context is regulated in § 13 par. 3 and 4 of the Act on Health Registries, where the consent from the patient is always required. This is an obvious barrier to electronic information flow among medical competencies, which are responsible for better healthcare provision, but at the same time – an important regulation to protect confidentiality of the health data, when the “teamwork” of specialties is unclear to the patient. Yet this dilemma is not solved for the emergence of the national e-health infrastructure in Norway.

Another issue, which Gevers (1983) highlights, is the issue of third parties and their right to insight to medical records of patient/individual user. Gevers (1983) discusses ethical and philosophical aspects of situations, when representatives or any other persons get aware of the health data about an individual. The dilemma here is transparency as one of the basic principles of contemporary democracies, and possible substitution of roles in decision-making instead of patient/individual user. These two issues are directly relevant for understanding directions of the health data flow in the emerging information systems. Norwegian legislation not only illustrates these two critical aspects, but gives even more grounds to think about. The Act on Personal Data in § 2, 8), c) considers the data on health relation as sensitive, and this Act is applied to regulate it. The Act defines who are the data controller and the data processor in the treatment of the personal data. However, according to § 18 of the Act on Personal Data, any person at a request has the right to insight (i.e. to be aware of) to what kind of treatment of personal data of someone the data processor treats. Moreover, any person can demand information about the purpose of such personal data treatment, description of types of personal data under the treatment, where the personal data has been taken from and, if the data has been transferred, who have got it. This norm stipulates the flow of health data in unpredictable directions and undermines the value of personal health data protection, possession and disposal. It is worth mentioning, that in Norway the legal institution of private property is not clearly developed to define the content of ownership/possession of the personal health data. Besides this, the performance of information systems in the data treatment processes raises the question on the legal status of metadata, scenarios of its use to defend interests of the patients/individual users in courts, and place of the metadata as control evidence in the data flow under the user-oriented approach.

The third important point determined by Gevers (1983) is the control over health data quality in the medical health records. The researcher claims that in the European legislation of patient records there is a vicious circle contained in the very right to insight into the records. The patient/individual user has the right to request the correction or deletion of the own health data stated in the medical records, if there are reasons for that. However, the right to insight, as a basic possibility to become aware of the content of the health data, may be denied by the treating personnel in case there are grounds to believe that the knowledge about the health condition may worsen up the health situation of the patient. The

problem is that the treating personnel can come up with the decision to deny the right to insight on the ground of incorrect data, which the patient/individual user wants to correct or delete. Absolutely the same pattern of regulation is found in §§ 5-1 and 5-2 of the Act on Patient and User Rights, and §§ 42-44 of the Act on Health Personnel in Norway nowadays. The question whether technologies shall meet this dilemma in practice and in what form under the user-oriented approach remains open. The answer requires detailed empirical investigation, which shall enlighten me about possible technological architectures of data control and processing in overcoming medical mistakes. Such mistakes can be barriers for information flow or stimulate the flow of wrong information out of any control of the patient/individual user.

Besides these old problems discussed in 1983 by Gevers (1983) in the framework of the European legislation, the right to insight in Norway has a couple of general challenges to deal with. For example, at the present the right to insight into health data in patient journal is not formulated specially for the electronic form of medical records. The problem is that the very definition for electronic journal is lacking in law. Thus, the object of the right is lacking. The law states that the patient journal *can* be in electronic form (§46 of the Act on Health Personnel). Moreover, the user-oriented approach is also out of legal regulation (as of spring 2013). So far, the approximate definition of the user-oriented approach is found in policy material and research on technologies.

Conclusions

In this document, I intend to map the directions to investigate problems and challenges of the right to insight into patient records as one of the basic conditions for the user-oriented approach in the development of e-health sector in Norway. Among the problems and challenges there are quite old ones, noticed already in 1983 as general European legal problems. There is, for example, the dilemma of health data confidentiality guaranteed by patient consent, which correlates with effectiveness of the provided treatment in the data flow environment. Here I find the need to look at the models of consent provided by different technological designs of user-oriented technologies and assess how such a legal requirement has influenced them. I shall also collect the data of such technological practices for further analysis of legal evolution to see whether technologies have influenced law and how. Similar strategy I am going to apply to investigate the second old dilemma. It is about transparency, the institution of legal representation of the patient versus third party participation in the information flow in healthcare, where the personal health data might be in wrong hands. The third dilemma is the vicious circle build on the right to request the correction/deletion of the health data by patient/individual user and the right of the treating personnel to deny the ongoing insight. In that case, the decision of the

denial is based on wrong health data. The latter two dilemmas raise not only the concern on how the formal legal model of relations interplays with technological solutions. These two matters impose the burden on the lawmakers to think over regulation of metadata as subsequent data in transfer of personal health information. The lawmakers might perhaps approach it as evidence to protect patients'/individual users' rights in the environment of information systems, where the participation of the third persons may not be fully excluded. Besides this, I am going to follow up the legislative evolution in defining electronic patient records and, perhaps, the general tendency in legal demarcation of the virtual space in healthcare, where "being aware of" means to have more or less unproblematic right to insight into the own data.

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