

MISSED CHANCES AND WRONG CHOICES IN PATIENT INFORMATION? AN ETHICAL EVALUATION OF THE FINNISH IMPLEMENTATION OF THE EU DATABASE DIRECTIVE

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Abstract

Patient information is a critical instrument in modern healthcare. The different interest groups involved in health care hold an interest for patient information. As the interests of these groups are to a degree mutually exclusive, the *de jure* status of patient information is of vital importance. Problematically, the Finnish legislation regulating patient information is, as this paper shows, neither clear nor does it meet the demands of efficiency or ethicality.

As ethics hold a critical position in determining the justified owner of patient information, the legislative solution to the different interests ought to be ethically well justified. This paper argues that an ethically acceptable formulation of ownership, if passed into law, prevent the harmful effects of unethical use of patient information. A strong philosophical understanding of patient information is necessary to judge whether the legislative solution is reasonable or not.

This paper presents some arguments from Locke and Kant, which point out problems in directive 96/9/EC, the so-called database directive, and in particular its Finnish implementation as regards patient information databases. This paper concludes that citizens should be the owners of their own patient information, in the sense of *datenherrschaft*, to meet the demands of ethicality.

Keywords

EU Database Directive, Ethics, Patient information, Datenherrschaft, Locke, Kant

1. Introduction

Hettinger states that “Property institutions fundamentally shape a society. These legal relations between individuals, different sorts of objects, and the state are not easy to justify. This is especially true of intellectual property”. (Hettinger 1989.) The case of patient information ownership is not easier even though the area is narrower when compared with the overall area of intellectual property. Some of the fundamental demands and values in healthcare are not similar to those in general IPR (intellectual property rights) expectations elsewhere. Therefore, it is obvious that in healthcare context ethics has great importance and thus proper arguments are needed for justification of patient information ownership.

This paper argues that ethical demands would be better served by clearly defined rules governing patient information and patient information databases. We need a clearer, re-defined concept of ownership compared to the prevailing situation. European Union Directive 96/9/EC directs member states to implement a law granting a *sui generis* protection to databases of facts to those who create said databases. This protection is remarkably similar to copyright in that it encompasses the exclusive right to use the database for financial gain. This paper starts by using the IPR sense of the word ‘ownership,’ as both the factual phenomenon and the suggested solution work with said definition. It is obvious that the concept of “ownership” is complex and that the current definition of “ownership” must be re-defined.

Current legal situation remains complicated, because legal precedents for IPR-protecting patient information are difficult to find. While the Finnish Copyright Act (404/1961) 40 b § grants ownership of the database containing e.g. patient information to the compiler of the database, the decree given by the Finnish ministry of social affairs and health on 30.3.2009/298 limits the use of patient information to only that which is necessary. The ownership is not stated clearly enough, which is problematic. In other jurisdictions, for example in the United States, there are organizations that buy patient records and make a profit by selling them. In many US states, patient records are treated as physical property of the hospitals and physicians. At the same time, citizens have a right to patient information that concerns them. (Rodwin 2009, 2010.) Ultimately, whoever owns the patient information (in this case, the patient information databases), can decide the uses to which it will be put.

As Grcic (1986) said “A moral right is a valid claim justified by reference to some moral principle”. Hence, what kind of ownership of patient information would be good and ethically justified must be considered first. Then the arguments for a viable legislative solution and definitions of health care practices (which fall outside this paper’s scope due to limitations of space) can be brought forward. The aim is to implement the philosophical basis and have greater moral legitimacy in health care.

This paper argues that the ownership of this IPR should be granted to the citizen on two main grounds: first, that the integration of patient information would be a natural outcome and secondly, that this solution would be ethically superior to the current legislative solution. This paper begins with an ethical evaluation of the five alternatives for ownership of patient information: the state, the healthcare worker, the healthcare provider organization (public or private), the provider of database and finally the citizen. This paper argues that the citizen has the best ethical claims to ownership of their own information. Critical arguments from Locke (commonly used in IPR discussion) and Kant show that citizen is the most justified owner of patient information and cannot be bypassed.

2. Ownership

First problem while analysing the ownership is that the term ownership itself is multidimensional. It has historical aspects, even the philosophers of history such Plato and Aristotle has taken it under consideration and not forgetting countless other philosophers from that time to current day. Ownership has also different manifestations which are dependent of the shape of object which is seen to be owned. Property can be physical objects, land, intellectual property, money (real or numerical credit of account) etc. Therefore, in this paper the premise and focus is on immaterial property. The choice is valid because obviously immaterial nature of patient information even it can be stored and become concrete through the physical objects as papers and different information systems. However, the definition as intellectual property is not accepted as it is commonly used in status quo IPR-legislation. Reason for this demarcation is that when usually granting ownership the intellectual work or act is seen as sufficient justification for ownership, which is seen problematic based on arguments presented in this paper. On chapter three there is presented the substitutive solution of ownership: datenherrschaft of citizen.

Patient information is fundamentally different when compared other immaterial (intellectual) property. Even creator of patient information can be, and usually is, healthcare professional the mechanism of that creation is exceptional. Whilst traditional intellectual process like artistic composition can be made solely by creator, situation is not equivalent when creating patient information. The fundamental source of information about patient is the patient not healthcare professional. Healthcare professional is actually not doing no more than diagnosis, especially when the modern healthcare rests on evidence based medicine. Hence, diagnosis cannot be done without the patient.

2.1. De jure ownership of patient information

Traditionally, the critical element necessary for granting copyright protection has been that there is a 'work' to protect. With the directive 96/9/EC the European Union directed the member states to implement a *sui generis* protection for all databases and copyright protection for databases that "by reason of the selection or arrangement of their contents, constitute the author's own intellectual creation shall be protected as such by copyright. No other criteria shall be applied to determine their eligibility for that protection." Finland implemented this directive via Finnish Copyright Act (404/1961) (hereinafter FCA) 40 b §.

"If a computer program ... is created in carrying out the employees work duties, the copyright passes to the employer ... this provision shall apply to databases created in carrying out work duties or official duties" [translation here]

To explicate, the FCA 40 b § grants ownership of the database containing e.g. patient information to the compiler of the database, or, if the compiler is an employee, to the employer in whose service the database is compiled. Note that the Finnish implementation grants higher level of IPR protection than the directive intended.

The European Court of Judgement (hereinafter ECJ) has given several decisions regarding this directive. In case C-444/02 *Fixtures Marketing* [2004] ECR I-10549, paragraphs 33 to 36, ECJ states that a database listing basic information enjoys the *sui generis* protection. However, in case C-604/10 *Football Dataco and Others* (not yet published) paragraph 27 ECJ states that copyright and the *sui generis* right are two separate rights. In paragraph 36 to 40 the ECJ states that, in order

to enjoy copyright protection, the author must express his creative ability in setting up the database by making free and creative choices.

It seems highly questionable that an electronic equivalent of a paper patient record could be set up following a set of free and creative choices. Rather, it seems that there is very little room for choices. The basic biometric information is not optional, and fields for diagnoses and medication seem equally mandatory. As an aside, the skill and labour necessary to create the data are irrelevant to the question of the databases' copyright (ECJ C-604/10 *Football Dataco and Others* paragraph 46).

An electronic patient record would hardly seem to qualify for copyright protection under the ECJ interpretation of the database directive. In paragraph 52 of *Football Dataco and Others*, the ECJ explicitly states that member states *may not* grant copyright protection to databases under *any other* conditions than those set out in Article 3(1) of the database directive. *Thus, the Finnish implementation of database directive has failed critically as it makes no differentiation between the sui generis right and copyright and extends copyright protection to all databases created in an employee-employer relationship.* There is, as of this writing, no pending revision of the FCA 40 b §.

Under the Finnish law, then, a patient cannot be the owner of his or her own patient information. The information is compiled into a database and the provider of health care (regardless of whether this provider is a public authority or a private health care provider) gains the rights to this information.

Provider of patient information database is the controller of database and contents of it. Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases gives sui generis protection for all databases. The explicit reasoning behind the directive is to compete with the USA in database-based enterprise

2.2. Right to verify personal information in a database and exercise of this right

Despite the lack of ownership, a citizen has on basis of the Finnish Personal Data Act (523/1999) (hereinafter PDA) an unwaivable right to know their personal data is being stored in a registry (PDA 24 §), check the accuracy (PDA 26 §) and correct (PDA 29 §) any data concerning themselves.

However, there is no law does guaranteeing that the exercise of this right should be free of charge. Accessing the different databases that are maintained by public authorities incurs a cost. The Finnish electronic handling and manipulation of client data in social and health services act (159/2007) (hereinafter CDA) 18 § states that if the client of social or health services wishes to access the log files documenting accessing of their client data, the service provider has a right to charge an access fee equal to the direct costs incurred by providing access to the log files. By way of analogy, the same applies to the health records themselves.

2.3. Arguments from Locke

Intellectual property is commonly justified with Locke's notions about property gained by labour (see e.g. Hughes 1988, Spinello 2003). Locke's (TTG II, V, 27) argument "*Though the earth, and all inferior creatures, be common to all men, yet every man has a property in his own person: this nobody has any right to but himself. The labour of his body, and the work of his hands, we may say, are properly his.*" seems *prima facie* plausible, but within even little deeper evaluation it is seen that

it fits only for physical property. Kimppa (2005) has argued that Locke's argument is valid only if the ownership is exclusionary; meaning that if someone else owns something and it is away from another, for example food, drink, cars or other material objects. But information is not away from anyone else. Thereby Locke's argument about property is not valid when considering the immaterial because the limiting factors of property over peoples life and liberty. Thus, we must reject the provider/complier of patient information database to be owners of information based on intellectual process. Same argument is valid when considering that healthcare workers or healthcare organizations to be owners based on labour.

Another problem is that if some other party, than citizen, owns (controls it) of patient information, what are the rights of the citizens? If someone else than the citizens themselves have ownership of the patient information, people's rights for information concerning them are actually restricted and thus their liberty and autonomy are restricted. This idea of someone else than the citizens themselves controlling the patient information is problematic because Locke's (TTG II, VII, 87) statement

"Man being born, as has been proved, with a title to perfect freedom, and an uncontrolled enjoyment of all the rights and privileges of the law of nature, equally with any other man, or number of men in the world, hath by nature a power, not only to preserve his property, that is, his life, liberty and estate, against the injuries and attempts of other men..."

The statement points that we cannot use Locke as justification if we lessen people's liberty and autonomy. At the other hand, when citizen own their patient information the liberty and autonomy of people is actually strengthened because they have more control, and thereby possibilities, to use that information as they wish.

Worth of notion is also that if one owns one's body, how can it be that some other party has rights over information about the body of the person and the person does not? Yet, more crucial is how someone can have rights over my *person*, which nowadays could be defined as an individual person. If there is an individual person, the health information about that person is basically private by nature when thinking about Locke's (TTG II, V, 27) view about a person. Therefore, the idea of someone else than the patient as the owner conflicts with Locke's idea about a *person* and thus cannot be justified because the health/patient information can be crucial for one's understanding about life and body of their own.

2.4. Arguments from Kant

Justification that someone else than citizen should be owner of patient information could not be found from Locke. Aforementioned problems in patient rights and Locke's view of property leads us towards the philosophy of Kant (1785) and his three categorical imperatives, which all are modifications of same moral law but differently presented:

1. *Act as though the maxim of your action were to become, through your will, a universal law of nature*
2. *Act in such a way as to treat humanity, whether in your own person or in that of anyone else, always as an end and never merely as a means.*
3. *Act only so that your will could regard itself as giving universal law through its maxim.*

Kant's categorical imperative's second formulation states: "*Act in such a way as to treat humanity, whether in your own person or in that of anyone else, always as an end and never merely as a means.*" (Kant 1785). Thus, the person should always be treated with respect to his or her humanity, not in an arbitrary fashion. Each person should be honoured because he or she is a human being, not because he or she is something which serves some personal end or goal. (Liddel 1970.) Therefore, the citizen cannot be bypassed when thinking about patient information; for if they are, people are treated as means only.

Restoring the citizen's health or curing a disease is not sufficiently fulfilling the Kantian second formula. People can be treated as an object by healthcare and healthcare professional while they are having care or medical treatments. This point is valid in situations where an owner of patient information is to be a healthcare professional, a healthcare organization, a provider of a patient information database or a state. If some aforementioned owner candidates (other than citizen) of patient information is granted the ownership, the patient as human being is not honoured as an end *per se*. Accordingly, if the patient is laid aside compared with other owner candidates, which have their own goals (even those goals can be same as goals of citizens), we do not respect people's autonomy and liberty to choose how information is used or is not used.

Example, people are not treated as an end, if healthcare professionals owns the patient information and thus have a paternalistic state over citizen. In paternalistic relation, healthcare professional can decide how the information is used and what is best for the citizen. Thus, there the citizen's humanity as a being person who has his or her own will and opinions about his or her life is lost by someone else's power over the citizen. There is loss of the person ahead in that paternalistic way of good intentions. It is obvious that if owner is some institution (state, healthcare organization or company) the problem is actually worse, institutions can treat citizen only as part of bureaucracy process, without trace of humanity.

The first categorical imperative, "*Act as though the maxim of your action were to become, through your will, a universal law of nature*" gives more to think about. A wider understanding and the bigger picture about ownership must be reached rather than solve some specific situation if the first categorical imperative is to intend to be fulfilled. The defined ownership of patient information should be formulated and legislated such way that it satisfies requirements to be a universal law. In this context that means that ownership must be formulated so that every rational being could apply that regulation. Taylor (2004) has analyzed the paternalistic maxim and came to a conclusion that it is not acceptable people are treated paternalistic way. If the world, where paternalism as a maxim is universal law, is imagined there would be situation where people could not be in self-control. Paternalism maxim converts rational agents to be less autonomous and diminishing the capacity for their self-control, which is a precondition for possibility to actually will effectively any action at all. Thus, by willing the paternalistic maxim to be universal law one takes away this capacity which makes that willing to be collision within itself. Thereby paternalism cannot be held as a universal law.

The first categorical imperative clearly brings out the flaw if the citizen is without the ownership of own patient information. If some other party is an owner of patient information, there are aforementioned problems with the paternalism, in this context some others power over citizen considering patient information. Thus, that solution where a citizen is not an owner cannot be a universal law because of the aforementioned problems of paternalism.

The third categorical imperative can be used to test if some action is ethical or not. In this paper, proposal that a citizen should be an owner is presented. If that solution is looked through the third

categorical imperative, it is seen that some constraint on that ownership must be acknowledged. Even it is argued that citizens cannot be displaced from an owner position without problems; either cannot the citizen's ownership be absolute over the patient information. There are occasions where the healthcare professionals or other authorities must have access to the patient information. Example, there is situations like lethal epidemic diseases or situations where access to the patient information is crucial for some other individual. In any case, information in some situations is premise for securing other lives and withholding that information hence cannot be seen as an act of universal law through its maxim. Nevertheless, this collision of patient rights and urgent need of others can be solved with giving criteria when patient information can be accessed without the permission of an owner (citizen). Citizens can, of course, give rights to access on patient information in all medical issues which makes the problem to disappear. But that consent must be informed and done by the citizen. That way regulated ownership seems to be acceptable by all three categorical imperatives and overtakes the aforementioned problems which came up if someone else was considered to be an owner rather than the patient.

2.5. Datenherrschaft as an solution of the ownership

Kainu and Koskinen(2012) presented the definition of *Datenherrschaft*, which needs redefining for it to be more applicable for patient information context:

“the legal right to decide the uses of, in a database or another compilation, collection or other container or form of data, over a entry, data point or points or any other expression or form of information that an entity has, regardless of whether they possess said information, with the assumption that sufficient access to justice is implemented for a citizen to have this power upheld in a court of law.”

In this context, a restriction is appended. As patient information can be critical in limiting the impact of epidemics, the citizen may not destroy information in patient information database. The public health care may, in carefully delineated circumstances, utilize this information to safeguard the health of others. While it may seem that this limitation undermines the scope of *datenherrschaft*, the limitation is necessary. The limited abridgement of *datenherrschaft* is judged a lesser evil compared to the major health impacts epidemics can have. Thus, for the purposes of this paper, *datenherrschaft* is defined as

“the legal right to decide the uses of, in a database or another compilation, collection or other container or form of data, over a entry, data point or points or any other expression or form of information that an entity has, regardless of whether they possess said information, with the assumption that sufficient access to justice is implemented for a citizen to have this power upheld in a court of law, with the limitation that requirements of public health prevent the citizen from having the right to delete information or obstructing the access of public authorities to it when said access is necessary for limiting the impact of epidemics.”

3. Conclusions

In this paper it is shown that current legislation of patient information is lacking. As the property interest is financially quite small, there will very likely not be any cases of a citizen appealing to the ECJ, and, therefore, it would be extremely important to take this matter under legislative revision without undue delay. The need for legislative revision is further underlined by the fact that the database directive has been incorrectly implemented. A critical argument exists, based on Locke and Kant, which supports that citizens should be the owners of patient information. *Datenherrschaft* as legal basis fulfils those arguments and emphasizes the status of citizen as person and as an end.

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