Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks

REACTION (FP7 248590)

D7.3 User Empowerment – Requirements, Principles and Concepts

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Abstract	This document explains the meaning of user empowerment, its aspects for different users, its relation to the medical and legal area. It also discusses how users can be empowered or empower themselves and, where applicable, how this process can be technically supported.
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1 Executive Summary

User empowerment is a concept mainly involving patients but can also be extended to physicians and carers. Important principles —or aspects— of empowerment are literacy (education), self-efficacy, self-determination, and choice. In the literature, the term “patient empowerment” is often used as it was originally introduced in the medical area and initially meant to just provide patients with information in order to come to an informed decision regarding treatment or therapy of their disease. Today, empowerment is seen in a much broader context and not only includes information about the disease but also information how to better cope with the illness, choices regarding lifestyle, and privacy rights.

In this document, we discuss various aspects of empowerment that should be borne in mind for developments in REACTION, especially those pertaining to patients. More specifically, two main requirements have been identified which should be taken into account: I) provide information and II) allow for (an informed) choice. Providing qualitative health information allows for improving the patients’ literacy while allowing choices, i.e., offering alternatives, is one way to give patients more control over the course of their treatment. The impact of empowerment typically involves quantitative dimensions, like clinical outcomes and costs, but also qualitative dimensions, like improved sense of well-being or greater self-efficacy. Such impacts on patients, carers, or health systems are discussed here as well.

The main requirements of empowerment are also relevant for the legal area and in particular for patients to know and execute their privacy rights. In fact, the notion of an “informed consent” is based on the same principles. The patient’s option to give consent or refuse it when personal data is requested for processing is a fundamental privacy right — but it is not absolute. There are also derogation rules for this right which allow the processing of personal data without explicit consent. Processing of health information by a physician for the purpose of preventive medicine or diagnosis is an example for such a derogation. Other derogations, e.g., the data processing being claimed to be of vital interest for the patient, are typically not applicable within the project’s scope. The conditions for the applicability of derogations and also the reasons for their non-applicability are discussed in this document as well as the requirements for cases where a consent is required.

Information technology developed within the REACTION project can aid patients and health professionals by automating and ’digitising’ certain tasks, like the recording of glucose levels, which can make life easier for both patients and health professionals. Furthermore, this technology establishes a communication link between patients and doctors in addition to regular appointments at the doctor’s surgery. Through this link, feedback is provided to the patient and the doctor regarding the patient’s ability to integrate proposed health-promoting changes into her daily life. On the one hand this allows to quicker determine if a therapy can be effectively executed by the patient and if not, to earlier look for other options which better suit the patient’s lifestyle. On the other hand, a monitoring solution should take into account that patients might feel uneasy, if they think they are being constantly watched by their physicians —or in fact are— which could have a disempowering effect. Therefore, different options for remote monitoring should be investigated, e.g., quantitative/short-term vs. qualitative/long-term feedback, such that patients have more choices than to either use remote monitoring or to abstain from it.

2 Terms and Definitions

2.1 Abbreviations and Acronyms

CFR	EU Charter of Fundamental Rights
ECHR	European Convention of Human Rights
EHR	Electronic Health Record
EU	European Union
GP	General practitioner
HIS	Hospital Information System
HON	Health On the Net foundation
HP	Health Professional
ICT	Information and Communications Technology
IT	Information Technology
LIS	Laboratory Information System
WHO	World Health Organization

3 Introduction

The REACTION project aims to research and develop an integrated approach to improved long term management of diabetes. The REACTION platform will provide integrated, professional management and therapy services to diabetic patients in different healthcare regimens across Europe, including support for self management of diabetic patients.

For chronic diseases, like diabetes, it is essential that the patients take an active part in their own health management. In general, the trend in chronic care is towards a higher degree of self-management in which patient empowerment plays an essential role. The REACTION project seeks to harness the potential of new information and communication technologies to address and support this patient-centred approach in order to help patients to better cope with their illnesses and their personal situation.

User empowerment is more a concept rather than a process set in stone. It can be supported by information technology (IT) but it cannot be guaranteed by the mere presence or use of technology. User empowerment as a concept mainly involves patients but can also be extended to physicians and carers. Important principles —or aspects— of empowerment are literacy (education), self-efficacy, self-determination, and choice. In the literature, the term “patient empowerment” is often used as it was originally introduced in the medical area and initially meant to provide patients with information in order to come to an informed decision regarding treatment or therapy of their disease. Today, empowerment is seen in a much broader context and not only includes information about the disease but also information how to better cope with the illness, choices regarding lifestyle, and privacy rights.

3.1 Scope and Outline

In this document, user empowerment is introduced as a term spanning information acquisition and decision-making mostly by patients but also by health professionals — the latter to a lesser degree though. When we talk about information, we typically mean information on diseases, their treatment and management, as well as on coping strategies but also information concerning the processing of personal data, which can be a major privacy issue for patients. Decisions will ideally be made based on the information directly provided to or acquired by the patient. Since such decisions are often life-changing for the patient, we provide a survey on the medical impact of empowerment as well as a legal assessment of when and how patients need to be involved in decisions regarding the processing of their medical data. Since the REACTION project’s development efforts are driven by two major scenarios [43] —in-hospital and primary care— we will also discuss how the technology developed within REACTION can support user empowerment.

In section 4, we provide an overview of patient empowerment and its relevance to healthcare. Different categories of user empowerment are identified and it is shown which stakeholders can benefit from user empowerment. Section 5 discusses the role of information technology regarding information and access to information within the scope of empowerment. In section 6, we present the legal perspective on user empowerment including the legal framework and data protection principles. We also highlight exceptions —and their preconditions— made by privacy laws which allow the processing of personal medical information without a patient’s explicit consent, which is particularly relevant for processing data on the REACTION platform. We will conclude this document with a short summary of our findings in section 7.

4 Empowerment

Empowerment in the context of health services has received a lot of attention and, in that process, also has been defined in numerous ways. In the health area, it is often called patient empowerment and roughly refers to the relationship between a patient and a health professional (HP) where the patient is actively participating in making choices regarding her/his treatment or therapy. This deliverable, however, uses the term user empowerment in its title because, in REACTION, the empowerment goes beyond the traditional patient role from a patient-health professional dyad. The choices offered to users do not only encompass medical decisions but also organisational and legal ones, like those related to access of information and privacy, respectively. However, choice should not be imposed on users as for some this might be a burden. If users feel more comfortable with fewer options, down to a single proposal, then they should not be overloaded with information they do not want to deal with.

In the following, when we speak of "users", we mean anyone making direct or indirect use of the REACTION system, e.g., health professionals or patients.

4.1 Categories of empowerment

Users in the REACTION context are primarily concerned with medical services, either as providers or consumers. Therefore, empowerment with respect to the medical area is of great importance. Empowerment in the medical area can be supported by information and communications technologies (ICT) which in turn requires users to not only acquire the necessary skills to operate the IT system but also to learn how the information itself can be used and who shall have the information. The latter touches the third area of user empowerment, privacy rights.

In the following, we will briefly highlight the meaning and scope of empowerment for the three areas.

Healthcare. Empowerment in health promotion is broadly described by the World Health Organization (WHO) as "a process through which people gain greater control over decisions and actions affecting their health" [45]. In the health literature, more fine-tuned definitions can be found and also discussions on how control can be extended from health professionals to patients and how this affects health outcomes. Empowerment as a concept is not limited to a single area in healthcare but is applied in various areas, e.g., mental nursing [34, 36, 38] or diabetes [36, 21, 10]. Empowerment is typically characterised as being patient-centred, promoting self-determination and self-motivation of patients, improving patient's self-efficacy and health literacy, offering choices to patients, providing information and counselling to patients, promoting shared decision-making between the patient and the HP, and assisting in making health-promoting changes, c.f. [26, 11, 4, 24, 33, 21]. In addition, Ellis-Stoll and Popkess-Vauter [11] see mutual participation (HP and patient), active listening ("attending to what is said and checking for understanding"), and individualised knowledge acquisition as the defining attributes for empowerment. Funnel and Anderson [21] even call for a "paradigm shift from provider-centered care to patient-centered collaborative care." □

Privacy. Empowerment with respect to privacy can be seen as a two step process. In the first step, data subjects, such as patients, are provided with information about who collects and processes which data for which purpose, and who will be given access to the data. In a second step, it needs to be determined whether the subject's consent for the processing must be sought. If consent is required, the data subject must be provided with a choice to give or refuse her consent. However, consent is not necessary if the processing of certain data is permitted by law, e.g., if the processing is required for diagnosis and carried out by a health professional that is bound by professional secrecy (c.f. Article 3, Directive 95/46/EC [13]). The informational rights of data subjects and the preconditions for lawful processing are codified in EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, also known as the Data Protection Directive [13]. A general discussion on the Data Protection Directive and on the general legal framework as well as on legal and socio-economic issues can be found in Deliverables 7.2 [12] and 9.1 [28], respectively. In section 6, we will come back to the Directive and discuss it with respect to the processing of health information and empowerment. □

Technology. Empowerment in the technological sense refers to the support that information technology can provide for achieving the goals of the former two categories. It should, however, not be mistaken for the user's skill in operating soft- or hardware, though this is clearly a precondition if the user is to directly interact with the technology [16]. In terms of the users' IT skills, training as well as a comprehensible user interface of an application can be seen as empowering the user to actively manage her/his health related information. Otherwise, users/patients may choose not to play an active role in managing their health information and are more likely to delegate this task to others [16, 7]. On the one hand, technology can support or even enable empowerment but on the other hand just having a technology in place does not empower a patient per se. □

4.2 Who needs to be empowered?

In the literature, different models for empowerment are suggested. Most suggest that patients need to be empowered [36, 21, 26, 5] and others suggest that health professionals, like nurses, need to be empowered before they can empower others [46, 8]. Another group of authors argues that patient empowerment actually opposes the interests of patients [35] or that patients are content with leaving medical choices to doctors [27].

Patients. For the empowerment of patients, acute cases and chronic cases should be distinguished as the patients' needs are different in each case. Angelman and Berman [4] state that, "in general, the more acute the illness, the less choice may either be available to or sought by the patient." This is consistent with the findings of Lewin and Piper [27] where 87% of patients from a coronary care unit said they are "content to entrust their care to the health professionals as experts". Salmon and Hall [35] even oppose empowerment —at least for clinical care— and mention that many successful 'empowering schemes' had really been disempowering as patients had practically no choice and were mostly following doctors' orders. They conclude that by imposing empowerment on patients, patients' interests are not served. Angelman and Berman [4] make a similar point in saying that by increasing choice options, patients could be overloaded with information which often leads to poor decisions. Poor decisions (from a clinical point of view) are even more likely, if patients have to make difficult, life-changing decisions by choosing from a set of undesirable options. So it would seem that patients should better not be empowered for their own good. However, empowerment does not suggest that every patient *must* make her own decision in every situation nor that empowerment should be imposed on patients. If the patients' self-determination is to be a goal in empowerment, it must also be accepted that some patients wish to delegate the medical decision-making to someone else [7], e.g., their physician. Indeed, as Käppli reports [24], for some patients personal responsibility can be a burden and thus they prefer to delegate decisions to their physicians. In a study by Coulter and Magee (cited in [4]), 26% of the respondents from eight European countries indicated that they prefer to let their doctor decide, 51% preferred shared decision-making with their doctors, and 23% said they should decide, possibly after consulting with their doctors. If patients decide on their own, another challenge to empowerment can be cases where a patient freely decides to stop treatment, accepting that this will ultimately result in her/his death. Such decisions can also be tough for physicians to accept as they are professionally dedicated to preserve life [24].

While some of the points mentioned before are also true for chronic diseases, the situation is still different. In chronic care, patients are not constantly watched, like in a clinic, but are managing their disease largely by themselves. Since patients with chronic conditions are faced with having to regularly make decisions about the management of their disease on their own, they tend to be more motivated to self-regulate than patients with acute conditions [4]. Hence, it comes as no surprise that literature reporting positive effects on patients' health by empowering them is mostly concerned with chronic diseases [36, 21], like diabetes. □

Carers. We distinguish two groups of carers, formal and informal carers. The former refers to persons with medical training, like nurses or other health professionals, and the latter to laypersons involved in care, like family members or close friends.

Regarding formal carers like nurses, Chavasse [8] notes that nurses practise with little power in healthcare and often are in a subservient position vis-à-vis administrators, doctors and often other healthcare staff — this, however, may vary from country to country. She argues that in a climate where nurses act without self-confidence, they cannot empower someone else and concludes that nurses have to first reach empowerment themselves. Wuest and Stern [46] also see the need for nurses to become more autonomous and play a more active role in healthcare. Ryles [34] notes that an empowered professional might be a precondition for the ability to empower others but does not guarantee that empowerment is extended to the patient. Skelton [38] also considers the possibility that empowerment of nurses could just be a *rhetoric vehicle* serving to shift power from doctors to nurses, though without any empowering effect for patients. However, Shojania et al. [37] and Walsh et al. [44] reviewed a number of studies to assess the effectiveness of quality improvement strategies in diabetes care and lowering blood pressure, respectively, and found that overall care quality was improved by expanding the professional roles of nurses, e.g., more actively involving them in patient monitoring or adjusting medication regimens.

Informal carers play an important role in helping diabetic patients in day-to-day life. Especially in families with diabetic children or adolescents, parents are heavily relied on as informal carers. In a study by Kanstrup et al. [5], communication and cooperation between patients and informal carers has been named an important topic. For instance, children often call their parents when they need help in calculating their insulin dosage. Children also want to get in touch with other diabetic patients at their age to learn how they cope with diabetes in everyday life and to learn from their experiences. Sharing of information and experiences of others has also been on the parents' and adult patients' minds. This includes information about coping strategies in daily routine, e.g., easier keeping track of insulin administrations during the day, and relevant information regarding food, like the ingredients of products. Kanstrup et al.'s study showed that learning about 'non-disease' related information was also deemed an important part of empowerment, for patients and informal carers alike.

Most of these points also play an important role for elderly diabetes patients. Especially the carer who does the cooking in the patient's home plays a key role. This carer does not only have to have information about the patient's condition and the management of the condition but also information about nutrition and diet requirements. Having information on food, recipes, and how eating and not eating certain food impacts the diabetic patient's condition is also helpful to empower the carer. Moreover, informal carers of elderly persons should also be provided with information on other illnesses that might occur in conjunction with diabetes and on the specialised health services available for such comorbidities. □

Physicians. In general, physicians are regarded as being empowered by virtue of their medical training. Hence, empowering of physicians is generally not discussed in the literature. However, Lau [26] suggests that empowered patients will actually 'empower' physicians too, though in a different way. Lau argues that patients regarded as being 'difficult', 'resistant', or 'non-compliant' under a 'traditional' regime actually provide valuable information to the physician under an empowerment regime. In the traditional model, a patient might be lectured about the consequences of non-compliance, e.g., that a diabetes patient's fatigue is caused by not adhering to the treatment plan. In the empowerment model, the doctor would seek out the reasons for a patient's non-compliance to find a solution together with the patient that better suits the patient's needs. Funnel and Anderson [21] make a similar point in saying that existing mechanisms, like goal setting with patients, need to be used differently. They mention that under a 'traditional' regime, doctors would set or negotiate metabolic goals with the patient, e.g. a certain level of blood glucose, and judge the patient's efforts based on this goals. Under an empowerment regime, the doctor and the patient would set behaviour change goals to help the patient identify problems and solutions for achieving *self-identified* goals. This is different from the compliance/adherence scheme of the 'traditional' regime as it takes into account the patient's lifestyle and lets the doctor better understand the patient's own needs. □

4.3 Why empowerment?

The motivation for empowering patients is typically medical, monetary, or both. On the scale of an "incremental cost per unit of health outcome gained", Angelmar and Berman [4] discuss efficient health outcomes and identify the three desirable results as

- better health outcomes with no increase in cost,

- same health outcomes at lower cost,
- better health outcomes at lower cost.

Costs here refer to overall health care costs and not necessarily only to direct costs, e.g., for pharmaceuticals. Note that "better health outcomes with increased cost" is not a goal on this scale as this would mean that even for marginal improvement any cost is acceptable. Although this might have been acceptable for long, it is clearly less desirable as the other results since it is economically inviable for the healthcare system in the long run. Angelmar and Berman point out that "[e]mpowering patients may or may not result in improved efficient health outcomes because of lack of patient motivation" referring to cases where patients had been given control over their treatment but simply chose to do nothing. Indeed, the question how to motivate patients to change unhealthy behaviours to health-promoting behaviours is important but, unfortunately, still open. The factors influencing patients' motivation and the time it takes for a behaviour change to occur is not explained in the literature [11]. For citizen participation, Zimmerman and Rappaport [48] found that there is a correlation between involvement of individuals and empowerment. However, they also point out that their results cannot be used to explain whether involvement enhances individual empowerment or if empowered individuals simply choose to participate more than non-empowered persons. Therefore, the causal relationship between involvement and empowerment, if any, is still unclear.

Despite this lack of understanding of patients' motivation, several studies have shown that the clinical outcome and the perceived health outcome of patients under an empowerment regime were better than under a standard care regime [36, 21]. In particular, for the diabetes case, patients' blood glucose, weight, and blood pressure have improved relative to standard care [36]. According to Funnel and Anderson [21], behavioural changes occurring due to goals identified by patients also achieve improved outcomes and are more likely to be sustained than changes recommended by others because the changes are identified by and important to the patients.

On the one hand, this suggests that giving patients more control also results in more efficient health outcomes, i.e., producing one of the three desirable results mentioned above. On the other hand, simply giving patients control over their treatment is probably not enough. If patients see little benefit in changing their unhealthy behaviours, the change may not occur [11]. A situation could even arise where patients change healthy behaviour to unhealthy behaviour because the latter is more convenient and the former is perceived as having little or no immediate benefit. Such a case is cited in [4] for an asthma patient that stopped using his steroid inhaler after he experienced no immediate adverse health effects after not using it during a holiday trip. From the patient's perspective, this might be the outcome of a rational decision making. However, such a 'rational' decision could prove to be myopic and cause adverse health effects in the mid- to long-term. Such overlooked long-term consequences, i.e., degraded health, are likely to also increase costs which clearly is undesirable from a medical *and* financial point of view. In the privacy area, a similar behaviour has been found by Acquisti [3] for customers choosing to disclose personal data for short-term benefits, neglecting any negative consequences in the future, e.g., being charged with higher prices due to price discrimination induced by the data they disclosed. Acquisti concludes that customers seem to have an "optimism bias" when confronted with potential negative outcomes in the future, which could also be said for some patients.

Angelman and Berman [4] cite a study of Kravitz et al. [25] which showed that drugs are likely to be prescribed if patients specifically ask for immediate treatment, even though a positive effect, if any, on the patients' health is unclear. Therefore, if patients are simply allowed to seize control, i.e., no shared decision-making is used, costs may increase without any or only with little benefit to patients' health.

4.4 What are the implications of empowerment for REACTION?

From the previous sections, it is clear that empowerment has many aspects that need to be considered. Perhaps, two general principles stand out from these many aspects and can be phrased as in the following two requirements which should be taken into account by the REACTION project.

I) Users must be provided with comprehensible information that suit their needs

II) Users must be provided with alternatives to allow for (informed) choice

Requirement I) also implies that information should be relevant and not excessive such that the user can understand the information's subject. Since the concept of empowerment also involves building up knowledge, different information will be required at different stages of this development. For instance, a freshly diagnosed diabetes patient would typically require different information than a patient already managing her illness for years. Thus, REACTION components should take into account different levels of patients' health literacy and therefore should be flexible enough to provide different types of information on the same subject.

The provision of alternatives is supposed to give patients control over the course of their therapy. Ideally, patients should be provided with two or more alternatives and naturally, as per requirement I), with information on the consequences —and possible risks— of choosing one of the alternatives. Alternatives could be provided at the medical level, e.g., choosing one therapy over another, at the privacy level, e.g., giving or denying access to certain data, or at the technical level, e.g., choosing if, how, when, and who to notify about the latest blood glucose measurements. However, it may not always be possible to provide alternatives which means that patients will sometimes be given a 'take it or leave it' kind of choice. In this case, it would be even more important to provide the patient with relevant information and possibly with information on why there are no more alternatives, e.g., science has not found any evidence on the effectiveness of other proposed therapies. This way, patients would at least be spared from most likely ineffective 'alternative' therapies that may have further adverse effects on the patient's health.

5 Information Technology

In this section, we will address some of the problems faced by diabetic patients when making use of information technology. Problems arise from the trustworthiness of information found by patients but also from inadequate service offerings which do not suit their needs. We also give examples how ICT can help to support patients in managing their illness and therefore to better cope with it. In addition, we present several examples where ICT provides choices to patients regarding access to their health information. At the end, we discuss some of REACTION's developments in relation to empowerment.

5.1 Information acquisition

The Internet led to the proliferation of all kinds of medical information for both health professionals and laypersons. Thus, finding information on a specific health issue is quite easy for persons with Internet access. In addition, information from the Internet is available around the clock and, in principle, accessible from any location which offers more flexibility to users. However, caution regarding the quality, trustworthiness, and accuracy of the information is surely advised.

In 1998 [45], the World Health Organization (WHO) coined the term *health literacy* and defined it as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health". In the same publication, the WHO says that access to health information and their effective use must be improved as "health literacy is critical to empowerment". Christmann [9] reinforces this point in saying that "health literacy is crucial to use the Internet in an effective way". However, as we will see in the following, the way to health literacy is often accompanied by uncertainties, doubts, and concerns.

Access. In principle, access to health information does not seem to be a big issue anymore — at least for Internet users. However, in a study from the Health On the Net Foundation (HON), 24% of the respondents were still seeing their lack of computer or Internet training as a barrier to access online material [31]. On the other hand, this means that 76% of the respondents are doing quite well with finding health-related information on the Web.

A poll from 2010 conducted in the USA by Harris Interactive [22] found that 73% of the respondents look often or sometimes for medical information online and 81% of the respondents said they had searched for medical information at least once “within the last month”. In a similar study, HON found that 75% of the respondents searched for health information online at least 2 times “within the last week” [31]. In the Harris poll, 86% of respondents said they had been “very” (41%) or “somewhat successful” (45%) in finding the health information they were looking for. However, this does not imply that the information found was accurate or credible. On the one hand, 85% believe that the information they found was “very” (23%) or “somewhat reliable” (62%). On the other hand, the number of respondents believing that the information they have found is “very reliable” is declining from 37% in 2005 to 23% in 2010. This could mean that the information available is deteriorating or that users are becoming more critical when reviewing health information. The latter could also be a sign of increased health literacy and/or empowerment. □

Quality. The quality of online health information is something that users had been concerned about for long. In a 2002 study, Ferguson [18] found that 82% of the respondents had been “concerned about getting online health information from an unreliable source”. This is consistent with studies from HON in 2005 [23] and 2010 [31] where on both occasions 80% of the respondents saw quality of information as the top barrier for seeking health information online. Therefore, knowledge about how to identify qualitative health sites would surely help to develop and foster health literacy and thus improve empowerment.

In its 2005 study [23], HON asked for the opinion of health professionals and non-professionals from the USA (43%), Europe (26%), and other countries (31%) regarding the use of health information from the Internet. In this study, HON asked which sites are preferred by respondents for obtaining health information. In general, respondents preferred academic sites —like universities—, consumer sites sponsored by medical journals, hospitals or non-commercial medical organisations, and governmental sites. The least preferred sites had been those of pharmaceutical manufacturers and sites sponsored by news media and commercial medical organisations. It is worth noting that the preferences of non-professionals and professionals in this regard are almost identical. HON also reports that respondents had been increasingly looking for site accreditation and certification to identify reliable health sites [23]. On the one hand, seals displayed on web sites, like HON’s own HONcode seal or the Trust-e[1] seal, could provide assurance. On the other hand, the seal providers only check the site’s adherence to their own standards and do not —and cannot— guarantee that medical information provided by the site owner is accurate. Thus, determining quality and reliability of medical information is still left to the end user.

Trust and assurance in online information sources could be inspired by means such as the application of scientifically sound methods for information preparation and processing, content that is peer-reviewed by medical professionals, traceability and documentation of incorporated sources, and legally binding assurance that no money was accepted from pharmaceutical companies or other advertisers for publishing certain information or recommendations.

Also in the 2005 study [23], HON found the following top four indicators which had been used by respondents to assess the quality of health web sites.

(a) availability of information

(b) ease of finding information

(c) credibility of information and the site owner

(d) accuracy of information

While (a) and (b) mainly represent convenience factors, (c) and (d) address the quality issue. Online patients and their doctors agree that much of what goes as ’online health information’ is not to be trusted [18]. However, many patients will *not* jump to conclusions after having consulted a single site but will compare and review information from different sites [18] — and this is what makes up health literacy.

[1] http://www.truste.com

Physicians, however, usually doubt that patients can tell the 'good' from the 'bad' information [18] and thus are concerned about adverse medical effects of knowledge acquired online. Hence it is important for patients to achieve a certain level of health literacy for their own good but also for the healthcare system as poor health literacy can "produce supplementary costs to the healthcare system because of inadequate or inappropriate use" [9]. □

Patient-Physician Relationship. Many physicians are still concerned about patients seeking online health information. In the HON study of 2005 [23], 90% of non-professional and professional respondents agreed that patients are becoming more knowledgeable through online searches but 67% of the professional respondents were concerned that online information increases patients' interest in self-treatment and 60% believe that it also decreases the patients' motivation to follow instructions regarding prescribed pharmaceuticals. On the one hand, such concerns are surely medically founded. On the other hand, it seems that concerns about a loss of authority also plays a role since more than 60% of the professional respondents were concerned that patients will challenge their professional authority and another 42% were worried that it also decreases the patients' adherence to their medical advices [23]. Still, in the 2005 study by HON, 88% of the professional respondents were convinced that patient-seeking health information improves the patient-physician relationship. However, this number has sharply dropped to 64% in 2010 [31], though the study offers no explanation for this drop. □

Peer support. Online health networks and peer groups are widely used by patients to share information about their disease and how to cope with it, e.g., tips about food and cooking in case of diabetic patients. Typically, information of experts is requested if the disease is newly diagnosed while peer generated information is sought when the patient becomes more experienced with the disease [5]. Although it has been reported that such groups are highly valued by patients and their relatives [5], quantitative evidence is missing that information provided through or gained from such a forum improves patients' clinical outcome [15, 39]. Additionally, concerns about the quality and complexity of the information disseminated in such forums have been raised. Since information is typically not addressed to a specific audience (professionals, layperson, etc.), it "could therefore generate emotional reactions, if, for example, it discusses survival rates for specific diseases" [9]. However, in the quantitative study of Eysenbach et al. [15], evidence about negative effects of participating in online support groups was not found, though no positive effect either (with respect to the clinical outcome). This does by no means imply that no positive effects exist —as the authors themselves admit— but that qualitative effects, like improved personal well-being, are not necessarily accompanied by quantitative improvements of physiological measurements.

In a critique on the study of Smith et al. [39], which like Eysenbach et al.'s study had a 'no change result', Fisher and Boothroyd [20] pointed out that the (diabetic) patients selected for the study had a clinical status that "was not remarkable", i.e., that there was not much room for improvement. On the one hand, this could mean that patients who are already knowledgeable and empowered are more likely to engage communities than less empowered persons. On the other hand, one could say that the study —or the community it built— did not reach the audience which would have benefitted more from education and support, i.e., less empowered patients with a 'bad' clinical status. Another limitation of the study by Smith et al. was that it was based on scheduled face to face courses. On the one hand this was a more personal approach, on the other hand it did not harness the strength of online communities which are available at all times and thus allow patients to drop in and out whenever they see the need for it.

Evidence for positive effects of eHealth systems had been found by Murray et al. [30] which reviewed several studies assessing eHealth systems that combine information and social support for people with chronic diseases. They conclude that such systems "appear to have largely positive effects on users, in that users tend to become more knowledgeable, feel better socially supported, and may have improved behavioural and clinical outcomes compared to non-users". However, they also indicate that these are preliminary findings that need to be confirmed by further studies. □

Lifestyle. Self-determination is an important aspect of empowerment and patients want to live a ’normal’ life free from paternalism [11]. Hence it is important for them to make their own choices, e.g., not to be restricted to make a choice from a list of prefiltered options that someone deemed suitable for them. For instance, in the study of Kanstrup et al. [5], a diabetic patient’s partner mentioned that he is not interested to learn of products labelled “suitable for diabetic patients” but generally wants to know what is in the product and then decide for himself whether it is suitable or not. The demand for such ’general’ information might also be a reaction to avoid stigmatisation as buying ’food for diabetics’ marks one as a diabetic patient while critically eying ingredients does not. In this regard, the study’s participants clearly preferred to blend in the crowd rather than stand out of it.

The case mentioned before makes a good example for a specific all-day situation where ICT can help patients to retrieve the information they want while not standing out of the crowd. It is already possible to scan barcodes of products using the cameras of mobile phones and retrieve related information from the Internet. Today, such information is often used to compare prices. However, it would likewise be possible to retrieve additional information regarding ingredients of food and, possibly, also automatically compare these with preferences set by the patient. This way, patients could get the information they are looking for in an easier and faster way. In addition, stigmatisation would not be an issue since product scanning is also done by non-diabetic persons, though for different reasons. □

5.2 Controlling access to information

With the help of ICT, personal medical data can be easily collected, managed, and shared. Access to these collections, such as electronic health records (EHR), helps physicians and formal carers to complete their daily tasks more efficiently. In addition, access to digital data does also enable physicians and formal carers as well as patients and informal carers to improve the patients’ treatment by providing everyone involved with more information and better communication.

Privacy. Personal medical data is stored in systems which integrate not only numerous medical applications, such as decision support systems, but also administrative components, such as accounting systems. Therefore, these systems are accessed by patients, medical professionals as well as accounting and administrative personnel. In some cases, a patient might not want all users of such a system to access his personal information for several reasons, such as confidentiality and privacy. In a study, cited in [19], the interviewed patients “were particularly concerned that their records could become available to employers or government agencies without their permission”. The results of another study, also cited in [19], showed that almost a quarter of the participating patients were concerned about the confidentiality of their medical records. This concern originated from mistrust in the security of the system as well as mistrust in the staff people. In [17], a case was reported that showed how such concerns can become a reality. In this case, medical staff in the UK was inappropriately accessing a celebrity patient’s EHR out of mere curiosity and thereby violating the patient’s privacy rights. The case also drew public attention, possibly damaged the respective hospital’s reputation, and entailed disciplinary investigations. More information on legal aspects concerning privacy, data protection, and the processing of personal data in eHealth applications can be found in [12].

Other concerns patients may have, could also result from the many aspects of life that are influenced by the information held in personal health records, such as obtaining employment, life insurance or consumer credit [19] but also stigmatisation and discrimination. All these concerns can have negative effects on the patient’s trust in the respective ICT system and, thus, be a burden for the relationship between patient and carers.

However, limiting access to personal medical data can also raise concerns by patients. In [16], interviews were conducted in order to determine patients’ opinions on user empowerment and their decisions — and the reasons for these decisions— about who should have access on their EHRs. The participating patients were questioned about their opinion on privilege management and access control regarding their EHRs and had to choose whether only doctors, the doctors and nurses, any health professional, or only the health professional that is currently taking care of the patient should have access on the patient's EHR. In general, the interviewed patients expressed their desire to be empowered. However, the majority (53%) did not wish to control their own EHR, thus, allowing any health professional to access them because they were afraid of not getting the same healthcare services in return if access would be limited.

Using ICT, access to information can be limited with the help of access control mechanisms. Access control is used for the enforcement of authorisation, whereas authorisation means granting access rights for specific information to an entity. In [12], authorisation has been introduced as one of the security, privacy, and trust requirements for REACTION. This document also provides an overview about different access control strategies and models, such as role based access control, in which users can perform tasks based on the privileges owned by their respective role, e.g., their position within an organisation.

In eHealth systems, access control mechanisms can be utilised to establish compliance with privacy laws. As an additional benefit, access control can support user empowerment. With appropriate access control mechanisms established, patients get the ability to decide and control who can access their personal information. Thus, self-management is improved and concerns regarding confidentiality, privacy, and social disadvantages are reduced which could strengthen the patient's trust in such an ICT system. Access control also enables the patient to easily share medical data with other users of the system, e.g., with a physician to obtain a second opinion or with an informal carer to support him in his efforts. □

Auditing. In addition to deciding and controlling who has access to one's data, it might also be helpful to monitor which data was accessed, by whom, and when. Giving users a chance to observe the access history of their data can enhance their trust in the ICT system because they have the option to verify that the systems enforces their decisions. Again, this supports empowerment since it adds another option for the patient to execute her right of self-determination.

Auditing mechanisms for monitoring access to patient data can be implemented and enforced using ICT. Audit trails, generated by such mechanisms, record relevant actions of accessing entities and allow to hold the entities accountable and responsible for their actions [12]. Thus, auditing provides a means to check if personal information is being maintained in accordance to the privacy principles and in accordance to the rule of law [17]. For instance, audit trails can be used to detect if a patient's personal data was accessed without her consent. From a security perspective, it might not be sufficient for such a mechanism to only provide answers to questions such as: Who owns the data? When and by whom was the data processed? It might also be important that these answers, for example in the form of log files or audit trails, are protected themselves. Several security objectives [12] should also be taken into account for audit trails in order to prevent manipulation from external as well as internal adversaries. □

Delegation and revocation. Another concept that is linked to access control is delegation. According to Sohr et al. [40], delegation is a process where one system entity delegates its authority to access specific data to another entity on behalf of itself. An example of delegation in the clinical domain could be a GP consulting a specialist. In this case, the GP delegates some of her access rights on the patient's data to a specialist. Another example would be a physically impaired patient —unable to use an ICT system— delegating control over her data to an informal carer to act as her representative.

As far as user empowerment is concerned, delegation can be seen as transferring the ability to control access to personal information to another user. In another way, this also resembles a transfer of trust as the delegating user can decide to authorise another user to act in her best interest.

Along with delegation, the concept of revocation plays an important role. Since delegation allows for a transfer of access rights it must also be possible to withdraw these access rights later on. Revocation refers to the process of taking away the delegated access rights or the desire to go back to the state before the access rights were delegated [47]. For example, a specialist's access rights on a patient's EHR should be revoked when the consultation has ended, e.g., when the patient is referred back to the GP. □

Obstacles. Besides the compliance to technical and legal constraints, a successful application of access control mechanisms in the clinical domain also depends on the cooperation with other participants in the healthcare system. For example, in [29] a commercial ICT eHealth application is presented which enables patients to control access over their medical information. However, this application requires cooperation from healthcare providers which, according to the authors, is often not obtained in practice. As a consequence, applications might fail to effectively support patients in the management of their personal EHR data if the required cooperation is not given.

It is also conceivable that physicians and formal carers see the utilisation and maintenance of patient information as an additional effort for which they expect financial compensation. Therefore, additional costs may arise which would have to be considered in health technology assessments by public decision makers, c.f. [41]. □

5.3 Technology support by REACTION

The REACTION platform provides its users with different kinds of medical information. Some of the information originates from third party medical information systems, such as Laboratory Information Systems (LIS) or Hospital Information Systems (HIS). Other information is entered manually by health professionals or administrative staff. Furthermore, information is also generated automatically by the system, for example by aggregating data from other sources and by collecting physiological measurements from patients using medical sensor devices, which is of particular importance for REACTION. The way that information is used and accessed in REACTION depends on its two main scenarios.

In-hospital scenario. In the in-hospital scenario, carers are the main target of empowerment since the patient is largely passive and the responsibility for the patient's health and treatment is in the nurse's hands rather than in the patient's own hands. In a typical use case of the in-hospital scenario [42], a patient's daily nutrition, glucose values, and the glucose injections performed are recorded in a mobile or stationary device carried by a nurse, see Figure 1. Here, empowerment of carers is supported by IT since no information regarding a particular patient's treatment gets lost or becomes temporarily unavailable when personnel changes, e.g., from day to night shift. Furthermore, carers will have the complete history of the patient's treatment within the clinic available at all times and from any place as it is electronically available from the REACTION system. Hence, the patient information processed and made accessible by the REACTION system helps the medical staff to make the right decisions and take action without delays. □

Primary care scenario. In the primary care scenario, empowerment is supported for health professionals and patients alike, since different options for accessing medical information are provided by the REACTION platform. For example, Figure 2 shows a screenshot of the REACTION platform's web interface for the primary care scenario, i.e., for GPs. This interface provides health professionals with medical information about a specific patient. Here, the measured data[2] of a patient's blood pressure is visualised in the form of a graph. Access to this kind of information constitutes an efficient means to get an overview or to keep track over the history of a specific trait. Furthermore, access to this data supports empowerment by improving the patients' possibilities to keep an eye on their physical condition and, for example, to detect irregularities. In addition, patients will be given an opportunity to access the platform from their computers at home or with mobile devices (smartphones, tablet PCs) providing them with comprehensive information, similar to the GP's shown in Figure 2. This allows them to easily keep track of their health status and have accurate and up-to-date information at all times.

It is also important to provide choices to patients how *they* want to make use of their data. For instance, some may prefer to have very accurate, quantitative information on their current blood glucose level and want to be informed right away if it deviates from their set goal, i.e., they prefer short-termed information. Others may not want to be bothered each time their blood glucose level is not within the ideal target

[2] The information visualised in this example is based on test data and not on real patient data.

Figure 1: Screenshot of the REACTION interface for the in-hospital scenario

corridor and prefer qualitative feedback telling them if they are 'generally doing fine', i.e., they prefer long-term trend information.

The other side of the medal is that information technology can also contradict user empowerment, if patients feel that they are constantly being watched by a physician who records and takes note of each of their lapses. If this happens, patients may feel pressured to meticulously adhere to their doctor's orders which may put them under constant stress. This, however, would certainly not improve empowerment. Thus, it is likewise important to provide patients with information on how the employed technology will be used by the health professionals that look after them. □

The data being collected, aggregated, and processed by the REACTION platform is based on established industry standards and specifications, e.g., the standards proposed by the Continua Health Alliance, see [12]. Using established standards serves to ensure consistent data encoding and data exchange between the REACTION platform and products of medical companies. This allows information to be not merely accessed by means developed within REACTION, but rather the user is given the option to choose between, or even reuse, tools provided by third party platforms. Examples of such third party platforms are the industry solutions Microsoft Health Vault[3] and Google Health[4]. Both products allow users to manage and share health information online and to import health data directly from different sources, such as the REACTION platform. Figure 3(a) shows a screenshot of the Google Health web interface that visualises blood pressure measurements collected with and made available by the REACTION platform. The same applies to Figure 3(b) which shows the visualisation of weight measurements imported from REACTION. Unfortunately, Google Health will be discontinued from the beginning of 2012 due to a lack of adoption and partnerships. Nevertheless, this example demonstrates that the users/patients of the REACTION platform are not limited to the means of access provided directly by the

[3] http://www.microsoft.com/healthvault/
[4] http://health.google.com

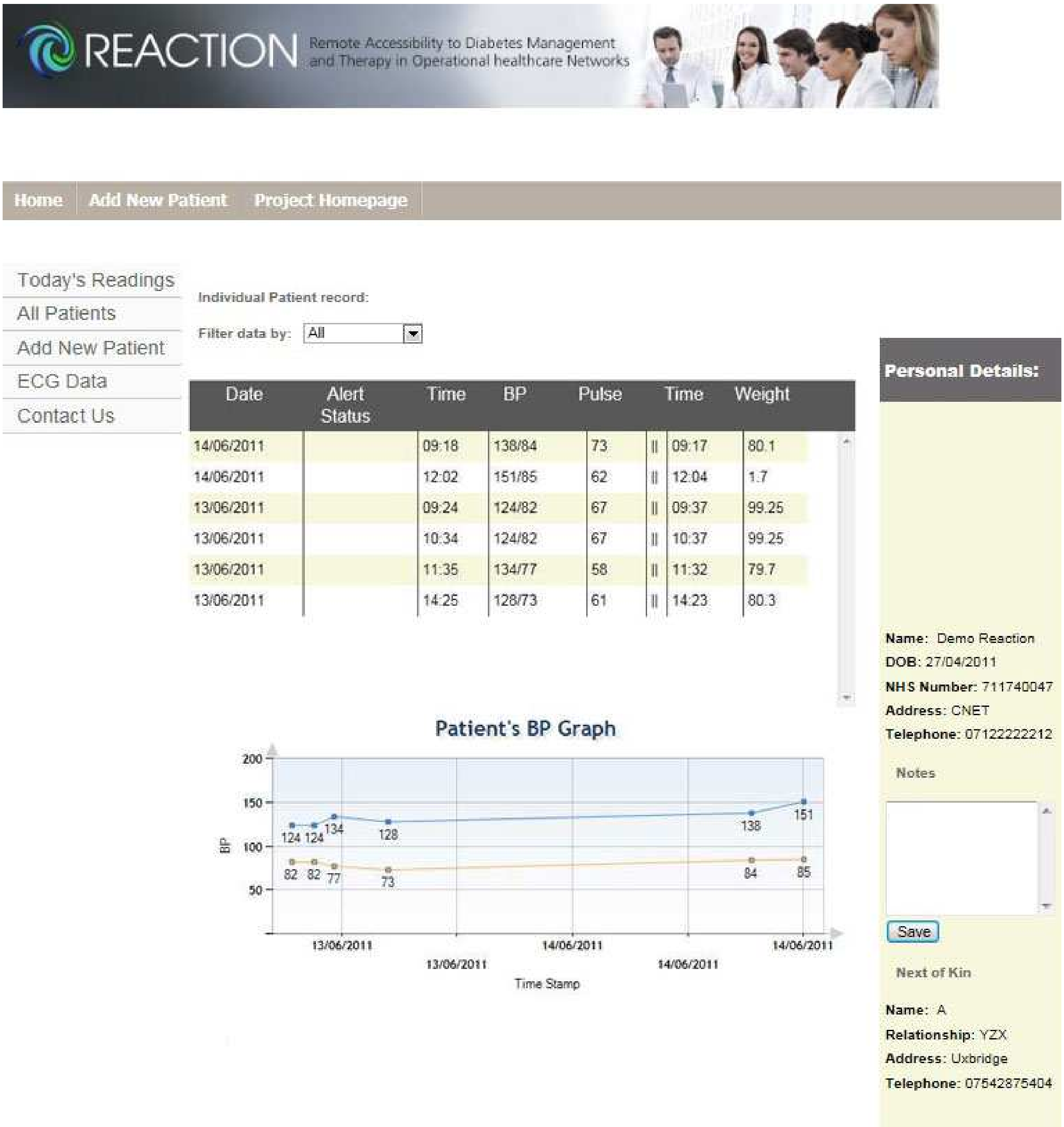


Figure 2: Screenshot of the REACTION web interface for the medical professionals in the primary care scenario

platform. Instead, patients are provided with more alternatives to access and manage their health data using the tools and ways of access that they prefer and thus allow for more flexibility.

6 Legal issues

Complex data processing systems in healthcare are based on continuous and multiple processing activities, multiple possible uses of data, in particular in profiling techniques. While eHealth platforms, such as REACTION, and electronic health records have the potential to achieve greater quality and security in handling medical information, from a privacy and data protection point of view, they pose challenges to patient's control over his or her medical information. ICT systems providing direct access to compilations of sensitive data on the medical status of individuals from different sources and throughout a sustained period of time weaken significantly the level of control and protection that individuals and society can exert on healthcare [6][5].

The notion according to which no processing of personal data can be legal without the informed unambiguous and free consent of the data subject is a fundamental condition to assess the level of control individuals can have. However, it is not an exclusive nor a sufficient one. Informed consent is an important component of a broader legal regime, the data protection framework. Likewise, its practical implications should be considered in this framework.

In the European Union, the fundamental right to the protection of personal data is essentially based on Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) [2] and on Article 8 of the EU Charter of Fundamental Rights (CFR) [1]. The right to protection of personal data is not absolute, and can be restricted if specific public interests do so require. However, these objectives in the public interest can only justify an interference with the protection of personal data, if it is in accordance with the law, is necessary in a democratic society for the pursuit of the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others, and is not disproportionate to the objective pursued (Article 8 (2) ECHR)..

The legal framework is detailed mainly in the Data Protection Directive 95/46/EC [13], in Directive 2002/58/EC [14] on privacy and electronic communications, national laws of the Member States implementing these and other minor directives, and in the case law of European courts.

The "unambiguous consent of the data subject" is one of the Data Protection Directive's essential *conditions* for personal data to be processed legally (Article 7).[6] Alongside the rule on consent, the data protection regime provides for *subjective rights for data subjects* (access, information, withdrawal, ...) and imposes *obligations upon data processors* (obligation of confidentiality, notification to national authorities, ...). Furthermore, the Data Protection Directive enacts a number of data protection principles.

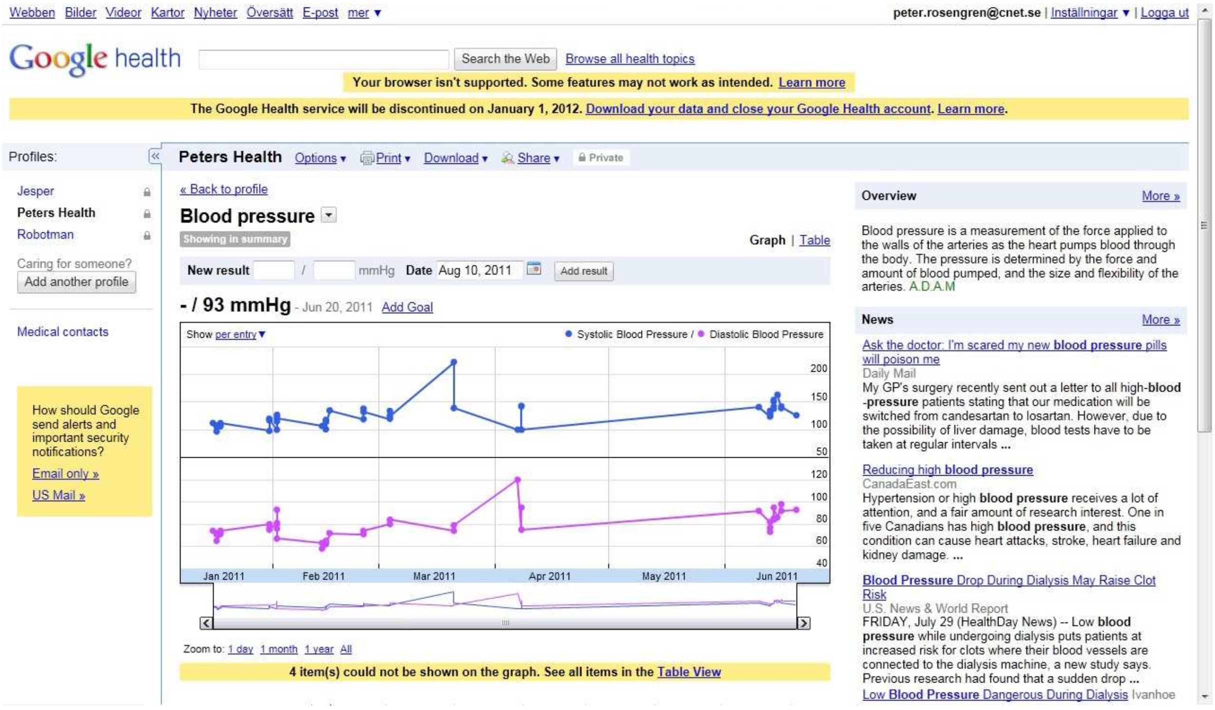
The following pages focus on a restricted field of data protection law, health or medical data and health systems based on health records. Using as principal source a working document on the processing of personal data relating to health in electronic health records, adopted on 15 February 2007 by the Article 29 Working Party [6], we will review briefly i) the data protection principles, ii) the special protection afforded to sensitive personal data, including health or medical data, and iii) the rules on the processing of such data, including the possible derogations.

6.1 General Data Protection Principles

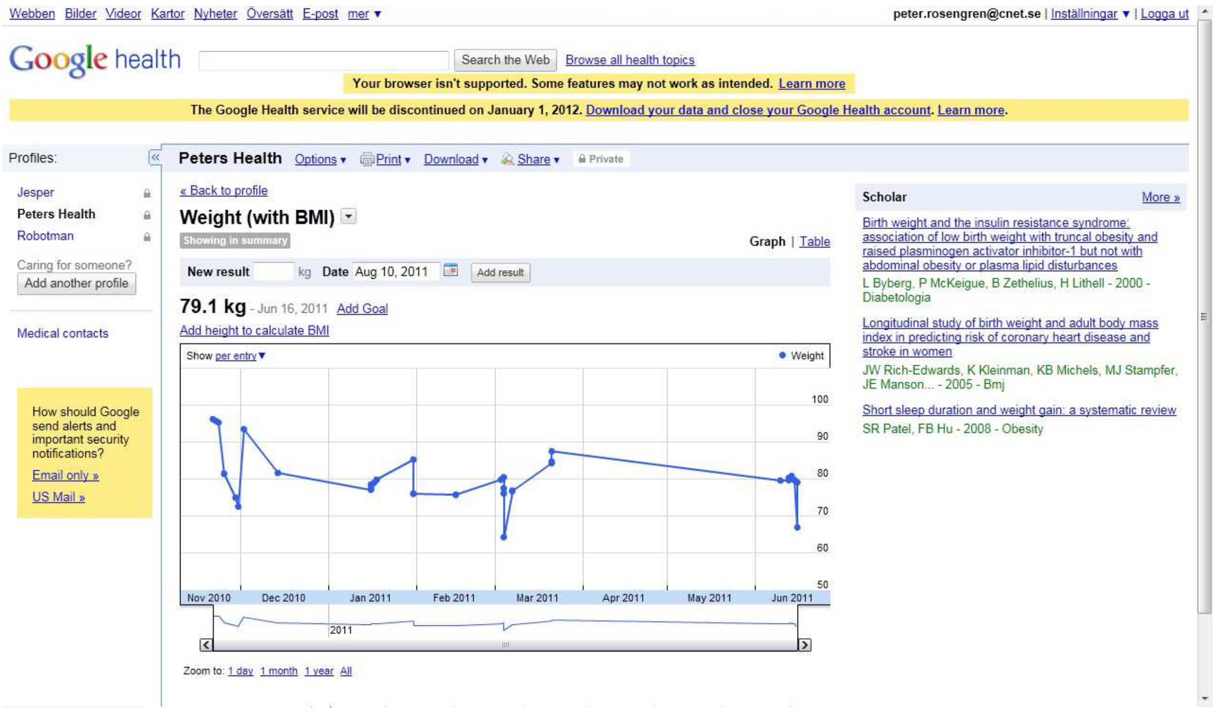
Data controllers collecting medical data must comply with data protection principles, including the following:

[5] For a general discussion on the role of the Article 29 Working Party see [32].

[6] Crucially, the processing of personal data must always be done "in accordance with the law" and be "necessary in a democratic society".



(a) Blood pressure



(b) Weight

Figure 3: Screenshots of Google Health showing the history of a patient's (a) blood pressure and (b) weight

a) The use limitation principle (purpose principle): This principle ([13], Article 6(1)(b)) prohibits further processing which is incompatible with the original purpose(s) of the collection;

b) The data quality principle: personal data must be relevant and not excessive for the purposes for which they are collected. Irrelevant data must not be collected and if it has been collected it must be discarded ([13], Article 6(1)(c)). Data must also be accurate and kept up-to-date;

c) The retention principle: This principle requires personal data to be kept for no longer than is necessary for the purpose for which the data were collected or further processed;

d) Information requirements: Data controllers processing information in EHR systems must provide certain information to data subjects, such as information on the identity of the controller, on the purposes of the processing, on the recipients of the data and on the existence of a right of access ([13], Article 10);

e) Data subject's right of access: Data subjects are permitted to verify the accuracy of the data concerning them and to ensure that data is kept up-to-date. These rights apply also to the collection of personal data in EHR systems ([13], Article 12);

f) Security related obligations: There is an obligation ([13], Article 17) upon data controllers to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or unauthorised disclosure. The measures can be organisational or technical. The transfer of data cannot be outsourced to third countries without the country having an adequate level of data protection and applying a set of EU standards and specifications.

6.2 Special Protection for Sensitive Personal Data such as Information on Individual's Health

Member States are required to place enhanced protection on the processing of special categories of data which are deemed to be 'sensitive'. The general rule is: prohibition of "the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life" ([13], Article 8 (1)). According to the Article 29 Working Party, such a prohibition applies to personal data that has a close and clear link with the description of the health status of a person: data on consumption of medicinal products, alcohol or drugs as well as genetic data are doubtlessly "personal data on health" especially if they are included in a medical file. Such data would also seemingly include blood sugar level, weight and regularity of exercise. Administrative data can also constitute personal data: information such as an individual's social security number, date of admission to hospital (all of which can be contained in the medical documentation of the treatment of a patient) can be considered as being sensitive.

Given the potential breadth of this class of data it is probably wise, the Working Party suggests, to consider all data contained in medical documentation, in electronic health records and in EHR systems as "sensitive personal data"[7]. When the processing of personal data relates to a person's health, such a processing activity requires special protection. This means that these data are not only subject to the general principles but are also subject to special rules. These rules are contained in Article 8 of Directive 95/46/EC.

6.3 A General Prohibition on the Processing of Health Data, with certain derogations

Processing of personal data concerning health is, in principle, prohibited.[8] However, the necessity exists in reality for sharing personal information in order to treat patients. Accordingly, certain derogations exist which permit processing of personal medical data. As these are derogations to the general prohibition rule, however, they must be construed in a narrow fashion and applied strictly.[9]

[7] This was a specific recommendation of the Article 29 Working Party.

[8] Article 8 (1). A general prohibition is also required according to Article 6 of the Council of Europe Convention No108.

[9] The Data Protection Directive provides for mandatory derogations laid down in Article 8 (2) and (3) plus an optional exemption in Article 8 (4).

Derogation 1 — "Explicit consent" A derogation from the ban on the processing of personal medical data is allowed where "the data subject has given his explicit consent to the processing of those data"[10]. Explicit consent can therefore constitute a justification for the processing of sensitive data. In order to be valid, consent must be "freely given" and contain "specific and informed indication of the data subject's wishes" ([13], Article 2(h)).

"Free" consent means a voluntary decision taken by an individual in possession of all of his faculties, taken in the absence of coercion of any kind, be it social, financial, psychological or other. Any consent given under the threat of non-treatment or lower quality treatment in a medical situation cannot be considered as "free". Consent given by a data subject who has not had the opportunity to make a genuine choice or has been presented with a *fait accompli* cannot be considered to be valid. It follows that, as a general principle, one should not be presented with the alternative to either give in his or her data or give up an essential service. This is a difficult conundrum to solve as more and more essential health services are provided through ICT. The Article 29 Working Party limited itself to state that where a health professional has to process personal data in an EHR system as a necessary and unavoidable consequence of the medical situation, it is misleading if he seeks to legitimise this processing through consent. Reliance on consent should be confined to cases where the individual data subject has a genuine free choice and is subsequently able to withdraw the consent without detriment.

"Specific" indicates that the consent must relate to a well-defined, concrete situation in which the processing of medical data is envisaged. Therefore a 'general agreement' of the data subject, e.g., to the collection of his medical data for an EHR and to subsequent transfers of these medical data of the past and of the future to health professionals involved in treatment would not constitute 'specific' consent.

"Informed consent" means consent by the data subject is based upon an appreciation and understanding of the facts and implications of a given situation and of an action. The individual concerned must be given, in a clear and understandable manner, accurate and full information of all relevant issues, in particular those specified in Articles 10 and 11 of the Directive, such as the nature of the data processed, purposes of the processing, the recipients of possible transfers, and the rights of the data subject. The data subject should be aware of the consequences of not consenting to the processing in question.

Consent in the case of sensitive personal data and therefore in an EHR must be explicit. Opt-out solutions will not meet the requirement of being "explicit". In accordance with the general definition that consent presupposes a declaration of intent, explicitness must relate, in particular, to the sensitivity of the data. The data subject must be aware that he is renouncing special protection. □

Derogation 2 — "Vital interests of the Data Subject" This derogation can apply where processing of sensitive personal data is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent. Such processing must relate to essential individual interests of the data subject or of another person in a medical context, viz., be necessary for a life-saving treatment in a situation where the data subject is not able to express his intentions. Accordingly, this exception could be applied only to a small number of cases of treatment, e.g., emergency treatment upon admission to hospital. In particular, processing of a patient's personal health information recorded in the standard care for chronic diseases would not be permissible under derogation 2 as it would be likely that the patient concerned would be able to express his consent, or lack thereof, for the proposed processing of personal data. □

Derogation 3 — "Processing of (medical) data by health professionals" (Article 8.3 95/46/EC) Derogation number 1, "the data subject has given his explicit consent to the processing of those data", relates to a specific situation in which an individual relinquishes freely, explicitly, and unambiguously a part of his control over his or her personal information to a third person, for instance a doctor. When the

[10] This derogation can not be used however where the laws of the Member State provide that the general prohibition "may not be lifted by the data subject's giving his consent" – Article 8 (2)

doctor receives consent he would then be able to lawfully store that piece of information on a data base or to use it, e.g., to provide a service, or to make a research.

Distinctively, Article 8(3) concerns what health professionals can do with sensitive medical data. The processing, in principle prohibited, is permitted if three conditions are met:

i) The processing of sensitive personal data must be specifically required "for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services"; the personal data in question "are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy".

   This derogation only covers processing of personal data for the specific purpose (preventive, diagnostic, therapeutic or after-care nature and for the purpose of the management of these healthcare services, e.g. invoicing, accounting or statistics). Further processing which is not required for directly providing such services, e.g. medical research, subsequent reimbursement of costs by a sickness insurance scheme, or the pursuit of pecuniary claims, are excluded. Equally outside the scope of the application of this derogation are some other types of processing in areas such as public health and social protection, especially those aimed at measuring quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system[11].

ii) The processing of personal data on grounds of Article 8 (3) must be "required" for the specific purposes mentioned above. In the context of EHRs, the Working Party stresses that "required" means that any inclusion of personal data in an EHR would have to be *fully justified*; the mere 'usefulness' of having such personal data contained in an EHR would not be sufficient

iii) The third requirement is that processing of sensitive personal data is carried out by medical or other staff subject to "professional [medical] secrecy or an equivalent obligation to secrecy". The medical profession's requirement of confidentiality is a fundamental tenet of traditional or Hippocratic medicine, first set out in the 'Hippocratic Oath'[12]. In the aftermath of World War II, the principle of confidentiality had to be re-affirmed and made explicit by the World Medical Association's Declaration of Geneva in 1948. This principle proscribes the divulgation of the information about a patient collected by a healthcare professional in the course of the treatment. Use of this information is allowed only within the limits of the treatment contract, and cannot be used or communicated to third parties. The confidentiality principle excludes all third parties, *even other healthcare professionals*, unless the patient has agreed to passing on his data or it is foreseen especially by law[13]. If it is non-medical staff who are to process such sensitive personal data, they also must be made subject to binding rules which ensure at least an equivalent level of confidentiality and protection.

As mentioned above, Article 8.3 of the Directive is a derogation from the general prohibition to process sensitive data and must therefore applied in a *restrictive way*. The question arises as whether Article 8.3 of the Directive could serve as the *sole* legal basis for the processing of personal data in systems working on the continuous processing of electronic health records. The Article 29 Working Party gives a strict interpretation of the letter of Article 8.3: according to this view, the derogations contained therein could only pertain to the processing of medical data for the medical and healthcare purposes mentioned above, insofar as the processing is specific and required, and granted it is performed by a health professional or by another person subject to an obligation of professional or equivalent secrecy. If the processing of EHRs is beyond these purposes and conditions, e.g., general public health policy goal or vaccination security reasons, Article 8 (3) cannot be invoked as the legal basis for the legitimate processing of that personal data (see below, Derogation 4).

[11] These are mentioned in recital 34 of the Directive as examples for invoking Article 8(4).

[12] "All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal." (Source: http://en.wikipedia.org/wiki/Hippocratic_Oath).

[13] The Working Party pointed out that the special obligation of professional secrecy must be either established in the national law of the Member States, or by national competent professional bodies with the power to adopt binding rules on the profession. These national rules on professional secrecy must also provide for corresponding effective sanctions in case of breach.

For the use of medical data in REACTION's primary care and in-hospital scenario, a patient's consent is typically not required since continuous patient monitoring would constitute an activity with the purpose of preventative medicine. It is permissible under derogation 3 if it is carried out by a health professional subject to national rules concerning professional secrecy, which would be typically the case in REACTION. If however, processing was carried out by third parties that were not subject to such rules, processing would not be permissible. Under such circumstances explicit consent would be required according to derogation 1. In particular, if a health professional makes use of the reaction platform to process sensitive health information of his patients but does not run the platform himself, the platform's provider must, according to the Working Party, be made subject to binding rules which ensure at least an equivalent level of confidentiality and protection. In general, should the necessity arise for non-medical staff to process these sensitive personal data, they must also be made subject to such binding rules. In particular, these rules must contain an obligation that the data will be used only for the purposes mentioned under Article 8 (3). □

Derogation 4 — "Substantial public interest exemptions" Article 8.4 of the Directive makes room for the opportunity, should the need or the possibility arise, to combine and strike an appropriate balance between the protection of the data subject's rights and other "reasons of substantial public interest".[14] Similarly, two recitals of the Data Protection Directive state[15]:

> "Whereas Member States must also be authorised, when justified by grounds of important public interest, to derogate from the prohibition on processing sensitive categories of data where important reasons of public interest so justify in areas such as public health and social protection — especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system — scientific research and government statistics;"
>
> "whereas it is incumbent on them, however, to provide specific and suitable safeguards so as to protect the fundamental rights and the privacy of individuals;"

Should a Member State intend to make use of this derogation, such a course of action should be provided for in national legislation. It should be subject to procedural rules ensuring participation and scrutiny. Any procedures so permitted under national legislation must be justified by substantial reasons of public interest[16]. In addition, measures adopted must be proportionate and there should not be other less infringing measures available. Member States must also provide sufficient safeguards in order to protect the rights of individuals. Uses of this derogation must be notified to the Commission ([13], Article 8(6)).

It is important to underline the reference contained in the second recital to *fundamental rights and the right to private and family life*. This means that new purposes of data processing should be in accordance with the principles developed by European courts on Article 8 of the European Convention on Human Rights[17]. This requires new data processing activities are tested against the basic requirements of "legitimate" and "necessary in a democratic society".

[14] Article 8 (4) of the Directive allows the Member States to derogate further from the prohibition of processing sensitive categories of data: "Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority."

[15] Recital 34

[16] These include the fields of public health and social security, to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system.

[17] National provisions in their compliance with Article 8 of the ECHR should be read in the light of the Strasbourg jurisprudence: it needs to be done "in accordance with the law" and be "necessary in a democratic society" for a public interest purpose. The Strasbourg jurisprudence has repeatedly stated that the law providing for the interference "must indicate the scope of any such discretion conferred on the competent authorities and the manner of its exercise with sufficient clarity, having regard to the legitimate aim of the measure in question, to give the individual adequate protection against arbitrary interference".

7 Conclusion

For a promising treatment of diabetes, it is essential that the patient takes an active part in her own health management. In REACTION, the general trend towards a more patient-centralised care model, in which patient empowerment plays an essential role, is pursued. In general, two requirements have to be fulfilled in order to support user empowerment. First, the user has to be provided with information. Information does not only help to increase the knowledge about diabetes and its management —and therefore to better cope with the illness— but it does also enable a patient to better understand her condition and the positive as well as the negative consequences of certain behaviour. Second, the patient must be allowed to make choices concerning her therapy, allowing her to play an active role in her own treatment.

Information technology can support empowerment of patients. It allows patients to communicate with other patients and share information about their illnesses as well as other information that can be helpful in day-to-day life. This can help to improve patients' health literacy which is a critical component of empowerment. IT also allows patients to take control of their medical files —if they want to— and decide who should have access to it which is a realisation of self-determination, and this in turn is an aspect of empowerment.

Informational self-determination, giving patients the right to give or refuse consent regarding the processing of their personal data, is another aspect of empowerment that needs to be taken into account in REACTION. Self-determination regarding information means that the patient has to be informed —among other things— about how her data is going to be used and by whom. Such information would be necessary for the patient to execute her privacy rights, e.g., to give or refuse consent to the processing of her data. However, in a typical REACTION scenario —primary care or in-hospital— the patient's consent is not required. Privacy laws permit the processing of personal, medical data *without* the patient's explicit consent provided that the data is processed by a health professional that is bound by professional secrecy. In addition, the data must only be used for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment, or the management of healthcare services. These requirements will typically be fulfilled within REACTION scenarios. However, in 'non-standard' scenarios, if patient data is to be used for other purposes, e.g., medical research, or if the REACTION platform would be run by a third party which cannot be made subject to binding rules with respect to privacy, the patient's explicit consent would be required before any transfer or processing of data can occur.

IT can help to make routine tasks more convenient by using automation, like in the recording of physiological measurements, and provide information in a more flexible and accessible way, e.g., choosing the time resolution (hours, days, month, etc.) and the form (graphical, numerical) of measurements. IT also allows patients to get more and faster feedback on behaviour changes and see for themselves the effectiveness of their therapy and their own engagement in it. Although the realisation of one's engagement can sometimes be disheartening, it can also be a wake-up call. Therefore, it is important that patients are not left alone with IT and its gadgets but that patients are trained and supported in using IT to help them reach the medical goals they have set for themselves or set together with their physician. Put in the right place, IT can aid patients in coping with their illnesses, improve health literacy, and eventually foster empowerment.

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