

The Digital Transformation in Healthcare as a Challenge for Autonomy and Trust in the Physician-Patient Interaction

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ISSN 1989-7022

La transformación digital en la atención sanitaria como un reto para la autonomía y la confianza en la interacción médico-paciente

ABSTRACT: Medical care is generally carried out between two agents: the patient in need and the helping physician. However, this relationship and its values are permanently changing: paternalism emphasized the patient's well-being; the contractualism and the shared decision-making model are based on their principles of patient autonomy. The digital transformation directly and radically influences the physician-patient relationship and its values. Very important issues of data protection and data autonomy are discussed. However, due to the radical and dramatic consequences of digitalization on the doctor-patient relationship, the principle of patient autonomy should not be forgotten as the overriding principle in professional ethics. In this context, evident deficits are overcome by recourse to concepts of trust and trustworthiness. First, the article discusses the chances and risks of digitalization for the physician-patient relationship. Second, it examines different successive waves that transformed the physician-patient relationship and its values. The insights of the research on trust illustrate how enormous and complex the challenge is to foster trust and autonomy in medical practice. The application of digital ICT also offers the opportunity to address this challenge more intensively again. Trust-based patient autonomy is the fundamental normative criterion for the use of digital technology.

KEYWORDS: digital healthcare, physician-patient interaction, patient autonomy, trust and trustworthiness

RESUMEN: La atención médica se lleva a cabo generalmente entre dos agentes: el paciente que lo necesita y el médico que lo ayuda. Sin embargo, esta relación y sus valores están en permanente cambio: el paternalismo hizo hincapié en el bienestar del paciente; el contractualismo y el modelo de toma de decisiones compartida se basan en sus principios de autonomía del paciente. La transformación digital influye directa y radicalmente en la relación médico-paciente y sus valores. Se examinan cuestiones muy importantes de la protección de los datos y la autonomía de los datos. Sin embargo, debido a las consecuencias radicales y dramáticas de la digitalización en la relación médico-paciente, no se debe olvidar el principio de autonomía del paciente como principio primordial de la ética profesional. En este contexto, los déficits evidentes se superan recurriendo a los conceptos de confianza y fiabilidad. En primer lugar, el artículo analiza las posibilidades y los riesgos de la digitalización para la relación médico-paciente. En segundo lugar, examina diferentes ondas sucesivas que transformaron la relación médico-paciente y sus valores. Los conocimientos de la investigación sobre la confianza ilustran lo enorme y complejo que es el reto de fomentar la confianza y la autonomía en la práctica médica. La aplicación de las TIC digitales también ofrece la oportunidad de abordar este reto de nuevo de forma más intensa. La autonomía del paciente basada en la confianza es el criterio normativo fundamental para el uso de la tecnología digital.

PALABRAS CLAVE: atención médica digital, interacción médico-paciente, autonomía del paciente, confianza y fiabilidad

1. Introduction

What are chances and risks of digital transformation for patient autonomy and for a trustful and trustworthy doctor-patient relationship? The following two scenarios show how differently these questions can be answered (Gigerenzer, 2016, 36):

(1) In one patient, an implant under the abdominal wall measures the blood sugar level and a bracelet measures blood pressure and pulse rate. The smartphone transmits this and more data to an algorithm. Instructions for action are sent to the patient by SMS, and if her mood should develop unfavorably, a Vita-Radio in the WLAN router has already detected the change by the patient's movement pattern and plays music that is supposed to influence her mood as favorably as possible.



sible. All data is transmitted to the private health insurance company, which calculates a personalized premium, and also transmits it to the patient's employer, who wants to be informed about her state of health with respect to a possible promotion.

(2) A well-educated patient systematically searches the Internet for quality-assured information. He thus becomes a competent decision-maker in health matters and is less dependent on his doctor. In this scenario, the high number of consultations in Germany would be reduced – everyone would understand, for example, that you don't need to see a doctor because of a cold. In addition, the consumption of pharmaceuticals would decrease, as people would recognize the low benefit and considerable side effects of certain drugs. This would also increase patient safety, since overmedication is one of the most common causes of death after heart disease and cancer. As a consequence of better patient expertise, overdiagnosis and overtreatment would also be reduced, thus significantly reducing the expenses of the health-care system while at the same time improving health.

In the first scenario, technology performs almost all of the work. The patient's freedom of decision and action – whether voluntarily or involuntarily – is limited. There is no interaction between doctor and patient, nor is the technology's application trustworthy because it can be used against the patient's interests. In contrast, the second scenario describes a patient who acts competently and autonomously with the help of technology. This applies to the technology's application as well as to the interaction with the physician. Furthermore, technology contributes to the fact that the patient does not have to trust someone or something "blindly", but can do so with good reason. The two scenarios show that the questions asked at the beginning are by no means trivial. In fact, they should not be asked in such an abstract way. As a rule, serious answers can only be given with regard to a specific technology application in a concrete setting, taking into account all relevant actors. This requires sufficient information on the entire process of technology application and its systemic conditions, as well as on the physiological, psychological and socio-cultural conditions of the actors involved and affected. On the one hand, technology assessment should do justice to the individual case. On the other hand, it is precisely the purpose of norms, standards, values or principles to standardize the requirements and specifications for technical systems as far as possible. Only with the help of abstraction can different requirements and interests be dealt with in a reliable and verifiable way.

In this context, the interdisciplinary debates on the responsible use of digital information and communication technologies (ICT) focus noticeably on norms and standards of data protection and data autonomy. The digital transformation in the health sector is also initially understood to be data-driven. And thus very important questions of data protection and data autonomy are at the centre of the debate. However, there is a risk that the principle of patient autonomy, which is both systematically and practically the overriding principle for the healthcare sector, will be ignored or that specific data protection regulations and their implementation will not be reviewed with regard to this principle. Regulations that conform to data protection should also be related to the code of conduct of the medical profession.

The present study underlines the central importance of a trust-based understanding of patient autonomy. It aims to illustrate that it is not enough to discuss data protection but that the debate about digital transformation in the healthcare sector only reaches the required level if challenges to patient autonomy are put at its center. First, the radical and dramatic effects of digitalization in the healthcare sector will be presented and problematized with regard to the physician-patient relationship. In the second and third section, different and

mainly successive waves that transformed the physician-patient relationship and its value orientation are examined. The fourth section understands the application of digital ICT and its influence on the doctor-patient relationship as interaction within a socio-technical system. Only in this way does the range of the challenges become obvious. Only in this way is it possible to ensure the autonomy of the patient and a trustful and trustworthy relationship between the actors in the health care practice. As a rule, medical treatment has been and still is carried out between two participants: The suffering patient seeking help and the physician offering this help. This interaction between doctor and patient was and is the nucleus and continuum of every medical treatment. At the same time, the physician-patient relationship is subject to continuous change. In medical ethics, this change was particularly evident in the paradigm shift from paternalism of medical care to the liberalism of informed consent. Due to his competence and expertise, the doctor is superior to the patient. Nevertheless, in this asymmetrical relationship, the patient should not only be the object of scientific action, but always the subject of medical treatment. The medical-ethical principle of patient autonomy should not only protect the patient from harm and guarantee his or her self-determination, but also maintain the relationship of trust between doctor and patient. For only a patient having trust in the healthcare personnel and system will be able to realize self-determination to a large extent. In this context, it is striking that obvious deficits in some models of patient and data autonomy are being addressed by means of concepts of trust and trustworthiness. Until recently, trust and trustworthiness seemed to be outdated and replaceable by sophisticated mechanisms of transparency and control. The digitalization of the healthcare system entails the delegation of increasingly complex and important tasks to ever more powerful and effective ICT. Technology is taking over central mediating and participatory tasks in the entire medical process which questions the previously exclusive relationship of trust and values between doctor and patient. Collected and stratified data sets influence the image of and interaction with the patient. This has (in)indirect consequences for the medical freedom of therapy, for the patients' self-determination and for the mutual trust between doctor and patient. Finally, it becomes clear that dealing with the promising potentials and precarious consequences of digitalization will ultimately have to be answerable to the concept of trust-based patient autonomy.

2. Chances and risks of the digital transformation for the health sector

Digitalization is currently transforming the entire system of healthcare and its provision. It is not limited to individual fields, such as the introduction of the electronic health card or an app-based treatment concept, or the use of artificial intelligence in diagnostics and therapy. Nor does the transformation only affect the core area of medical care or the so-called second healthcare market, but all determinants of health, such as healthy nutrition, physical activity, or the avoidance of alcohol and nicotine. The Digital Transformation "refers to an ongoing process of change based on digital technologies that encompasses the entire society, the healthcare system, the companies involved, as well as the healthcare professions and medical professions" (Kuhn, 2018, A 633). This is why the scientific literature does not shy away from comparing the Digital Transformation with electrification.

However, the digital transformation of healthcare and the use of digital ICT is not an end in itself. Rather, the aim should be to maintain and improve the quality of healthcare. The prom-

ise that digitalization will make healthcare as personalized and efficient as possible and at the same time help to cut costs does not bear up against a differentiated view, nor does the fear that digitalization will lead to healthcare being managed only externally and commercially (Europäische Kommission, 2014a, 2014b; Gigerenzer, 2016, 10).

An overview of the key potentials of digitalization is provided by the figure of Dörries, 2017:

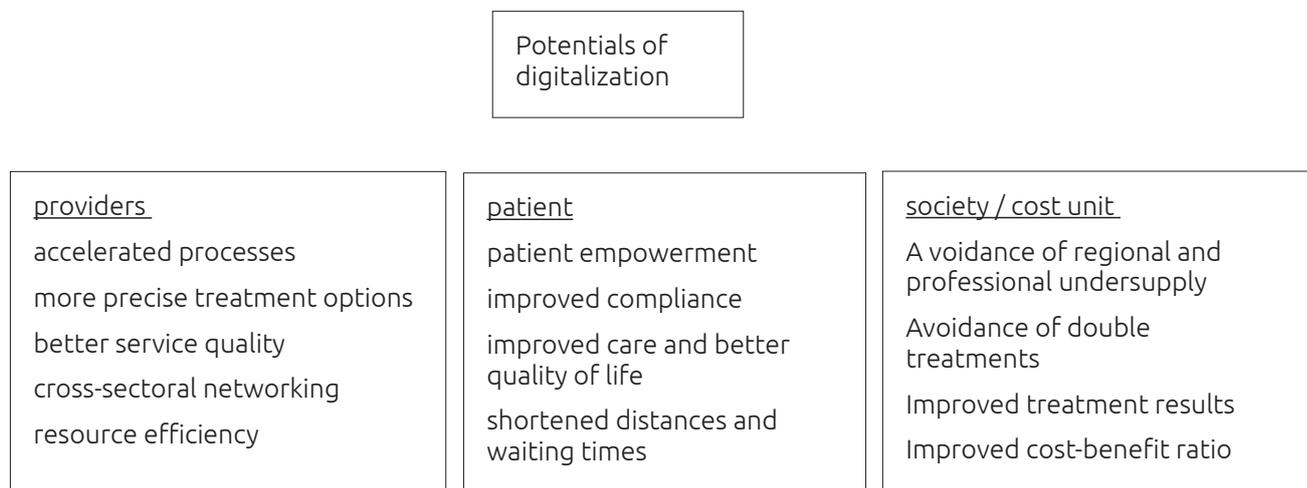


Figure 1: Potentials of digitalization (Dörries, 2017, 693)

For the service provider, standardized and cross-sectoral computer systems (e.g. documentation, reporting and communication systems) can make procedures more cost-effective and accelerate them. Undesirable deviations in regional supply can be reduced and interdisciplinary networking (doctors, nursing, physiotherapy, midwives, speech therapy etc.) can be promoted. Digital medical systems can support the medical profession in fast and reliable diagnosis and in the selection of evidence-based treatment methods. Double examinations, medication errors and the resulting consequences can be avoided. Medical care assistants could delegate more tasks to non-medical personnel.

With the help of digital ICT, patients can inform themselves more easily and play a more active role in shaping the treatment process. They can communicate with other patients and evaluate providers. It may be possible to reduce and sometimes even eliminate travel and waiting times. Through techniques of self-measurement (apps, wearables), possible health risks can be detected in time. The quality of life can be improved by health-promoting lifestyles, the use of digital health offers and auxiliary means. Patient safety can be increased if information regarding the patient and the treatment is provided in real time and independent of location for the respective outpatient or inpatient healthcare facility. That way, therapy options that have already failed, double examinations or unnecessary measures (overdiagnosis and over-treatment) can be excluded and other available treatments can be taken into account.

In addition to the points already mentioned, some cost bearers hope that digitalization will ensure high-quality healthcare even in undersupplied areas. Likewise, efficiency can be enhanced and costs reduced in many areas of healthcare. Moreover, big-data analyses offer the potential to identify cases of fraud in the system (Dörries, 2017; Gigerenzer, 2016, 21-39; Sachverständigenrat, 2018, no. 800).

Digitalization in medicine has the potential to improve prevention, diagnostics and treatment as well as the overall healthcare system. However, in addition to the strengths and opportunities, there are also serious shortcomings and risks, as illustrated by the following analysis by the German Ethics Council:

<p>strengths</p> <ol style="list-style-type: none"> 1. expanded and diversified database and accelerated information gathering 2. mutually enhanced development of innovative data processing tools and extended data bases 3. high-level networking and ubiquitous access 	<p>shortcomings</p> <ol style="list-style-type: none"> 1. heterogeneous data quality 2. Intransparent data flows and loss of control 3. greater expenditures in regard to coordination, regulation and qualifications
<p>chances</p> <ol style="list-style-type: none"> 1. refined stratification in diagnostics, treatment and prevention on the basis of broadened knowledge 2. increasing effectiveness and efficiency 3. encouraging health-promoting behavior 	<p>risks</p> <ol style="list-style-type: none"> 1. eroding solidarity and diffusion of responsibility 2. monopolisation and data abuse 3. informational self-endangerment

Figure 2: SWOT analysis Big Data in health care, Deutscher Ethikrat, 2017, 121

General risks of digital ICT are posed by the growing dependence on a few (non-European) providers who dominate the market. In addition, non-transparent algorithms can be applied largely lacking scientific evidence or knowledge of effects on clinical endpoints. The regulation of medical devices remains also an unanswered challenge (Gigerenzer, 2016; SVR, 2018, no. 802-3).

In particular, questions of data protection, data security, access rights and data abuse are raised. Patients are and remain vulnerable in a new way, as personal and intimate information – usually unidentifiable – can be stolen and misused. By using the right data, individuals and their environment can be easily and accurately identified in other contexts. When patient data is collected, linked and evaluated, there is always the possibility of discrimination against individuals or groups. Even highest security standards cannot prevent highly sensitive data from being circulated beyond control. If one does not want to completely dispense with the collection and use of such data, one has to live with an irreducible remaining risk that ultimately unauthorized persons will also be able to access this data. Not all risks of digital ICT can be discussed here. For example, there are further questions regarding the reliability and validity of the data, some business models, medical confidentiality, IT system failures and malfunctions, equal access and opportunities, and digital literacy of all those involved. However, it should be clear that – as the German Ethics Council notes – the concrete assessment of digital ICT in the healthcare system “depends to a large extent on the respective actors involved with their different interests and their own assessments of chances and risks as well as on the social context. It must also be taken into account who will benefit and who will be harmed by the collection and use of data, what the respective benefit or harm consists of, whether this benefit can be classified as significant or the harm as tolerable, and how the respective probability of certain events occurring can be estimated” (Deutscher Ethikrat, 2017, 122).

The digital transformation has a substantial impact on the role of the physician and the patient, their mutual relationship and communication. Medical practice has always been characterized by the freedom of therapy and the physician-patient relationship. On the one hand, the relationship between physician and patient is asymmetrical: The patient asks for help. The physician has the competence and power to help. However, the patient is also the expert of his own values and personal biography. He is not just looking for an expert in the doctor, but also for a partner. Together with the doctor he wants to overcome the illness. Therefore, the patient is not only the doctor's "object of action", but also his partner and co-actor. The physician does not enter into a relationship with the illness alone, but with a whole person whose health should be maintained or improved (Woopen, 2009, 192). The physician-patient relationship can be interpreted as a well-established social practice based on a shared horizon of binding values and norms (Fritz, 2020a, 2020b; Hartmann, 2011; Wiesemann, 2016, 81f.). As a social practice or institution, naturally, the medical profession and the physician-patient relationship are affected by social and cultural transformations. The relationship remains asymmetrical (Engels, 2011, 397; Pöltner, 2006, 90). However, the understanding of roles and mutual communication has changed radically. In the following sections, three transformations of the physician-patient relationship will be examined:

- The personal encounter between the suffering person and the helping person: *salus aegroti suprema lex*.
- From a contract between a provider of services and a customer to a relationship between partners: *voluntas aegroti suprema lex*.
- The interactions between humans and computer systems: *notitia non sine voluntate suprema lex*.

The study focuses on diverse models of patient autonomy and on the importance of trust. In order to make visible the radical changes, the process and the difference between the phases and models are presented in a simplified form.

3. The personal encounter between the suffering person and the helping person: *salus aegroti suprema lex*

The medical psychologist Viktor Emil von Gebattel structured the classic encounter between the physician and his patient into three phases: "First of all, the empathetic, human dialogue is appropriate, which creates trust, then – inevitably alienating, but in the interest of the patient – the cool analysis, in which the physician turns into a critically observing, thoroughly distanced natural scientist. Once the results of the examinations and analyses have been completed, a further empathetic dialogue follows, which usually has the character of a consultation and refers to the initial dialogue" (Bergdolt, 2009, 113). According to Gebattel's Triad of Treatment, the doctor must be both an empathetic person of trust and a modern natural scientist. In German healthcare until the 1980s, the individual patient was generally seen as an individual and the physician-patient relationship was respected as a highly individual interaction: "Patients saw their illnesses as fate and regarded their doctors as bearers of hope, as healers or at least as helpers and also as consolers. They trusted them that they would keep their promises to respect the principles of medical professional ethics. [...] Doctors promised to respect the *salus aegroti suprema lex*, to observe the principle of *primum nil*

nocere, to feel like advocates for their patients, to exercise absolute discretion and not to prefer personal, especially mercantile motives in the care of their patients” (Hoppe, 2009, 1). Similarly, politicians, healthcare insurers and the legal system respected and accepted the individual physician-patient relationship and the principle *salus aegroti suprema lex* was taken for granted: “There was a taboo on the doctor-patient relationship. The emphasis on uniqueness, incomparability, intimacy, the indispensability of a protected relationship of trust prevented any objectifying access” (Katzenmeier, 2009, 45).

In the classic doctor-patient encounter, the medical profession felt obliged to the Hippocratic oath and the code of professional ethics, but less to state regulations. The medical ethicist Edmund Pellegrino describes the core obligation of the medical profession: “With the question ‘Can I help you?’ I promise to meet the expectations of the patient. I promise that I am competent, that I have knowledge that can guarantee the assistance required. I invite him to trust me. To trust me, both in my ability to help him and that I use this competence only for his good: neither for my good nor for the good of society” (Pellegrino, 2008, 11). In this profession, the doctor commits himself to a certain behavior, which Pellegrino expresses in virtues: “Justifying trust, keeping promises. Then benevolence: to act in such a way that the good for the patient is promoted. This good still needs further clarification in content. Thirdly, intellectual honesty: openly admitting that you do not know something – instead of trying to do what you do not know. [...] The fourth virtue is to put self-interest aside. [...] Fifth: Courage, audacity – the ability and willingness to expose oneself” (Pellegrino, 2008, 12). Sixthly, compassion or empathy as “the ability to understand the patient’s situation, to empathize” (Pellegrino, 2008, 13). By the declaration of being a doctor, he commits himself to this catalogue of virtues.

The classic physician-patient relationship, as described by Pellegrino, is the prototype of a professional relationship of trust. The doctor promises to do what is best for the health of his patient. The patient trusts the doctor – partly due to incompetence and partly due to a lack of alternatives – that the doctor will do everything possible to promote his or her health and prevent harm. The patient “blindly” trusts the doctor’s authority and delegates the power of decision in medical matters to him. The patient intuitively accepts the doctor’s decision and does not ask for any justification. Nevertheless, this relationship of trust does not stand in a moral vacuum. The doctor is committed to the ethos of care: He should not harm the patient (*primum non nocere*) and should promote the patient’s health (*salus aegroti summa lex*) in the best possible way. This normative expectations are accepted as binding by the doctor and by the patient. Therefore, this relationship of trust is based neither on a mere feeling nor on a rational calculus, but on the implicit or explicit expectation of the patient that the doctor will fight his illness and promote his health in the best possible way.

4. From a contract between a provider of services and a customer to a relationship between partners: *voluntas aegroti suprema lex*

The modern physician-patient relationship is based on and oriented towards the principle of patient autonomy. The patient has the right to decide freely and self-determined and the doctor is obliged to inform the patient comprehensively.

4.1. Systemic and organizational drivers of the first transformation

Before discussing the informed consent and the shared decision-making model as two divergent interpretations of a liberal relationship between doctor and patient (Fritz, 2020b), we will first look at two systemic drivers that have a lasting impact at least on the German healthcare system. The US philosopher Allen Buchanan urges that the physician-patient relationship should not be separated from its organisational and systemic conditions. It is thus an illusion to believe that physicians are obliged to provide all medical services that can benefit health (Buchanan, 2000).

Since the seventies of the last century, the physician-patient relationship in Germany has been immensely influenced by two separate developments: the policy of implicit rationing and the changed jurisdiction (Borgetto, 2006).

On the political side, a number of laws were passed with the aim of reducing the cost explosion in the healthcare system. It was politically intended that public health insurance funds and hospitals, formerly social institutions of welfare provision, should become enterprises that have to succeed in the competitive market economy. DRGs and disease management programs were designed according to medical but also financial aspects. There were restrictions on the freedom of doctors to treat patients, and the healthcare system no longer recognized patients as ill individuals, but rather recorded them as owners of a diagnosis. These developments had a lasting negative impact on the physician-patient relationship. Patients often have the impression that doctors (must) pursue economic interests to a greater extent (Hoppe, 2009, 3). The medical ethicist Eckhard Nagel states: "It cannot be denied that health policy guidelines, which are primarily geared to business management objectives, affect medical decision-making at many levels and overshadow the relationship with patients" (Nagel, 2009, 37).

Another keyword from the last century, besides the economisation of medicine, is that of judicialisation. Social areas and social contacts were increasingly subjected to legal standardization and thus controlled and steered by the state (Katzenmeier, 2009, 46-7). Thus, the medical mandate to heal became a legally verifiable treatment contract. This also had positive implications for the physician-patient relationship: Medical actions and the patient's interests being legally verifiable can certainly promote the building of trust between doctor and patient. Where trust is given, responsibility is handed over and, if necessary, demanded. The relationship of trust can be stabilized if responsibility can be legally clarified (Katzenmeier, 2009, 48; Müller, 2009, 75). However, a judicialisation weakens the binding force of classical professional ethics, which has been central to doctors so far. The medical law expert Christian Katzenmeier points out that only that which is objectified and guaranteed in the relationship between doctor and patient will count. As a result, the previously exclusive physician-patient relationship is changing into a purely commercial affair (Katzenmeier, 2009, 50). Economization and judicialization are accompanied by increasing objectification and depersonalization: excessive controlling and monitoring, bureaucratic restrictions, desk duties and forms of billing endanger the relationship of trust between doctors and patients (Bergdolt, 2009; O'Neill, 2002a).

4.2. The substitution of the classical physician-patient relationship by the Informed Consent

Not only economists and jurists base their work on the free and self-responsible decision-makers, whose will must be respected. The sentence – *voluntas aegroti suprema lex* – has become an integral part of medical ethics. Since the middle of the last century, some forms of the classical trust-based relationship have been criticized as paternalistic because they restrict freedom (Beauchamp, 1978, 1194; Maio, 2017, 158). In a paternalistic physician-patient relationship, the doctor decides – in case of emergency even without consulting the patient – what is to be done for the patient’s health. Like the child to his father, the patient should trust his doctor (Düber, 2015, 122). The primary intention of such a relationship of trust was to protect the vulnerable, more dependent part (O’Neill, 2002a, 17-19). Here, trust is based on the medical care ethos.

For critics, a paternalistic practice is morally unacceptable if it does not respect the patient’s right to self-determination (Beauchamp, 1978, 1194; Schöne-Seifert, 2007, 51). Persons, and thus also patients, should be authority in questions of their own lives (Wiesemann, 2013). This liberal view outlines on the one hand an individual right of defence: the patient should be able to refuse or agree to a medical intervention. On the other hand, it is a positive demand that the patient should also be empowered to make a decision in a concrete situation. This positive demand especially concerns the conditions of the patient’s capability of self-determination (Steinfath, 2013, 27-28).

Therefore, trust in the physician is only well placed where the patient is sufficiently informed about the medical intervention, understands the physician’s explanations and can decide for or against a medical intervention. The patient must be able to understand the situation, the scope and implications of his decision. In the medical-ethical discussion, informed consent with its two components disclosure and consent is the standard model of a modern physician-patient relationship (Beauchamp, 2013; Schöne-Seifert, 2007). According to Ruth Faden and Tom Beauchamp, an informed consent is given when the patient’s decision is a) intentional; b) understanding – the patient receives the relevant information and understands it appropriately – and c) free from others’ controlling influence – this excludes forms of coercion and manipulation (Faden, 1986, 241-262). For Tom Beauchamp and James Childress, the respect for the patient’s autonomy entails both negative and positive obligations: “As a negative obligation, the principle requires that autonomous actions be not subjected to controlling constraints by others. [...] As a positive obligation, the principle requires both respectful treatment in disclosing information and actions that foster autonomous decision making” (Beauchamp, 2013, 107). The informed consent focuses on particular, situation-related actions and decisions. It adapts a local and procedural concept of autonomy, since it focuses on concrete actions and does not prescribe any substantial conditions (Ach, 2013, 47).

The model of informed consent has its origins in the law. It interprets the physician-patient relationship as a contractual one (Vollmann, 2008, 44). Generally, the patient should be more informed by the doctor and less dependent on him or her (Beauchamp, 2013, 124). The patient is equal to the doctor. After being informed, he can either consent to treatment or refuse it. The patient decides for himself and is solely responsible. The doctor’s “only” job consists of informing the patient fully and as non-directively as possible so that the patient can give informed consent to medical treatment. To put it somewhat pointedly: The doctor assumes the role of the service provider, the patient acts as a customer (Pöltner, 2006, 88-99). Within

the contract model, trust is not based on the ethos of care, but on respect for the patient's autonomy – understood in a liberal-individualistic way (Faden, 1986; Wolpe, 1998; O'Neill, 2002a, 37-48). The classic caring physician-patient relationship is transformed into a service contract. Above all, professionals vehemently criticize the fact that doctors are degraded to interchangeable service providers and patients are no more people seeking help, but customers who demand only the best product at the lowest price (Hoppe, 2009, 6; Maio, 2009, 20-26).

But also many moral philosophers doubt that informed consent interprets the principle of respect for patient autonomy in a reasonable way (Becker, 2019; O'Neill, 2002a; Steinfath, 2013, 2016; Wiesemann, 2013). In the differentiated and widespread debate on patient autonomy, many would like to establish an understanding of patient autonomy that, firstly, is not too demanding and thus excludes as few people as possible, secondly, allows self-determined decisions to be distinguished from arbitrary, manipulated or coerced decisions, and thirdly, that the decision is respected regardless of specific life plans and views (Ach, 2013, 54). Informed consent seemed for a long time to be the appropriate formula for all three concerns ensuring sufficient trust being gained and autonomy being respected. Therefore it was recommended as a universal blueprint for the physician-patient relationship. However, clinical practice clearly shows that the contractual model or informed consent does not always meet these expectations. Informed consent is deficient where patients can no longer be empowered to give the required level of consent. Informed consent often demands too much and overburdens all those involved: Pain, fears and lack of self-confidence, uncertain disease progression, too much information, functional limitations and dependencies, dementia, etc. can impair the capability for self-determination. In particular, terminally ill patients and/or their relatives have to overcome complex and threatening situations and are often overwhelmed (Boakye, 2016; Wiesemann, 1997, 71). In such situations, most patients do not want to bear the responsibility alone and decide for themselves between apparently equally important options. Rather they want to get medical advice and trust it. They want to come to a decision that is mutually shared (Engels, 2011, 401). Simultaneously, patients are very much interested in being morally respected as persons and actively participate in "their" medical processes (Wiesemann, 2016, 99).

4.3. The shared decision-making model

The conflicting interests and needs of patients are best served by participatory decision-making between doctor and patient, as required by the *partnership* or *shared decision-making* model (Emanuel, 1992; Klemperer, 2003). Patients do not receive medical care passively, like in the paternalistic relationship model. Rather, they participate actively and autonomously in the treatment and its conditions. What counts is the will of the patient and not what is best from a medical point of view. In this partnership between doctor and patient the patient's will is plainly respected (Pöltner, 2006, 90). In contrast to the liberal-individualistic informed consent, the physician does not only provide a non-directive disclosure. He accompanies the whole decision-making process of the patient with professional recommendations and a lot of empathy. In this sense, the doctor is co-responsible for the patient's decision (Schöne-Seifert, 2007, 88). He aims to strengthen the patient's capability to decide and act in a self-determined manner. To this end he communicates confidence and reliability to the patient (Benson, 1994; Ach, 2012). However, the physician will also respect the patient's decision if it is not reasonable from his point of view or was not made under optimal conditions (e.g. lack of self-confidence or self-esteem) (Ach, 2013, 54). The shared decision-making model does

not promote a substantial-paternalistic or procedural-individualistic concept of autonomy. It implies a personal and relational understanding of autonomy. Hence, autonomy essentially means governing yourself in accordance with who you really are (Anderson, 2013). It is important that the concrete decision is in coherence with one's own wishes (Frankfurt 1987), one's own life story (Christman, 1991) or one's own preferences (Ekstrom, 2005). In addition, the partnership model takes into account that self-confidence and self-respect, social acknowledgement and cultural factors significantly influence the formation and development of autonomy (Mackenzie, 2000; Schicktanz, 2010; Steinfath, 2013). One cannot deny that interpersonal dialogue helps people to find out what is really important to them.

In a practice of trustful partnership, the doctor must meet the patient's expectations and needs with empathy. Doctors not only provide information, they must be able to communicate in a patient-oriented way (Steinfath, 2016, 22). At the same time, the patient is not the object of medical care, but directly influences the way things happen. He is an active partner in so far as he observes the professionals, communicates problems he has with the treatment, communicates his expectations of trust and looks for signs and gestures that confirm his relationship of trust (e.g. intensive eye contact or a long handshake) and gives feedback to the medical staff (Wiesemann, 2016, 82-85).

4.4. An ethics of trustworthy and truthful communication

Both theoretically and practically it is obvious that respecting autonomy and building trust are interrelated in a substantial way. Trust is built where the patient's will is asked and respected. Only if there is no coercion or deception people should trust medical staff and organisations (O'Neill, 2002a, 145; Steinfath, 2016). The interdependence between autonomy and trust is most evident in clinical practice where trust between patients and professionals is the basis and resource for self-determined action: Only because my self-determination is respected I can trust; only because I can trust I can act in a self-determined way. Without trust, the struggle for self-determination ends in a *regressus in infinitum*. A person can realize his or her self-determination and trust only in reciprocity with another person (Maio, 2017, 224).

Therefore, Steinfath (2016), among others, pleads for an ethics of trustful communication based on general norms such as truthfulness, goodwill and respect for the decisions of patients (Steinfath, 2016, 22; O'Neill, 2002a, 165ff.). This is the only way to guarantee sufficient autonomy and trust. The change from a liberal contractual model to a partnership-based relationship ensured that the communication between doctor and patient was given the importance it deserved. The physician-patient relationship is characterized not only by asymmetry, by certain roles and models, but above all by the communication between doctor and patient. Since humans are dialogical and social beings they can unfold their autonomy only in reciprocity with others (Maio, 2017, 223). Communication is the basis of every personal relationship and thus also of the doctor-patient relationship. Especially non-verbal signals (facial expressions, gestures, intonation, volume, tone of voice) are extremely important in case of illness. Many patients have difficulty communicating their complaints and feelings directly and verbally to the doctor. They often signal their discomfort non-verbally (Groß, 2007). If the doctor does not respond to these non-verbal signals, he or she jeopardizes the patient's trust and compliance, which are essential for successful treatment (Schnichels, 2019). The partnership model is based on a good personal relationship. The patient informed by the

doctor must be able to discuss his or her health needs with the doctor on an equal standing. To do this, the doctor must not only be competent in his field, but also be able to act in a patient-oriented manner. He or she must be capable of empathy, to listen actively to the patients and to react appropriately to their emotions (Retzlaff, 2008).

Successful and trustful as well as trustworthy communication not only increases the patient's self-confidence and self-determination. It also helps the patient to better cope with stressful and complex information. It helps to ensure that the medical treatment is successful (Geßner, 2017). When patients trust their doctors, there is better compliance, better patient information, a stronger placebo effect and better physician's caring behavior (Lee, 2009a, 2009b). People who trust expect more from their self-efficacy and from the treatment outcome. This has positive effects on adherence behavior, communication and decision making and on the subjective coping with disease (Hunter, 2007). Patients who trust their doctor remain in his treatment (Platonova, 2008) and communicate more, which improves diagnosis and therapy (Skirbekk, 2011).

High levels of autonomy can exist alongside high levels of trust and most likely lead to the best health outcomes. However, self-determination must not be understood in an individualistic way and trust must not be identified with naivety. Patients who naively trust their doctors become too dependent on them and are not sufficiently motivated to participate in medical treatment (Lee, 2009b). This is not the only reason why the relationship between autonomy and trust is ambivalent and needs to be continuously reviewed. We should not trust anyone. We need to trust the trustworthy and distrust the untrustworthy (O'Neill, 2002a; O'Neill, 2002b). The difference between trust and trustworthiness must not be forgotten. Trust can be gained through competence, honesty and reliability, but also by wearing a white coat and stethoscope or by displaying certificates. Ethnicity and gender are discriminating trust determinants (Rockenbauch, 2012, 47-8). Being trustworthy helps to build trust but is neither necessary nor sufficient. Both distrust and trust can be rightly or wrongly placed.

A physician-patient relationship can be very variable. We discussed the paternalistic, contractual and partnership model. Each patient sets different priorities in the relationship according to his or her socio-cultural background, personality and medical condition. Most probably, a healthy and educated patient expects something different from her doctor at a standard checkup than a person who is terminally ill. Nevertheless, there are structural analogies between these individually unique situations: an illness affects everyone existentially, the asymmetry between doctor and patient remains and both depend on each other. For this reason, the medical ethicist Christiane Woopen emphasizes that empathy and trust are indispensable for any physician-patient relationship (Woopen, 2009, 191).

5. The interactions between humans and computer systems: voluntas dominus de notitia suprema lex

Medicine is increasingly transforming into a data-driven science. More and more data is being collected and processed. Health data are very sensitive data that are legally protected. The importance of digital ICT is increasing with the datafication of medicine. In principle, health-relevant data about people has a dual-use character: It can be used for and against a

person. Patient data are often at the centre of the discussion on the digitalization of healthcare. This focus on the data tends to overlook that data only represent a – very important – context. In order to avoid data centrism it has to be acknowledged that the use of ICT turns the conventional dipolar physician-patient relationship into a multipolar human-computer interaction. Respect for patient autonomy and trust therefore do not only affect the personal and direct physician-patient relationship or the use of technology, but also the socio-technical system (Heil, 2019, 31-34). Trust in the socio-technical system is the basis of patient autonomy in the digital transformation.

5.1. The digital transformation of the physician-patient relationship

The digital transformation and the application of digital ICT radically change the classic relationship between physician and patient: Doctors and patients interact intensively by means of digital applications; both parties can inform themselves in equal measure; the generation and analysis of data becomes more and more important; healthcare is done by a network; gigantic volumes of data can be shared rapidly. The WHO defines E-health as “the use of information and communication technologies (ICT) for health.” Examples of E-health use include treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health (WHO, 2017). E-health cannot replace the personal conversation and personal medical examination of a doctor. A telemedical treatment or statistical calculation of a very well prepared data set is not at all comparable with experiences made in a personal physician-patient encounter or with the empathy and intuition of a doctor. Nevertheless, E-health systems do not only complement healthcare, but they become more and more part of its substance. The personal physician-patient relationship cannot be replaced. But it might in fact no longer be offered or demanded, especially in rural areas where not all doctors find successors who take over their practice (Trill, 2018, 45). The introduction of digital ICT into the medical care routine will be the logical consequence for the coming years (Kuhn, 2018, A 634).

As a result of digitalization, the roles and tasks between doctor and patient will be redefined and redistributed. Digital ICT has broken into the exclusive relationship between two human beings. Now, there is a triangular relationship between humans and machines. The many hands involved in the process of technological development and application, as well as the technology itself, cannot be fully grasped. Doctors have to manage role conflicts and trade-offs, which are intensified by ICT (Katzenmeier, 2009, 51; Hoppe, 2009, 6):

- the medical role of the healer and helper: the physician must know the state of the art;
- the social role of the gatekeeper: the physician must meet different health needs with limited resources;
- the psychological role of the counselor, comforter and pastor: the physician must act in a human and professional patient-oriented manner;
- and the economic role of the contract partner: The physician must think economically and observe bureaucratic regulations.

Digitalization is adding a new role:

- the information and communication technology role of the user: the doctor must have digital literacy.

Given the numerous and varied conflicts of roles and objectives, medical historian Klaus Bergdolt makes the following pointed observation: “Ironically, one could say that the good doctor has a universal talent that nature has not created outside its own standing. In reality, by raising his level, he jeopardizes the conversation, the building of trust and credibility. He is constantly under pressure and basically finds himself in a schizoid situation. It seems inhumane to ask too much of the doctor” (Bergdolt, 2009, 112). Digital technologies can lead to a situation where, on the one hand, the doctor is more of an expert and less of a partner to the patient. On the other hand, the competent patient can obtain comprehensive information on the Internet about possible treatments and is thus strengthened in his role. On the one hand, digital ICT focuses on objectively ascertainable and stratified data, dysfunctions and evidence-based proof of effectiveness instead of the subjective experience and expertise of a doctor and the personal needs and circumstances of a patient. On the other hand, health professionals can network digitally and thus obtain a more holistic picture of the patient. Due to the opportunities and risks that the digital transformation offers, professionals face conflicts between empathy for the person seeking help, scientific objectivity, economic and bureaucratic tasks and competent handling of digital ICT. Contradictory behavior on the part of both the doctor and the patient can destroy their mutual trust.

Digitalization influences the roles and tasks of doctors and patients not only from the exterior but digital ICT participates itself directly in the medical process – starting with mediation in telemedicine and continuing where cognitive computer systems control and govern treatment processes. We delegate more and more complex and risky tasks to machines. In the health sector in particular, it is evident that this penetration of ICT is in no way morally neutral. The use of technology here is not a neutral tool to an end. The role of digital ICT is not limited to preparing or executing a doctor’s recommendation or a patient’s decision. Rather, human recommendations and decisions are brought about by technology: for example, in app-based treatments of chronic diseases or in the use of artificial intelligence for the diagnosis and therapy of cancer. The approach of the Dutch philosopher of technology Peter-Paul Verbeek is one of many approaches to understand such interaction and agency between humans and machines. In Verbeek’s mediation theory, technology has the role of an active mediator between humans and the world. This mediation takes place on two levels: On the one hand, technology influences human perception of the world (hermeneutic mediation); on the other hand, it actively participates in actions (pragmatic mediation) (Verbeek, 2006, 2011, 2015; Fritz, 2019). Consequently, medical procedures and processes as well as decisions and actions of doctors and patients are the joint products of humans and technology. Medical procedures that interact with digital ICT are “hybrid”. Consequently, a medical treatment decision is not caused by the human being or the computer system alone, but by a differentiated interaction between human being and artifact (Johnson, 2019). Once “mute” technical artifacts begin to communicate or become part of communication processes (Hartmann, 2008, 102).

If a new “actor” is added to the hitherto dipolar physician-patient relationship, if for temporal or technological reasons its causality is perceived as a “black box” (Castelvecchi, 2016) so that its influence on what is happening cannot be clearly identified, this directly threatens patient autonomy and trust in the physician-patient relationship. For the problem starts with the question of who is to be trusted or on whose reliability one is relying: (1) digital technology, although it is an artifact; (2) the doctor and/or the patient who (must) use a system they do not fully understand; (3) health policy and management that neither understands the black box nor makes

individual decisions; (4) the system and the organisation; (5) the data engineers, although they do not make decisions about individuals; (6) the (often ignorant) individuals who provide the training data; (7) the software engineers, although they are not able to predict the behavior of the system after learning; (8) the algorithm developers who created the multipurpose black boxes in the first place. Can one or more of these eight candidates be trusted? Which of these actors can be trusted completely, and to what degree? Is the entire socio-technical system to be trusted, without individual responsibility? Is nothing and no one to be trusted? (Fritz, 2019).

In general, the digitalization of the health sector is perceived in terms of the networking, evaluation and use of vast amounts of health-related data (Big Data). In order to protect patients from abuse, data protection and data autonomy are put into position. Data protection serves the informational self-determination of the persons involved. It is the right of a person to determine the content of her communication (Deutscher Ethikrat, 2017, 252). As the owner of personal data, each individual must be able to decide for himself/herself to whom he/she wishes to disclose the data and to what extent.

5.2. Data protection and the challenge of a trustworthy physician-patient relationship

In the previous section, it was argued that a patient can achieve the best self-determination possible only within a trustful and trustworthy physician-patient relationship. The place par excellence to build such trust has so far been the personal encounter between the patient and his doctor. From the beginning, healthcare was characterized by the encounter between a person seeking help, often existentially threatened, and a competent helper (Bergdolt, 2009, 105). Whether this will be the case in the future cannot be answered conclusively given the potential but also the risks of using digital ICT. It is essential that this basic form and core content of medical practice be re-anchored in the socio-technical system of healthcare. Given the depth and range of the digital transformation of the healthcare system, data protection regulations are necessary but not sufficient conditions for a personal relationship of trust and autonomy between doctor and patient. Data protection and data autonomy have an instrumental function. In the healthcare practice they are at the service of patient autonomy. For example, the use of mobile health (e.g. wearables, smartphone apps) can be an expression of self-determination. However, such devices can also exert an inner coercion on the user (self-induced heteronomy) (Deutscher Ethikrat, 2017, 120). Yoan Hermstrüwer (2016) speaks of “informational self-endangerment” when people provide personal information themselves and thus make themselves dependent on external factors. The “privacy paradox” refers to the irritating fact that people are more willing to share sensitive information in the digital than in the analogue world (Deutscher Ethikrat, 2017, 193).

If respect for patient autonomy is taken seriously even in digitalized healthcare, then we cannot stop at data protection and data autonomy. We need to think about how medical empathy and personal presence can be maintained even when digital ICT is used. Otherwise, the protective space in which a trustworthy relationship between patient and doctor can be built and stabilized will be undermined. By use of digital ICT, direct-personal communication between doctor and patient is supplemented or completely replaced (Bittner, 2014). For example, telemedical treatment prevents a direct and personal physician-patient relationship and weakens non-verbal communication (Gassner, 2017). Professionals focus on physical and stratified data, and have a limited perception of the patient as a person with her needs and

wishes (Groß, 2007, 21). With a mass of data you can differentiate roles or types, but you are blind to singular or personal elements. Personality cannot be limited to one data set. The individual patient must not disappear behind the data (Heil, 2019, 34).

It is not a paradox if the increased use of digital ICT simultaneously highlights the need for a personal and trustworthy physician-patient relationship within a socio-technical system. Even in the analog field, the challenge of how to communicate trust in the healthcare sector is extremely complex and presuppositional (Dalferth, 2012). Although trust is a dynamic, empirically challenging phenomenon, literature, despite some differences, provides a relatively consistent picture of which communication promotes patient trust: agency (acting in the best interest of the patient), competence (professional competence of the physician), honesty (credibility of information) and confidentiality (empathy) (Rockenbauch, 2012, 46). The qualitative research study by the US physicians Thom and Campbell is one of many qualitative studies that categorizes what makes patients trust their physician (Thom, 1997).

<p>1. <i>Thoroughly evaluating problems</i> Carefully reviewing history Demonstrating up-to-date knowledge Willingness to refer Searching for additional information Ordering tests Giving best effort</p> <p>2. <i>Understanding patient's individual experience</i> Responding to patient's needs Knowing patient and family Taking into account patient/family preferences Avoiding assumptions Tailoring treatment to patient Treating patient as unique Considering "whole person"</p> <p>3. <i>Expressing caring</i> Concern for patient's comfort Expressions of concern/empathy Offering to help Reassuring and comforting Being hopeful Putting patient's interests first</p> <p>4. <i>Providing appropriate and effective treatment</i> Recognizing condition being serious Correct diagnosis Achieving desired outcome Use of preventive services</p>	<p>5. <i>Communicating clearly and completely</i> Active listening Acknowledging patient's concerns Explaining completely and honestly Answering questions Direct communication Being sensitive Being relaxed and calm</p> <p>6. <i>Building partnership/sharing power</i> Providing options Treating patient as an equal Trusting patient Open to new ideas, flexible</p> <p>7. <i>Demonstrating honesty/respect for patient</i> Admitting mistakes Honoring commitments Respectful, nonjudgmental</p> <p>8. <i>Predisposing factors</i> Training Age, sex Recommendations of other patients Professional appearance</p> <p>9. <i>Structural/staffing</i> Courtesy of office staff Messages to physician Obtaining laboratory results Access to physician On-call arrangements</p>
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Figure 3: Categories of Patient Experiences Positively or Negatively Affecting Trust (Thom, 1997, 172)

Patients very rarely express explicitly whether they trust their doctor or not. The openness or manner in which patients reveal themselves depends not only on how the doctor presents himself or herself, but also on the severity of the concern. Furthermore, several studies have shown that trust in professionals or institutions depends on systemic conditions (working atmosphere, frequency of contact and accessibility, transparency and participation opportunities) (Balkrishnan, 2003; Kowalski, 2009; Rockenbauch, 2012; Wendt, 2003). The insights of trust research show how serious, large and complex the challenge is to enable trust and self-determination in healthcare practice. Its complete accomplishment is a necessary utopia, which the art of healing has been pursuing from the very beginning. The use of digital ICT also offers the chance to address this challenge more intensively again.

However, the search for suitable forms of enabling a trust that helps the patient's self-determination is only at the beginning. How will digitalization change communication structures and conditions? How will the conventional personal-direct form of the physician-patient relationship change? How can the personal-direct physician-patient relationship be guaranteed in the context of digitalization? It is therefore not enough to check whether the personal direct physician-patient relationship or the use of technology is trustworthy. It must be examined whether it is appropriate to trust the socio-technical system.

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