

**Digitalisation in the health sector -
responsibility of medical-ethical assessments
using the example of a health app**

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Introduction

Recently, the article "Health app "Well" begins national roll-out" (1) appeared on the website www.netzwoche.ch. The website states: "The operators of the health app "Well" want to advance the digital transformation in the Swiss health care system and network all relevant actors on one platform. The starting signal for the national roll-out has now been given."

In the Czech Republic, such a nationwide health app is not (yet) available.

In the coalition agreement of the Czech government of 08.11.2021, it says about the health care system, among other things: "Greater responsibility of health insurance companies and price competition in the health care system; goal: reduction of costs through greater efficiency, transparency, systematics and control." (2)

Who are the relevant actors in such health apps? What does this mean for the citizens, for the patients, for the doctors, for the nursing staff, for the entire health care system as well as for the entire society? Will all citizens be obliged to use such an app or only those who are interested or voluntarily choose to do so? How are doctors, hospitals, nursing staff prepared and involved here? Will participation in this health app have an impact on the insurance premiums of citizens who do or do not participate?

How can such a health app be evaluated from a medical-ethical perspective? How are medical-ethical evaluations carried out here? Which risks and which ethical values are considered?

In the first step, I would like to consider this in general terms. In the second step, I would like to take a critical look at these questions with the help of "Smart Health and Ethical Issues" by Victor Chang, Yi Cao, Taiyu Shi and Patricia Baudier. (3)

Consideration of the issue

Digitalisation in the health sector is developing very dynamically. New products and related software are appearing on the market every day, ranging from a smartwatch with new functions to an expert system for doctors.

From simple move trackers to apps for monitoring body weight to ECGs and the monitoring of sleep patterns with a smartwatch - the range of so-called wearables and the associated apps is growing every day. The variety of products is increasing rapidly and is almost unmanageable. Such products are offered as new products on Amazon alone on about 20 pages. And on eBay, such products are offered second-hand on almost 50 pages. One can almost speak of a product glut.

In this complex field of topics, I would like to limit my considerations to so-called wearables (smartwatches) with their apps.

How can or should such products and solutions be classified in the health care system? What are the challenges in medical-ethical evaluations of these products?

Before I try to answer these questions, it is helpful to look at definitions. The terms "eHealth" and "mHealth" exist. In addition, there are the terms telemedicine and telehealth, which I will not consider further here.

eHealth describes "tools and services that use ICT (note: information and communication technology) and can improve prevention, diagnosis, treatment, control and management". (European Commission, 2015) (4). These include, among others, the e-health record and the e-prescription, but also medical expert systems that provide decision support to hospital staff during medical operations.

mHealth focuses, as the name suggests, on the use of mobile technologies "for health information and services" (Nacinovich, 2011 (5)). This includes trackers, smartwatches and health apps that are offered to the consumer.

eHealth products are medical devices. Products of mHealth are not necessarily medical devices. However, the boundaries between these two terms and products are also not clear. A smartwatch with a pedometer can be used both by a hobby walker (mHealth) and by a patient suffering from lung disease who needs a minimum daily exercise (eHealth).

Medical devices and thus also eHealth solutions must be qualified and approved through a legally regulated and defined procedure. In addition to technical tests and qualifications, this also includes medical-ethical evaluations.

Let's look at the tools for ethics evaluation of e-health and then see if they can be applied to mHealth products and solutions.

Within the framework of the approval of medical devices, clinical data must be proven. This is always done with the evaluation of scientific literature and, if necessary, with clinical trials. For each clinical trial or study of medical devices, a vote of the respective responsible ethics committee must be available before the start. This is based on European law (6).

The state ethics committee in the Czech Republic is the Ethical Committee of the Czech Republic, 2nd dept of medicine, 3rd medical school of Charles University, Srobarova 50, 10034 Praha 10, Czech Republic. In addition, every health care institution, such as hospitals, also has ethics committees. See for example "Etická komise Uherskohradištské nemocnice" and "Etická komise, Krajská nemocnice T. Bati, a. s. - KNTB “.

What criteria are considered in medical-ethical evaluations? How are risk assessments carried out?

In 1977, the American medical ethicists Beauchamps and Childress developed a justification model with the so-called ethics of principles (7). In this model, four principles are postulated: Patient autonomy, non-maleficence, beneficence and justice. This model of principle ethics is still valid today and is used.

On the basis of principle ethics, further models and methods for medical-ethical evaluations, so-called evaluation instruments, emerged. A well-known example is MEESTAR (Model for the ethical evaluation of socio-technological arrangements) (8).

In this model, the ethically relevant criteria of "privacy, participation and self-image" are considered in addition to the four principles of principle ethics "care, self-determination, security, justice". All criteria are evaluated individually from the perspectives of the societal, organisational and individual levels. The evaluations lead to the results "unobjectionable" (level I)", "ethically sensitive (level II)", "requires permanent attention (level III)" or "application should be rejected (level VI)".

In medical-ethical assessments using this model, one can create a matrix in tabular form as a support and for visualisation purposes:

Criteria	Aspect	Evaluation	Rating level			
			I	II	III	IV
Care	social					
	organisational					
	individual					
etc.						

Table 1, Scheme for medical ethical evaluation according to the MEESTAR model

When considering these criteria, one must ask whether such a model for the medical-ethical evaluation of eHealth products (and mHealth products) and all influencing factors is taken into account in today's world and is thus up-to-date.

o this end, I would like to consider the approach taken by Victor Chang, Yi Cao, Taiyu Shi and Patricia Baudier in the paper "Smart Healthcare and Ethical Issues". These reflections were discussed at the "International Conference on Finance, Economics, Management and IT Business", May 3-5, 2019, in Heraklion, Crete, Greece and published in the FEMIB Yearbook, 2019.

Already from the title of this paper we see that they do not distinguish between the terms eHealth and mHealth. The authors use the term "Smart Healthcare" for these technologies."

On the ethical evaluation of smart healthcare, they quote Mittelstadt and Floridi (2016) "Healthcare ethics can be defined as the ethical regulations and requirements while handling sensitive and private data such as patients' records."

In their medical-ethical considerations, they not only take into account the four basic ethical principles according to Beauchamps and Childress, but also the state of the art and technical developments in the field of smart healthcare. The state of the art is the Internet of Things (IoT). "By IoT we mean the network of physical objects ("things") that are equipped with sensors, software and other technology to connect them to other devices and systems via the internet so that data can be exchanged between the objects." (7).

To understand IoT technology for Smart Healthcare, the explanations of the authors Chang and colleagues are very helpful. IoT technology for Smart Healthcare is a "smart medical information network platform system".

It consists of four levels. On the first, the lowest level, data is collected from various medical devices, for example analysis devices, but also from smartwatches. On the second level above, this data is processed, condensed and evaluated. The third level is the service level. Here, the data collected on the first level is made available to doctors, for example. On the fourth level, the so-called interface level, all the participating systems are finally combined and interconnected.

Nach Chang und Kollegen werden in diesem sehr komplexen Gebilde der Smart Healthcare über das "smart medical information network platform system" drei Systeme miteinander vernetzt: Das "Smart Hospital", das "regional Health system" und das "Family health System".

For a medical-ethical evaluation, the risks must now be considered and assessed in this system, which already exists in many parts today.

Chang and colleagues point to three areas of risk. Firstly, the risk of data being tapped through unauthorised access to a device. Secondly, the risk of misuse of data in social networks. Chang and colleagues see the third risk in inadequate legal requirements.

What does an interim conclusion look like after considering the ethics of principles, the MEESTAR model and the considerations of Chang and colleagues?

If we look at the four principles of Beauchamps and Childress, I think they are still fully valid today. But they do not take into account today's state of the art, especially IoT technology and the responsibility it requires. The MEESTAR model also does not take IoT technology into account.

If we look at the risk assessment of the authors Chang and colleagues, we see that they take into account the current state of the art. However, in my view, the aspects of principle ethics are not taken into account enough.

The attempt to bring these considerations together results in an evaluation model with the ethically relevant criteria of today:

"doctor-patient relationship (care)"

"non-maleficence"

"Patient autonomy"

"justice"

"functional capacity",

"Benefit potential",

"data protection" and "data security",

"efficiency",

"medical decision-making autonomy and competence" and

"Responsibility aspects".

Against the backdrop of rapid technological development, the issue has become and continues to become increasingly complex and complicated. As already discussed, the boundaries between eHealth and mHealth are blurring. This makes the combination of the two terms into "Smart Healthcare" very sensible.

Now the question arises whether, given the multitude of stakeholders in the healthcare system, a single institution, an ethics committee, has sufficient expertise to conduct medical-ethical assessments on smart healthcare. In other words, can a single institution in the healthcare sector responsibly conduct a risk assessment, i.e. identify risks and formulate recommendations to mitigate them?

To answer the questions, I would like to take up the approach of the authors Chang and colleagues. In their paper, as shown, they speak of three parties in the health care system: "Smart hospital (system)", "Regional health (system)" and "Familiar health (system)". I would like to try to assign the ethically relevant criteria and thus their responsibility to the individual parties in these groups. The consideration can only be exemplary and it can never be complete and exhaustive.

Party	Level I: Smart Hospital (system)		Level II: Regional health (system)		Level III: Family health (system)	
Participants	Ethical responsibility	Risks	Ethical responsibility	Risks	Ethical responsibility	Risks
Government (legislator)	Ethical responsibility: Risks		Verantwortungsaspekte Technik entwickelt sich schneller als Gesetze			
Health insurance	Justice Responsibility aspects Efficiency Medical decision-making autonomy and competence	Not all citizens are offered equal benefits	Health insurance companies do not access this system.		Justice Responsibility aspects Efficiency Medical decision-making autonomy and competence	Not all citizens are offered equal benefits
Medical device manufacturers (devices and medicines)	Functionality Non-maleficence Benefit potential	Insufficient or faulty tests, faulty product descriptions	Functionality	Insufficient or faulty tests, faulty product descriptions	Functionality Non-maleficence	Insufficient or faulty tests, faulty product descriptions
Clinic management	Responsibility aspects Efficiency Medical decision-making autonomy and competence	Economic aspects are valued more highly for reasons of profit	Clinic management does not access this system		Responsibility aspects	Transmission of erroneous data from clinical treatments
IT, IoT technology	Data protection and data security	Patients' data is transmitted incorrectly Data security not ensured	Data protection and data security	Patients' data is transmitted incorrectly Data security not ensured	IoT technologies are not directly involved at this level.	
Medical doctors	Caring Patient autonomy Non-maleficence Justice	No equal treatment Faulty decisions	Non-Maleficence Justice	Faulty decisions Faulty documentation	Caring Patient autonomy Non-maleficence Justice	No equal treatment Faulty decisions
Nursing staff	Caring Patient autonomy Non-maleficence Justice	No equal treatment Faulty decisions	Non-Maleficence Justice	Faulty documentation	Caring Patient autonomy Non-maleficence Justice	No equal treatment Faulty decisions
Patients	(Participation)	Patient does not respect the doctor	Patients do not access this level.		Potential benefits of data protection and data security	Careless handling of data

When we look at this overview, we see, among other things

- Clear 1:1 relationships of responsibilities do not exist (anymore);
- Responsibilities shift and new responsibilities emerge;
- Different competences exist;
- The difficulty for a single institution to carry out ethical evaluations at all levels.

What could be an answer to this?

To this end, I would like to develop a proposal with the help of the work of Chang and colleagues.

Furthermore, it is the responsibility

- of the state to develop fair and up-to-date guidelines in the health sector.

To this end, it must react more quickly to technical changes.

- of the health insurance funds to ensure efficiency.

However, cost reductions must not restrict the autonomy and competence of doctors in decision-making.

- of the management in the hospitals to ensure both the economy and the autonomy and competence of doctors in decision-making.
- of doctors and nursing staff to respect the four principles of the ethics of principles.

In future, it will be the responsibility

- of the manufacturers of medical devices, especially electrical and electronic devices, to ensure data security and data protection, thus protecting the systems from data theft.
- of the IoT (departments) to ensure data security and data protection. Both the systems and the transmission of data must be protected against unauthorised access. IoT represents a sub-section in each case, both at the medical device manufacturer and in the clinic
- of the patient or citizen to be aware of the risks when handling their health data.

The manufacturers of medical devices could post the data on their devices and applications in a database. Compliance with responsibilities can be checked and monitored by an ethics committee.

Compliance with responsibilities at the health insurance funds and in the clinics can be monitored by audits. The results of these audits could also be entered into a database.

The greatest risk, however, is posed by people. Unlike doctors (Hippocratic Oath / Geneva Vow) and nurses (professional ethics), patients or users often share their health data too carelessly and thoughtlessly. For example, health data is exchanged in communities at its competition. Doctors (doctor-patient relationship (care)) and health insurance companies (regular information about risks and dangers) should assume greater responsibility here.

Conclusion

The increasing digitalisation in the health sector leads to new risks and responsibilities. Digital capturing of health data increases efficiency and leads to time and cost savings. Digital networking in the healthcare system improves patient care. Clinics, doctors, nursing staff, but also the management in the clinics and the IoT departments know the risks and act accordingly.

What is new is the patient's responsibility in dealing with their health data, which is now available to them - quasi autonomously. The risks in dealing with this data must (still) be learned. In this context, I see that greater assistance and education by doctors, health insurers and the manufacturers of medical devices is necessary.

Resources

(1) Netzwoche, 04.05.2022, Joint Venture von CSS und Visana, „Gesundheits-App Well beginnt nationales Roll-out“

(2), <https://www.gtai.de/de/trade/tschechische-republik/branchen/healthcare-monitor-tschechiens-krankenhaeuser-investieren-674454>

Germany Trade and Invest - Gesellschaft für Außenwirtschaft und Standortmarketing mbH, Berlin, Artikel „Healthcare Monitor - Tschechiens Krankenhäuser investieren“, 15.11.2021
Autorin: Miriam Neubert, Prag

(3) “Smart Health and Ethical Issues”, Victor Chang, Yi Cao, Taiyu Shi und Patricia Baudier, Finance, Economics, Management and IT Business (*FEMIB*), 2019, ISBN: 978-989-758-370-4, p. 53-59

(4) Auszug aus „Wir schaffen Begriffsklarheit in der eHealth-Domäne“, Beitrag der TU Dresden, <https://tu-dresden.de/bu/wirtschaft/winf/digital-health/die-forschungsgruppe/news/wir-schaffen-begriffsklarheit-in-der-ehealth-domaene>

(5), Mario R Nacinovich, Boston University, , Journal of Communications In Healthcare 4(1):1-3 April 2011, Defining mHealth

(6) Verordnung (EU) 2017/475 über Medizinprodukte (MDR), Artikel 62, 3.) ff. und Anhang XV, Kapitel II, 1.16.

(7) Principles of Biomedical Ethics, Beauchamps und Childress

(8) Technisierung des Alltags – Beitrag für ein gutes Leben? (pp.247-262), Chapter: MEESTAR: Ein Modell zur ethischen Evaluierung sozio-technischer Arrangements in der Pflege- und Gesundheitsversorgung, Publisher: Steiner, Editors: Karsten Weber, Debora Frommeld, Arne Manzeschke, Heiner Fangerau