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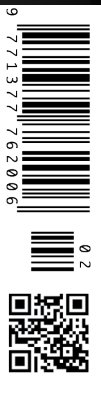
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One AI to Rule Them All?!

Ethical consideration of Greatness and Limits of data-driven smart medicine

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"The development of full artificial intelligence could spell the end of the human race. It would take off on its own, and re-design itself at an ever-increasing rate. Humans, who are limited by slow biological evolution, couldn't compete and would be superseded."

Stephen Hawking, BBC, December 2014

"Our intelligence is what makes us human, and AI is an extension of that quality."

Yann LeCun, VP and Chief AI Scientist, Facebook

"I don't have a life. I have a programme."

The Doctor, an Emergency Medical Hologram Mark, Voyager

Digitalisation of medicine and healthcare is, apparently, the not so distant future. But to make it practically successful, we need to explore and understand AI and its interaction with data use and protection policies. An ethics expert looks into the challenges imminent to the current digital health landscape and outlines the benchmarks for its transition to 'common good'.

Key Points

- While technology has always been used to progress medicine, its moral values should be critically evaluated, especially considering the potential impact of AI and data.
- In Germany, finding the balance between good use of good data and protection of personal data is challenging. In theory, policies are on the right track but their implementation may be questionable or even the opposite of what was intended.
- Present digital landscape might not always be amenable to consensus so in real-life settings an expert ethical evaluation of new technologies should come to the forefront.
- Between public and private health concerns, justice and autonomy, the common good should prevail as the critical point of AI and data-model implementation in medicine and healthcare.

The Ultimate Seduction, or: Redemption?

"Two things fill the mind with ever new and increasing wonder and awe" – the stunning human-like AI, often called artificial general intelligence (AGI), we created and the decisions that are finally being taken away from us, especially in ethical matters. Well, something like that. Kant meant: "the starry heavens above me and the moral law within me." The original Kantian power-quote from conclusion of The Critique of Practical Reason hits the point. True Heaven is the moral law.

The existential question of healing, of redemption from illness and torment is so close to all of us that almost any means may justify this end at first glance. But only almost. In the long history of medicine, technology has always been a popular instrument for achieving progress. Progress in a profession between science, art, ethics and craft. Only the craft is really interchangeable with digital technologies, to a large extent and only insofar as it is interpreted manually. But even there not completely, because as long as we humans

are bodily beings, empathetic touch is also an expression of a professional closeness and a relation which itself can develop a positive medical power. Of course, no doctor will mourn the old procedures in which urine had to be tasted – diagnostically imprecise and burdened with shame for both doctor and patient. And yet technology is not in principle simply an instrument; rather, it is closely interwoven with the ethical quality of medicine itself and must therefore also be addressed from the point of view of values.

AI makes it particularly clear at this point how much the deep chances of positive progress in medicine itself can be morally commanded to be used, on the one hand, but on the other hand, should also be critically questioned. Between seduction and redemption. Perhaps the AGI will play the central role in the future, assuming that this is possible in principle (which is probably the case, Gödel's theorems a *no a priori* limit). It has already become impressively clear, even more so in pandemic times, that successful public and private health can no longer be guaranteed or at least legitimately supported by Analogicity. Data, AI and me and you. And all of us. Everywhere.

No Medicine Without Good Data

It is hard to grasp, even harder to bear. How can a successful, highly industrialised democracy like Germany in the middle of Europe be so clearly overwhelmed politically and administratively in the corona crisis? There may be many reasons for this, which cannot be discussed here (cf. Heinemann and Richenhagen 2021); however, at least one element is to be found in the lack of digitisation of the public health system. Without good data (valid, etc.), there can be no good pandemic prevention (and also no further diagnostics, therapy and after-care). Without good algorithms, i.e. good AI, no smart use of this data. So far, so good. Or not. Because: the German fear of the data octopi (think tech corps) unfortunately ultimately ensures the weakening and endangerment of the basic idea of a solidarity-based healthcare system such as in Germany, which is actually legitimately worth protecting – not 'only' in the corona times. Developing and protecting the common good does not succeed against, but only with data and AI. But responsibly, with secure and protected, above all personal, data. The current data strategy of the German government shows good perspectives here (Bundeskanzleramt 2021). The German Ethics Council had already recommended 'data donations' as a sensible system supplement in 2017 (ibid.), especially for research and medicine. All these initiatives are good and right, but they do not have nearly the impact that would be necessary to manage a pandemic. Even the sensible legal initiatives of the last two and a half years, starting from the Federal Ministry of Health (Box 1), admittedly could not make up for many years of digital backlogs in medicine and the healthcare industry. But the concern that in the end the many good foundations will not have sufficient effect is not unfounded. At this point, there is a risk of a massive loss of credibility for politics as a whole, of not being able to mediate

adequately between protection and freedom and of having too little outcome. Article 1 (1), (3) of the GDPR actually formulates an enabling of data use.

Box 1. German Legal Initiatives

"The 'app on prescription' as the first access to standard care with the corresponding financing instruments according to §§33a and 139e SGB V is widely discussed – also under ethical aspects. With various testing procedures (including 'fast track' within three months) at the German Federal Institute for Drugs and Medical Devices (BfArM), the quality is assured, at least according to the claim, and the inclusion of the corresponding mobile eHealth application as a reimbursable digital health application in the 'DiGA directory' (digital health application) can be made.

Telemedical consultation in care facilities (by physicians) (nurses-Support Act PpSG), ePA (electronic health record – EHR), including the 'Appointment Service and Care Act' (TSGV), e-prescription (Act for More Safety in the Supply of Pharmaceuticals GSAV) and, of course, the eHealth Act as well as the planned changes to the Approbation regulation for Doctors (ÄApprO) and the eAU (Certificate of incapacity for work) resulting from the Ministry of Health's 'Master Plan for Medical Studies 2020' (Heinemann 2020, p. 2; primary source in German translated by author).

And of course, the Act to Improve Healthcare Provision through Digitalisation and Innovation (Digital Healthcare Act – DVG) approved and adopted at the end of 2019 by the Bundestag and by the Bundesrat.

In the current report of the German Expert Council, the strategic section correctly states:

"A patient-centric approach will simultaneously facilitate the meaningful development and use of future digital applications in healthcare. In this context, particular attention must be paid to personal rights and individual security needs. The protection of informational self-determination by means of data security measures, as well as substantive data protection law, are structured in Germany with great regulatory depth and regulatory density. In the process, a strongly pronounced one-sidedness of interpretation of data protection has developed in the sense of minimising the processing and further transmission of data. This interpretation, particularly in the form of the 'data economy' principle, is based on the unquestioned assumption that misuse of the processed data represents the greatest risk for patients. The significant risks to life and health of not processing data, on the other hand, are often underestimated as minimal or non-existent. Data protection in the healthcare system should protect not only data, but at the same time and above all the life and health of patients. This protection is a necessary prerequisite for being able to exercise self-determination, including informational self-determination, at all" (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen 2021, p. 711; primary source in German translated by author).



It is understandable that data protectionists are placing data protection at the forefront of their efforts somewhat more clearly than perhaps other players. However, in view of digital medicine and the healthcare industry and thus the future of medicine and the healthcare industry in general, and even more so in view of the sad developments of the pandemic in Germany in particular, it seems to be becoming clear that data protection in the way it is interpreted and practised may itself be subject to increasingly critical scrutiny, given the financial and technological possibilities that Germany actually has or should have. The author himself has a hard time with this finding, because as an ethicist, autonomy, as it is valued and promoted in the GDPR, is very important and central, and we read right at the beginning of the GDPR that it is, of course, not about obstacles or barriers, but actually just the opposite. However, the *de facto* situation is that data protection, while certainly not always justified, has meanwhile commonly come into a critical light. On the one hand, this is not entirely harmless, because if it becomes too crit-

are difficult, but they do not affect everyone and certainly not everyone's existence. The right basic idea is to set up data protection in such a way that it gives every person the chance of sovereignty over their own data, limits the possibility of radical data monopolies by large Internet corporations, and also prevents something like a 'Health Schufa' (Schufa is a German private credit bureau). De facto, this good basic idea is mostly settled by a few clicks, with corresponding more or less effective consents, and checking these corresponding provisions is hardly to be done by the corresponding agencies due to the mass. It is ethically quite critical to ask whether a construct, which factually already contains a real illegality perspective for a normal justifiable action, can still be meaningful. And, moreover, it makes its own *ratio legis* appear impracticable.

Veil's (2020) criticism that a 'one-size-fits-all' approach to the GDPR does not do justice to the subject matter can rightly be followed. The tax authorities are certainly to be evaluated differently than a blogger and multinational corporations or the craft business around the corner. The person

Technology is also but not only and not merely an instrument; rather, it must be addressed from the point of view of values

ical, one could gamble away the actually good basic facilities of the GDPR through inadequate implementation. On the other hand, it is equally dangerous, because the possibilities that are undoubtedly associated with data, especially in medicine, must not be gambled away without necessity – and this can only be meant without absolutely first-rate and clear arguments as to when the privacy of persons in the broader context that is actually to be protected is to be preferred to health in the broader context (or even in the specific context).

It is true, of course, that the much-maligned GDPR allows for much more and offers many more solutions than most people are aware of, but only for those who are familiar with these solutions. For the majority of professional players in medicine and the healthcare industry, and even more so for patients and their relatives, it is at best a nebulous piece of legislation whose effects are often perceived as a problem in practice and which, moreover, punishes violations with very high penalties. Ultimately, data protection in the form in which it is often lived in Germany is a clear overreach. From day care centres to university clinics, there are hardly any opportunities left not to immediately think of difficulties when it comes to personal data. Which, as I said, is not always fair to data protection, but on the other hand, it is because a law needs not only a good *ratio legis* but also a correspondingly transparent and feasible implementation dimension. Of course, there are other areas of law that are complex and legal frameworks that

processing the data would have to be reconsidered in their own power and risk as well as benefit of the processing. The narrow focus on personal data in the sense of the GDPR is too undifferentiated and cannot distinguish the in reality very different protection needs and processing risks. Data are not objects, and the structure of data protection law in the EU does not allow any consideration of which specific use of which data should or should not be permissible. With this prohibition principle, even ethically desirable and even fundamentally protected processing of data is subject to constant justification and always on the border of illegality. So, what exactly does the GDPR protect? As long as this question cannot be answered clearly – ideally in a meaningful form as indicated – the interpretation will always remain problematic. Ultimately, data protection does not become the protection of data where it would be justified and appropriate. At the operational level, so to speak, data protection understood in this way turns life, the profession and ultimately everything into a risk-prevention matter. As if there could be no one on a private or professional level who did not want to comply with rules that were already in place before the GDPR. Data protection thus threatens to become a self-contradiction.

In addition, the data economic perspective will become increasingly important: how can and will patients participate in a possible economic perspective of 'their' data? This question will be asked more strongly, even if no ownership of data

	Ethical Concern	Explanation	Medical Example
Epistemic Concerns	Inconclusive evidence	Algorithmic outcomes (e.g. classification) are probabilistic and not infallible. They are rarely sufficient to posit the existence of a causal relationship	EKG readers in smartwatches may 'diagnose' a patient as suffering from arrhythmia when it may be due to a fault with the watch not being able to accurately read that user's heartbeat (for example due to the colour of their skin) or the 'norm' is inappropriately calibrated for that individual (Hailu 2019)
	Inscrutable evidence	Recipients of an algorithmic decision very rarely have full oversight of the data used to train or test an algorithm, or the data points used to reach a specific decision	A clinical decision support system deployed in a hospital may make a treatment recommendation, but it may not be clear on what basis it has made that 'decision' raising the risk that it has used data that are inappropriate for the individual in question or that there is a bug in the system leading to issues with over or under prescribing (Wachter 2015)
	Misguided evidence	Algorithmic outcomes can only be as reliable (but also as neutral) as the data they are based on	Watson for Oncology is in widespread use in China for 'diagnosis' via image recognition but has primarily been trained on a Western data set leading to issues with concordance and poorer results for Chinese patients than their Western counterparts (Liu et al. 2018)
Normative Concerns	Unfair outcomes	An action can be found to have more of an impact (positive or negative) on one group of people	An algorithm 'learns' to prioritise patients it predicts to have better outcomes for a particular disease. This turns out to have a discriminatory effect on people within the Black and minority ethnic communities (Garattini et al. 2019)
	Transformative effects	Algorithmic activities, like profiling, re-conceptualise reality in unexpected ways	An individual using personal health app has limited oversight over what passive data it is collecting and how that is being transformed into a recommendation to improve, limiting their ability to challenge any recommendations made and a loss of personal autonomy and data privacy (Kleinpeter 2017)
Overarching	Traceability	Harm caused by algorithmic activity is hard to debug (to detect the harm and find its cause), and it is hard to identify who should be held responsible for the harm caused	If decision made by clinical decision support software leads to a negative outcome for the individual, it is unclear who to assign the responsibility and /or liability to and therefore to prevent it from happening again (Racine et al. 2019)

Table 1. Ethical Criteria for Assessing Public Health Interventions (Marckmann 2020, p. 203; primary source in German translated by author).

is considered justifiable as of today (with good arguments, cf. Hummel et al. (2020) as well as Data Ethics Commission of the Federal Government (Datenethikkommission der Bundesregierung 2019)) – licensing models (Kerber 2016) as tested for decades in the media industry could form a bridge.

The Doctor Is In

The mediation of legitimate healing interests with justified concerns about dehumanised medicine, driven by minimal economic calculations, is the main task in medicine and the healthcare industry in the 21st century. Especially the data-driven use of AI, in this case, of course, ANI (Artificial Narrow Intelligence), is very impressive as far as the use cases in medicine are concerned, not everywhere but in many fields of application, and gives hope to many people but also professionals. However, in the closer context of concrete use cases, ethical considerations are substantial, as Morley and Floridi (2020) have elaborated (Table 1). In this context, a somewhat different logic of values is used as a basis for the digital public health sector than in Table 1, but the concerns are nevertheless comparable.

In particular, it is about algorithms, their development and application logic and their ethical evaluation. At first glance, it is clear that a kind of nomenclature of differentiated ethical issues is required, as well as intensive expertise in the field of digital medicine and the healthcare industry, in order to arrive at justifiable ethical conclusions. It is easy to imagine that

since ethical values, their validity and justification have always been and continue to be the subject of struggle, and since the intricacies of the digital transformation are not always amenable to consensus despite their scientific basis, such a conclusion is not always easy to reach consensually. For the private health of each individual and the further development of the professions, the question of the ethical evaluation of digital innovation in medicine and the healthcare industry will become central.

Digital Public Health Meets Ethics

Of course, digital public health is no more free of fundamental ethical questions than digital medicine and the healthcare industry are at the individual level, for example in the doctor-patient (AI) relationship. The medical ethicist Marckmann (2020) lists eleven ethical criteria for assessing public health interventions (Table 2).

This list makes clear already in the first access that value conflicts arise, and with those also the well-known solution challenges; one thinks of the middle principles of Beauchamp and Childress (2001) which also find application with Marckmann. In the end, it remains methodically comprehensible but logically unsatisfactory how the four principles can be clearly weighed against each other in materially rich cases in practice – consensus usually works better under ideal conditions than under real ones.



Evaluation Criterion		Ethical Foundation
Functionality	<ul style="list-style-type: none"> Technology objective Degree of goal achievement ("effectiveness") Data and information quality Technical efficiency 	<ul style="list-style-type: none"> End-means rationality Principle of non-maleficence Principle of beneficence
Alternatives	Possible alternatives to digital public health intervention	End-means rationality
Potential benefits for the target population	<ul style="list-style-type: none"> Improvement of mortality, morbidity and quality of life Validity (level of evidence) of the proof of benefit 	Principle of beneficence
Damage potential for the participants	<ul style="list-style-type: none"> Safety, low susceptibility to errors Burdens and health risks Validity (level of evidence) 	Principle of non-maleficence
Self-determination	<ul style="list-style-type: none"> Promotion of health literacy Possibility of informed decision Impact on freedom of choice 	Respect for autonomy
Protection of privacy and health data	<ul style="list-style-type: none"> Informational self-determination Procedural and technical data protection measures 	Respect for autonomy
Data security	Security against system-related loss of the integrity of health data	Principle of non-maleficence
Justice	<ul style="list-style-type: none"> Non-discriminatory access to intervention Distribution of health benefits and potential for harm Contribution to the reduction of health inequalities 	Principle of justice
Efficiency	<ul style="list-style-type: none"> (Incremental) cost-benefit ratio Validity of efficiency measurement 	<ul style="list-style-type: none"> Distributive justice in the face of scarce resources End-means rationality
Responsibility	Attributability of responsibility in the use of digital applications	Principle of non-maleficence
Legitimacy	<ul style="list-style-type: none"> Legitimate decision-making authority Fair decision-making process 	<ul style="list-style-type: none"> Principle of justice Respect for autonomy

Table 2. A Summary of the Epistemic, Normative and Overarching Ethical Concerns Related to Algorithmic Use in Healthcare (Morley and Floridi 2020, p. 6).

In any case, the relationship between private and public health is particularly tense; in the pandemic, we learn that not every person is able to recognise their own health in the health of others. Various criteria named by Marckmann are challenging in justification and implementation, especially justice and autonomy can be mentioned here. Autonomy presupposes much for the individual, justice for the many. The impending digital health divide affects the public sector in particular. If inclusion in schools is already hardly successful, what will be the impact of ineffective digital inclusion in healthcare?

In the case of health data in the sense of public health, it is particularly important that every person can trust the state to use their own data only for the common good. This is already a prerequisite. In addition, the concept of sovereignty is a convincing theoretical illustration of the protection of the each individual's privacy with the opportunities

for medicine as a whole and for the individual in particular, but in practice, as is becoming increasingly apparent, it is extremely difficult to implement.

An AI that is used responsibly in medicine is not 'a ring to rule them all', but a sharp sword which should be used very consciously; but then also really used and not pettily talked down by the naysayers. Ethics is the absence of pettiness and the presence of rational argumentation that does not confuse the emotions with one but also does not forget, because: the Good should have an impact in our world. So, it is in the end also true with the smart medicine.

Conflict of Interest

The author states that no conflict of interest exists. For this article the author has not used any studies on humans or animals. ■

REFERENCES

For full references, please email edito@healthmanagement.org or visit iii.hm/18m5