DIGITAL HEALTH

ETHICAL, LEGAL AND SOCIAL PERSPECTIVE FOR A SUSTAINABLE FUTURE



9-10 December 2020 Zagreb, Croatia

Agenda: Digital Health: ethical, legal and social perspective for a sustainable future

Digit-Heal

1

Meeting venue: Virtual meeting room

Wednesday December 9th 2020

- 10:00-10:15h Welcome address Anto Čartolovni, PhD, Digital healthcare ethics laboratory (Digit-HeaL), Catholic University of Croatia Prof Željko Tanjić, PhD, Rector, Catholic University of Croatia
- 10:15 12:45h **Panel 1: Impact of Digital health on healthcare** (Chair: Anto Čartolovni, PhD)
- 10:20 10:50h Keynote lecture 1: Sphere transgression and sector creep: the multiple sphere ontology of the digitalization and Googlization of health (Prof Tamar Sharon, PhD)

Participants presentations:

- 10:55 11:15h HealthCare 4.0 as human-centric process (Laura Corti, Prof Pierangelo Afferni, PhD, and Prof Marta Bertolaso, PhD)
- 11:20 11:40h Expectations and possible consequences of digital technologies in the field of health, medicine and health care (Ivana Marasović Šušnjara, MD, PhD, Maja Vejić)
- 11:45–12:05h Post-phenomenological and ontological reconstruction of the principle of vulnerability at the doctor-patient relationship in the digital age (Prof Julián Camilo Riaño Moreno MD, M.Sc, PhD)
- 12:10 12:40h **Discussion**

12:45 – 14:00h Lunch break

- 14:00 16:00h Panel 2: Current perspectives in Digital health (Chair: Ana Tomičić, PhD)
- 14:05 14:35h Keynote lecture 2: Digital Health Research: Truth or Consequences? (Prof Robin L. Pierce, PhD)

Participants presentations:

- 14:40 15:00h Big data in diabetes; technology as a useful servant but a dangerous master (Maja Baretić, MD, PhD)
- 15:05 15:25h Medical Ethics in Digital Health Era Should We Worry About Its Survival? (Morana Brkljačić, MD, PhD)
- 15:30 16:00h **Discussion**

Thursday December 10th 2020

- 10:30 13:00h Panel 3: Artificial intelligence in healthcare (Chair: Anto Čartolovni, PhD)
- 10:35 11:05h Keynote lecture 3: "I don't think people are ready to trust these algorithms at face value": Trust and the use of machine learning algorithms to augment the diagnosis of rare disease (Prof Nina Hallowell, PhD)

Participants presentations:

- 11:10 11:30h A.I. algorithms as the new medical experts: who should assess a medical case? (Jojanneke Drogt, Prof Annelien Bredenoord, PhD, Karin Jongsma, PhD and Megan Milota, PhD)
- 11:35 11:55h Implications of AI regulation on healthcare at the level of EU law (Prof Nina Gumzej, PhD)
- 12:00 12:20h Therapeutic relations in the age of AI: from paternalism to mutualcooperation (Cristina Voinea, PhD, Constantin Vică, PhD, and Alexandru Dragomir, PhD)
- 12:30 13:00h Discussion
- 13:00 14:00h Lunch break

- 14:00 17:00h Panel 4: : Integration of digital health in healthcare (Chair: Ana Tomičić, PhD)
- 14:05 14:35h Keynote lecture 4: Technological Innovation and the Future of Human Health (Marcello lenca, PhD)

Participants presentations:

- 14:40–15:00h The Role of Medical Professionalism for Non-Technical Innovations in Healthcare: Evidence from Hospitals (Anna Żukowicka-Surma, PhD and Albrecht Fritzsche, PhD)
- 15:05 15:25h CoViD-19, fundamental rights and the digital transition (Carlo Botrugno, PhD)
- 15:30 15:50h Ethical considerations in enforcing the use of a digital contact tracing app during the COVID-19 pandemic: do the benefits outweigh the risks? A case study from India (Saurav Basu, MPH, MD, DNB)
- 15:55 16:25h Discussion
- 16:25 16:30h Closure



(Panel 1)

Impact of Digital health on healthcare

(Chair: Anto Čartolovni, PhD Digit-HeaL, Catholic University of Croatia, Croatia)

Keynote lecture 1

Sphere transgression and sector creep: the multiple sphere ontology of the digitalization and Googlization of health *Prof Tamar Sharon, PhD

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4

The digitalization of health and medicine has engendered a proliferation of new collaborations between public health institutions and data corporations, such as Google, Apple, Microsoft and Amazon. Critical perspectives on this "Googlization of health" tend to frame them as an instance of market transgressions by tech giants into the sphere of health and medicine, in line with a "hostile worlds" doctrine that upholds that the borders between market and non-market spheres should be carefully policed. In this talk I discuss the limitations of this approach in the context of the Googlization of health. In order to move beyond these, I will advance a framework based on a multiple, rather than a dual, sphere ontology that draws on Boltanski and Thévenot's orders of worth and Michael Walzer's theory of justice. I show how this analytical framework is better equipped to identify and address the numerous risks posed by the involvement of these corporations in health and medicine.



Participants presentations

HealthCare 4.0 as human-centric process

*Laura Corti, *Prof Pierangelo Afferni, PhD, and *Prof Marta Bertolaso, PhD

*Università Campus Bio-Medico of Rome

We are experiencing a situation that sees the emergence of a new paradigm of care, called Healthcare 4.0. This new model brings the following improvements: strengthen prevention processes, improve health systems' sustainability, make better care services for chronic patients and aged patients.

From a theoretical point of view, the Healthcare 4.0 paradigm especially stresses a shift from patient-centred care to a patient-centric approach, in which the patient is actively involved in a personalized model of care. This new patient becomes increasingly 'smart' using modern technological devices to monitor his or her health condition. However, such change implies both theoretically and practically a shift from a control paradigm to a paradigm of care, i.e. a way of doing things that invest in the Spatio-temporal dimensions of human beings.

This paper thus aims to investigate and shed light on the positive and negative consequences, i.e. the benefits and risks, of this now pervasive use of technology in the health sector. We will examine, therefore, the human-technology relation that can be outlined in two essential models: technology as a tool for care and technology as a replacement for the human operator. Based on this consideration, the specific objective is to highlight two ethical and social issues that urgently emerge from the use of this technology:

1. the substantial and qualitative difference of the human relationship mediated by technology versus a direct interaction with an artificial assistance system, in the event of the onset of disease;

2. the pervasiveness of technology that leads to an abuse of technological solutions with consequent ethical repercussions on the management of health data.

To achieve this goal, we will reflect on the concept of disease as an emerging state that requires a flexible approach, sensitivity and detailed knowledge of the patient's past conditions in order to define the medical diagnosis and therapeutic treatment, rather than interacting solely with "chatbots" or relying on virtual agents, based on Artificial Intelligence, which by their nature follow predefined protocols. On the other hand, the pervasive use of technology and its application in healthcare also requires a reflection on the flow of data and their storage, observing how digital tools can be a fundamental resource for the doctor.

In conclusion, we want to point out that the best use of technology in the treatment process is not so much the complete replacement of the human operator, but the mediation of technology in the relationship between patient and caregiver. Technology becomes essential healthcare support to develop personalized medicine in which the human being is at the centre of progress in a participatory and proactive way.

Expectations and possible consequences of digital technologies in the field of health, medicine and health care

*Ivana Marasović Šušnjara, MD, PhD, **Maja Vejić

 * Teaching Public Health Institute of Split and Dalmatian County, Split, Croatia
** Faculty of Humanities and Social Sciences, Department of Philosophy, University of Zagreb, Zagreb, Croatia

As modern technology has become more advanced and widespread, it has found its place in all segments of society, including healthcare. The implications of using technology to promote health and health care or e-health are significant. One of the main arguments supporting this is that the various tools (such as mobile applications, mobile phones, patient monitoring devices, personal digital assistants etc.) could "empower" individuals with the data they need to be proactive in advancing their health and preventing disease.

It is therefore necessary to consider certain issues related to the usage of modern technologies in the fields of health, medicine and healthcare as well as possible negative consequences. To what extent are end users able to use technology? That is, what is their level of e-literacy? Does the digital divide lead to the creation of vulnerable groups (citizens and / or countries)? What are the chances that digitalization in medicine and healthcare will be manipulated by powerful technology companies? What new framework is being created in physician-patient communication?

Certainly, some answers could be sought in both the professional and ethical approach of all participants, from creators to users of various digital technologies.

Post-phenomenological and ontological reconstruction of the principle of vulnerability at the doctor-patient relationship in the digital age

*Prof Julián Camilo Riaño Moreno MD, M.Sc, PhD

* Department of Bioethics, Universidad El Bosque, Bogotá D.C., Colombia Faculty of Medicine, Universidad Cooperativa de Colombia, Villavicencio. Colombia

The doctor-patient relationship is the center of medicine. It is built on contact and trust and aims to ensure proper medical practice. It is commonly perceived as a dissymmetrical contractual relationship, where one actor -the doctor- has wisdom and is healthy while the other actor -the patient- lacks health and knowledge. This characteristic fosters the dependence on the doctor and gives him(er) great powers that can harm the patient, that is, vulnerability is born.

The classic -and romantic- principle of the vulnerability used in health services, derived from the "Ethics of care" or the "Caress ethics ", focuses on a form of what I call "unidirectional relational vulnerability", where only the patient is a vulnerable agent and the ethical obligation is to recognize him(er) as such and take care of him(er). However, what these approaches do not identify is that the doctor is also a dependent subject and vulnerable. The doctor depends both: on the patient to define his experience and purpose for the world, and on political, social, economic and market agents, who define the conditions of possibility for his(er) activity. Although this is less obvious, the doctor vulnerability is both relational and existential who in the encounter with other vulnerable -the patient-, risks and damages may emerge.

Digital technologies open the medicine dynamics to the world. Pull off the ritual, mystical and doctor restricted activity and transgress the limits of the human being as object of study of medicine. Digitalization also brings to the medicine previous alien industries and institutions, grants new and greater powers to traditional ones. Increases the distance and minimizes the contact between health agents, introduce new agents (machines and algorithms) within the doctor-patient relationship. Creates new and technological needs and dependencies. In short, the doctor-patient relationship is transformed by reducing the role of the doctor and boosting the role of the technology. Thus, the already exhausted approximations of the vulnerability from the Ethics of care and Caress ethics are insufficient to understand the doctor-patient relationship dynamics in the digital age.

First, I argue that the perpetuated and obsolete view unidirectional relational vulnerability) of the vulnerability at the doctor-patient relationship results from a deliberate exclusion of the technology from medicine. The health agents perceiving medical technologies as tools, devices or mere externalities what makes technologies look neutral and their consequences depends upon its modes of use. In this sense, the responsibility lies on the user, the doctor. Therefore, I propose that traditional vulnerability in health require a reconstruction from a post-phenomenological point of view plus and existential-ontological approach of the technology and vulnerability this enables the comprehension of the medical technology as a system-like way, allows identify new forms of vulnerability, where, from the beginning the doctor (and the patient) is a vulnerable agent and this enables a better and expanded understanding of the traditional and the renew doctor-patient relationship dynamics in the age of digital health.



Current perspectives in Digital health

(Chair: Ana Tomičić, PhD Digit-HeaL, Catholic University of Croatia, Croatia)

Keynote lecture 2

Digital Health Research: Truth or Consequences? *Prof Robin L. Pierce, PhD

*Tilburg Institute of Law, Technology, and Society (TILT), Tilburg Law School, Tilburg University, The Netherlands

8

This paper explores the shifting, blending, and porous ethical and legal boundaries of digital health research, with particular focus on deep digital phenotyping. This comprehensive approach to data collection for the purposes of health research and monitoring holds out possible benefits, but the ethical and legal challenges abound. Standard approaches to ethics governance, e.g. via Research Ethics Committees, are effective up to a point. The new territory presented by digital health research and deep digital phenotyping, in particular, present new and pressing challenges. This paper identifies key limitations of current oversight, the emerging landscape of risk, and offers possible approaches for addressing the gaps.



Participants presentations

Big data in diabetes; technology as a useful servant but a dangerous master *Maja Baretić, MD, PhD

> *Department of Endocrinology, University Hospital Centre Zagreb, Croatia School of Medicine, University of Zagreb, Croatia

The future of healthcare is taking shape before our eyes with the advances of digital technology. A new dimension of life, the digital interface, is replacing the interpersonal one. Technology is a new form to humanity; it is infiltrating all aspects of life. It is changing the pattern of thinking and behavior of homo sapiens. Diabetes mellitus is a metabolic disorder characterized by high blood glucose. Glucose regulation is one of the most refined ones in the body; slight elevation of glucose results in many hormonal and metabolic actions. The consequence of such swings could be devastating organ damages. While treating diabetes the key word is information, with current glucose level being the most important one. On the basis of such information important decision considering diabetes therapy are made every day. Treatment of diabetes mellitus is currently experiencing huge improvement due to technological progress. The future of diabetes treatment will greatly benefit from the new technologies mostly through innovation from glucose measurement. In the recent past, people living with diabetes had to prick their fingers to check their blood sugar levels from several times a day.

Recently, technology has provided innovative approaches like Continuous Glucose Monitoring (CGM), a method developed to track glucose levels throughout the day and night at regular intervals, 24 hours a day. CGM uses an electrochemical enzymatic sensor measuring glucose in subcutaneous tissue at and does not require fingerpick. CGM is converting the readings into dynamic data, generating glucose direction and rate of change. The huge amount of data is precious, but not easy to interpret. At a glance, clinicians and patients can determine the extent to which glucose values are within the target range, and the times of day that pose potential danger for low or high glucose values. Such vast amount of data is beneficial; however, they are putting a new challenge for both medical professionals and patients.

The new scheme of data processing is totally different from the one in use 20 year ago; mankind is not looking for information anymore; it is mining for the appropriate one. It is not clear who is responsible to educate healthcare professionals regarding the usage of technology and regarding the cybersecurity. Should they be self-educated, is it responsibility of School of Medicine, a facility they are employed in, is it the duty of the health insurance system or a task for the IT software provider? Who is going to educate healthcare professionals who are not advanced in digital literacy, but are excellent in clinical practice?

In order to improve health professionals' knowledge, educational solutions for digital skills should be developed. A proper individual education should be incorporated in innovative medical curriculum. In that way, despite the obvious concerns regarding security, the advantages of technology use in healthcare will outweigh the disadvantages.

Norwegian diplomat and Nobel Peace Prize Winner in 1921, Christian Lous Lange, said "Technology is a useful servant but a dangerous master." He saw it coming.

Medical Ethics in Digital Health Era – Should We Worry About Its Survival ? *Morana Brkljačić, MD, PhD

* Medical Clinic "Sveti Rok M.D." Zagreb, Croatia Catholic University of Croatia University of Zagreb, Medical Ethics

Ethics, sometimes known as philosophical ethics, ethical theory, moral theory, and moral philosophy, is a branch of philosophy that involves systematizing, defending and recommending concepts of right and wrong conduct, often addressing disputes of moral diversity. The field of medical ethics is really about reflections on how to behave as a medical professional as well as the morality of particular medical interventions. Medical ethics are simply some key ethical principles applied to the practice of medicine. These principles are the bedrock of good clinical practice - autonomy, nonmaleficence, beneficence and justice. Using these principles in each individual case, it can be easier to make difficult decisions with your patients as you guide them through their care.

The practice of medicine is an art and a science. The art comes from dealing with human beings, who can be fragile and unpredictable when they are sick and are in need of help. The science comes from years of research and study.

Medical ethics puts the art and science together in practical applications to tricky problems. Everyone makes mistakes, but it's possible to learn from medical errors and design your/our practice so they are recorded and fixed before they become serious problems or affect patients. Can traditional medical ethics – bioethics satisfactorily encompass the explosion of biological and medical technologies?

While the plethora of artificial biomedical applications is enriched and combined with the possibilities of artificial intelligence, bioinformatics and nanotechnology, the variability in the ideological use of such concepts is associated with bioethical issues and several legal aspects. The convergence of bioethics and computer ethics, attempts to illustrate and approach problems, occurring by the fusion of human and machine or even through the replacement of human determination by super intelligence.



Artificial intelligence in healthcare

(Chair: Anto Čartolovni, PhD Digit-HeaL, Catholic University of Croatia, Croatia)

Keynote lecture 3

"I don't think people are ready to trust these algorithms at face value": Trust and the use of machine learning algorithms to augment the diagnosis of rare disease *Prof Nina Hallowell, PhD

> *The Ethox Centre and Wellcome Centre for Ethics & Humanities, Nuffield Department of Population Health, and Big Data Institute, University of Oxford

> > 11

It has been argued that trust and trustworthiness are essential aspects of the healthcare relationship and are extremely important for the uptake of AI within healthcare. My presentation will look at the ways in which ways in which trust and trustworthiness in AI research is conceptualized by clinician researchers and data scientists from the public and private sector who work in the field of computational phenotyping research. Computational (or digital) phenotyping is perceived as providing a potential breakthrough in the diagnosis of rare genetic diseases. It involves the use of digitized photographs (and other biomedical data) of people with a clinical or molecular diagnosis of a rare (genetic) disease to train facial recognition (FR) algorithms to identify (and classify) the phenotypic features associated with different disorders. The aim of our qualitative project was to investigate data scientists and clinical researchers' views on the ethical issues emerging from the use of this type of FR technology in rare disease research and the sharing of identifiable data. Data was collected in online interviews (n=20) with researchers from the public and private sectors. Trust and trustworthiness emerged as an important issue in the interviews from the outset. The different ways in which trust is conceived by interviewees and the implications of this for the implementation of AI in healthcare will be discussed.



Participants presentations

A.I. algorithms as the new medical experts: who should assess a medical case? *Jojanneke Drogt, *Prof Annelien Bredenoord, PhD, *Karin Jongsma, PhD and *Megan Milota, PhD

> *Medical Humanities department at UMC Utrecht and Utrecht University

The ability to assess a medical case typically resides with the physician, the expert who has the experience and knowledge to judge its medical severity. Yet the current digital transition in medicine might change the frameworks in which medical expertise is viewed. For example, the rapid development of artificial intelligence (AI) systems for image-based medicine (radiology and pathology) focus on supporting the physician in her diagnostic process.

The driving force behind this development rests on the increasingly validated hypothesis that certain diagnostic tasks can be performed through the use of AI – with the same or better diagnostic accuracy and speed as the radiologist or pathologist (Esteva et al. 2017; Gulshan et al. 2016; Rajpurkar et al. 2017; Watson et al. 2019). With AI algorithms becoming increasingly prevalent in diagnostic processes, this raises the ethical question whether AI should be leading in medical decision making. In this talk, I intend to address this ethical question and argue that the final judgment concerning a medical case should remain to be the domain of the physician. Medical judgements incorporate complex, sometimes fuzzy, elements of medical practice and connect the relevant parts with one another in order to form a diagnosis. Furthermore, I assert that while AI algorithms might have or attain superior knowledge on certain aspects of a medical assessment, the ability to deal with medical uncertainty, the specific context and moral considerations associated with a medical case can (at least for now) and should belong solely to the human mind.

Implications of AI regulation on healthcare at the level of EU law *Prof Nina Gumzej, PhD

*Chair of Information Technology Law and Informatics University of Zagreb Faculty of Law

In this presentation critical steps toward AI regulation at the level of EU law are explored. The analysis is made in the context of upcoming regulatory proposals from the European Commission and by taking into account selected key reports and results of the recently closed consultations on the Commission's White Paper on Artificial Intelligence. It is beyond doubt that the AI has astounding potential to transfigure healthcare by creating many breakthrough opportunities and benefits. At the same time, the legal and ethical issues raised by its deployment in healthcare are diverse and complex. In order to minimize future risks it is necessary to analyze and evaluate how it can be ensured that the AI solutions are suitable for the intended use, i.e., that they do what we want them to do, and that they do it correctly and safely. The capacity of the AI to perform tasks which are now performed by humans will lead to the replacement of human action in a number of important segments of the provision of the health services. While AI can be faster, cheaper, more accurate and advanced, it is imperative that the potential risks and negative consequences in relation to its deployment are kept in mind. Consequently, in-depth understanding of the implications that the use of AI has and may have on patients, the healthcare sector, and the society in general should be permanently cultivated. A number of concerns over deployment of AI relate to its transparency, explicability, security, reproducibility, and interpretability. For example, questions are raised whether it is possible to discover why and how AI has made a specific decision, or why and how a robot acted in the way it did. This is crucial in particular in the context of safety-critical systems that may have direct consequences for physical harm, such as medical diagnosis systems. Where regulatory responses are concerned, for example, the rules fostering principles of transparency and fairness that are already in force at the level of EU law appear to respond well to some of those risks. In other aspects, new and/or updated regulatory responses may be necessary. Overall, it is concluded that the area of healthcare necessitates appreciation of the AI as an important tool that should be designed and used in a manner serving the benefit of humankind, and that any consistent regulation at the level of EU law should primarily support that higher goal.

Therapeutic relations in the age of AI: from paternalism to mutual-cooperation

*Cristina Voinea, PhD, **Constantin Vică, PhD, and **Alexandru Dragomir, PhD

> * Bucharest University of Economic Studies, Department of Philosophy and Social Sciences ** University of Bucharest, Department of Philosophy

Medicine has always been constituted by technology. From microscopes and stethoscopes, to thermometers and defibrillators, technological artifacts were always used in order to enhance, improve and render more efficient patient care and management. Artificial intelligence systems used in clinical settings are the latest development in the relation between medicine and technology. But unlike previous medical technological artifacts, whose main role was to mediate and enhance physicians' senses and physical capacities, current AI systems have a completely different purpose. Their aim is to increase or, at least, improve, physicians' reasoning and decision-making capacities. As such, AI systems are important moral proxies in doctor-patient relationships, with the potential to assist and guide doctors in their reasoning, but also able to make their own decisions concerning the treatment and care of patients. The main claim of this paper is that current AI systems have the potential to introduce another layer of paternalism in doctor-patient relationships. We show that because they assume decision-making authority and impose their own answers regarding what is patients' best interest, they can hamper shared decision-making between physicians and patients. Medical decisions involve not just clinical information, but also values and preferences. For example, not everyone values the prolongation of life in any circumstances, some may value the quality of life more. As such, when Al systems are used, it is not the patients' values which drive the ranking and decisions about treatment options. Moreover, current AI systems are unable to produce comprehensible explanations for human experts, who in their turn cannot share relevant information with their patients. Reduced comprehensibility prevents patients from acting autonomously. As such, we stress that medial AI systems should be designed with an eye on how they alter therapeutic relationships. More specifically, medical AI should foster patient-centered therapeutic relationships, which have been proven to increase adherence to treatment, enhance autonomy of both doctors and patients as well as trust between them and decrease the general discomfort of medical services and treatments. The patient-centered orientation is based on two ideals: firstly, patients should be treated as individuals whose values, beliefs and social contexts shape their health. This ideal is based on the fact that medical decisions involve not just clinical information, but also values and preferences. Secondly, if the therapeutic process is value laden, then doctors should treat patients as partners in decision-making processes, as treatment should also be shaped by patient's values. In the end we discuss some of the criteria that must be met by AI systems that enhance both patients' and physicians' autonomy and foster shared decision-making in clinical settings.

(Panel 4)

Integration of digital health in healthcare

(Chair: Ana Tomičić, PhD Digit-HeaL, Catholic University of Croatia, Croatia)

Keynote lecture 4

Technological Innovation and the Future of Human Health *Marcello Ienca, PhD

*Chair of Bioethics | Health Ethics & Policy Lab Competence Center for Rehabilitation Engineering and Science (RESC) Department of Health Sciences & Technology (D-HEST) Swiss Federal Institute of Technology | ETH Zurich

Big data, Artificial Intelligence and Neurotechnology hold promise for improving prevention, enabling earlier diagnosis, optimizing resource allocation, and delivering more tailored treatments to patients with specific disease trajectories. At the same time, due to their methodological novelty, computational complexity and reliance on data mining for knowledge generation, these technological trends raise ethical challenges. This talk presents an overview of the major ethical challenges associated with the technological transformation of human health. These include demarcating the boundary between personal health data and non-health data, re-defining the notion of private information, sustaining trust in health data sharing, preventing data-driven discrimination, empowering people through technology and ensuring a fair distribution of health benefits among all stakeholders. Case studies from dementia research and public mental health will be discussed to illustrate these challenges and provide an ethical assessment. Furthermore, this talk will provide an overview of the normative proposals that have been recently advanced to align technological innovation for human health with established regulatory frameworks such as data protection regulation, regulation on human subject research and ethics review. Based on this analysis, suggestions will be made on how to maximize the benefits of technological innovation while minimizing ethical risks.

Participants presentations

The Role of Medical Professionalism for Non-Technical Innovations in Healthcare: Evidence from Hospitals

*Anna Żukowicka-Surma, PhD and **Albrecht Fritzsche, PhD

* Kozminski University Warsaw, Poland ** Ulm University, Germany

The digital transformation is driven by two kinds of innovations: (1) technical innovations regarding the effects and efficiency of tools, machines and systemic infrastructure and (2) non-technical innovations regarding the organisational settings in which technical tasks are performed. While technical innovations receive a lot of attention in research, non-technical innovations are rarely addressed. In many cases, they are considered as mere adoption efforts that appear in the aftermath of technical innovations. This may be defensible in manufacturing and other mechanistic fields of industry, but healthcare and other services with an inherent relation to human well-being require a more elaborate approach.

In our paper, we study non-technical innovations in healthcare on the example of hospitals in Poland. Our research is guided by the question how such innovations are enabled or restrained by the given organizational setting. Based on extant literature, we identify the conflict of different institutional logics in hospitals as a critical issue for the success of non-technical innovations. Unlike other organizations, hospitals do not only struggle with the co-existence of bureaucratic rules and market-based self-organization, but they are also affected by a different institutional logic. With Freidson, this logic can be called "professionalism". It finds expression in the professional ethics, codes of conduct, outwards appearance and claims of responsibility of medical personnel. For our empirical work, we use an ethnographic approach. We perform case studies in hospitals from a participatory perspective and corroborate the findings with semi-structured expert interviews. Based on the collected data, we identify different scenarios in which professionalism in-between bureaucracy and self-organization restrains non-technical innovations, but also other scenarios where it enables such innovations. We discuss examples related to the design of decision-making processes, the introduction and break-up of standards, time management and communication patterns. On the one hand, our findings show that professionalism can foster rivalry and reduce the willingness to take over responsibility for uncustomary tasks. On the other hand, they show that professionalism can motivate a deeper engagement in problemsolving activities and persistence in searching better solutions for the patients. Based on our findings, we develop the concept of Innovation Action Commitment as a guiding principle for the enablement of nontechnical innovations in healthcare. We critically discuss possibilities for implementation and explore the role of dedicated innovation spaces to overcome the conflict between organizational logics.

CoViD-19, fundamental rights and the digital transition

*Carlo Botrugno, PhD

* Research Unit on Everyday Bioethics and Ethics of Science L'Altro Diritto Inter-university Research Centre Department of Legal Sciences, University of Florence, Italy

The spread of CoViD-19 has upset the ways of living of a great part of the population worldwide, leading to an unprecedented compression of fundamental rights and individual freedom in the name of public health protection. Most of the strategies adopted to combat the infection have accelerated the transition towards the 'digital'. Insofar as we have switched a significant part of our lives to remote working and virtuality, ICTs gained momentum and reshaped the landscape and the meaningfulness of our social relations. Indeed, most of the countries gravely affected by CoVid-19 have relied on new technologies to implement strategies aimed at curbing its spread. Consequently, also the discussion around the use of new technologies came out from the narrow boundaries of the academic debate. This acceleration has made the ambivalence of technologically-mediated services evident, given that they bring impressive opportunities whilst at the same time threaten consolidated notions and principles inspiring the guarantee of fundamental rights and freedoms.

On the one hand, ICTs are playing a fundamental role in allowing the (remote) delivery of healthcare services despite imposed restrictions – i.e. lockdown, quarantine and self-isolation. Indeed, digital healthcare services have proven to be fundamental for respecting social distancing and thus protecting both healthcare professionals and patients from further risk of infection. On the other hand, ICTs have been pivotal in the spread of services and tools – e.g. drones, biometric bracelets, and contactless body heat detectors, proximity tracing apps – aimed at controlling the population's respect of the aforementioned restrictions. Very divergent interpretations have been given about the implementation of these technologies: while someone claimed that they could be fundamental in containing the virus outbreak, others have looked at its spread as the opportunity to inaugurate a permanent state of exception' in contemporary societies.

In my communication, I will briefly identify and comment on the main ethical, legal and social implications posed by the use of ICTs for containing pandemics. These issues can be clustered in three categories: a) the digitalization of healthcare-delivery; b) the challenge of protecting most vulnerable groups; c) surveillance and other restrictions to fundamental rights in the name of public health. A special attention will be paid to the latter, aiming at highlighting the (e)merging logics of health protection and control which could indelibly change the face of contemporary societies, i.e. incorporating notions of "risk" and "preventive defense" that provide a legitimate ground for feeding policies of technological innovation.

Ethical considerations in enforcing the use of a digital contact tracing app during the COVID-19 pandemic:

do the benefits outweigh the risks? - A case study from India

*Saurav Basu, MPH, MD, DNB

* Department of Community Medicine, Maulana Azad Medical College, New Delhi, India

Contact tracing is a well-established epidemiological driven mechanism for interrupting the chain of transmission of infectious diseases. During the COVID-19 pandemic, the World Health Organization (WHO) has strongly emphasized the need to implement contact tracing involving the identification, location, and assessment of the contact-people followed by their testing, quarantine, or isolation. However, the feasibility of manual contact tracing is diminished during widespread community transmission of the infection. During this period of intense transmission, specifically designed mobile phone applications have been used to enhance contact tracing through both automated and participatory disease surveillance by the users.

Digital contact tracing has obvious advantages compared to manual operations since it does not require dedicated health workers who are prone to infection and may lack motivation over time. Moreover, the application can digitally record the entire travel history of a suspected patient without any recall bias, and the pooled data can be examined for recognizing hotspots. Contact tracing applications can prevent several excess cases and forewarn individuals at higher risk of infection, especially from asymptomatic contacts. However, a single contact-tracing application needs to be adopted by a critical population mass for it to translate into an effective public health intervention.

Nevertheless, several civil rights organizations and ethicists have rejected the idea of compulsory installation of any such app due to concerns over violation of the user's autonomy and privacy through potential mass surveillance. However, persuading people to install a mobile phone application voluntarily has limited effectiveness compared to legislation or executive orders mandating compulsory installation. Consequently, there is a need to assess the ethical considerations involved in the government using its coercive power to promote a contact tracing app for curbing the disease. Previously, ethical frameworks for application in public health emergencies have recognized specific justificatory conditions that uphold ethical virtue despite the state's coercive action towards promoting the greater public good (Ushur: 2002; Childress: 2002).

We argue that within functional democratic societies, during a pandemic, the responsibility of the government is limited to satisfying the reasonable individual's concerns over issues that restrict their autonomy or privacy such as the mandatory adoption of digital contact tracing, a position consistent with Mill's classic harm principle for the prevention of 'harm to others'.

To date, India is the only democratic country in the world where the mandatory installation of a governmentdesigned contact tracing smartphone application, the Aarogya Setu (from Sanskrit, the bridge to health) was approved under certain situations involving public interactions. Using this case study, it is shown that the ethical legitimacy of digital contact tracing as a pandemic response strategy entails demonstration of trust and commitment to transparency. The Aarogya Setu app includes an explicit privacy policy with predefined limits on data collection, usage, and data destruction timelines, together with an open-source release and a bounty hunter program. However, peer-reviewed research showing the app data's effectiveness in slowing the pandemic is still needed for ethical validation of the principle supporting the app's continued and compulsory usage.

Contents

Conference Agenda

Panel 1: Impact of Digital health on healthcare

Keynote lecture 1: Sphere transgression and sector creep: the multiple sphere ontology of the digitalization and Googlization of health (Prof Tamar Sharon, PhD)

HealthCare 4.0 as human-centric process (Laura Corti, Prof Pierangelo Afferni, PhD, and Prof Marta Bertolaso, PhD)

Expectations and possible consequences of digital technologies in the field of health, medicine and health care (Ivana Marasović Šušnjara, MD, PhD, Maja Vejić)

Post-phenomenological and ontological reconstruction of the principle of vulnerability at the doctor-patient relationship in the digital age (Prof Julián Camilo Riaño Moreno MD, M.Sc, PhD)

Panel 2: Current perspectives in Digital health

Keynote le	ecture 2:	Digital	Health	Research:	Truth or	Consequences?	(Prof Robin L	 8
Pierce, Ph[D)							

Big data in diabetes; technology as a useful servant but a dangerous master (Maja Baretić, MD, PhD)

Medical Ethics in Digital Health Era – Should We Worry About Its Survival? (Morana 10 Brkljačić, MD, PhD)

Panel 3: Artificial intelligence in healthcare

Keynote lecture 3: "I don't think people are ready to trust these algorithms at face value": Trust and the use of machine learning algorithms to augment the diagnosis of rare disease (Prof Nina Hallowell, PhD)

A.I. algorithms as the new medical experts: who should assess a medical case? (Jojanneke Drogt, Prof Annelien Bredenoord, PhD, Karin Jongsma, PhD and Megan Milota, PhD)

Implications of AI regulation on healthcare at the level of EU law (Prof Nina Gumzej, PhD)

Therapeutic relations in the age of AI: from paternalism to mutual-cooperation (Cristina Voinea, PhD, Constantin Vică, PhD, and Alexandru Dragomir, PhD)

Panel 4: Integration of digital health in healthcare

Keynote	lecture	4:	Technological	Innovation	and	the	Future	of	Human	Health
(Marcello	lenca, P	hD)								

The Role of Medical Professionalism for Non-Technical Innovations in Healthcare: Evidence from Hospitals (Anna Żukowicka-Surma, PhD and Albrecht Fritzsche, PhD)

CoViD-19, fundamental rights and the digital transition (Carlo Botrugno, PhD)

Ethical considerations in enforcing the use of a digital contact tracing app during the COVID-19 pandemic: do the benefits outweigh the risks? – A case study from India (Saurav Basu, MPH, MD, DNB)

9

1

4

5

6

7

11

12

13

14

15

16

17

18

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