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Application of Artificial Intelligence in healthcare: potential, risks and legal challenges

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Application of Artificial Intelligence in healthcare: potential, risks and legal challenges

*Ekaterina Kasyanova**

ABSTRACT: This paper provides an overview of potential and actual application of artificial intelligence in the healthcare sector through displaying the ongoing projects and recent developments in the field, including the integration of AI into biotechnology. The attention to possible risks and legal challenges is drawn through the analysis of issues arising from biases and complexity of compliance with data protection regimes. The focus remains on the EU. The paper is concluded by drawing the line of relevance to the covid-19 pandemic, and AI potential to contribute to the resolution of the crisis.

KEYWORDS: Artificial intelligence; healthcare; biotechnology; personalised treatment; covid-19

1. Introduction

Through years, one of the purposes of healthcare worldwide has been saving people's lives through the development of various ways that result in advancing the diagnosis and treatment stages, and deepen understanding of the nature of diseases.

Life sciences have been playing an enormous role in achieving these goals. One of innovations is utilisation of biotechnology to discover treatment to the illnesses of different nature and make this treatment work for a patient with specific biological features.

Biotechnology essentially modifies DNA and proteins to shape the living cells in order to make them more useful for specific purposes. In other words, it is manipulation conducted with the DNA, found in nature[1]. It might sound as something remote from everyday life, however, products created with the use of biotechnology are more spread than we assume at first. The examples are many, from development of pest resistant plants, new breeds of plants and animals to the advancement of vaccines and antibiotics. In medicine, DNA sequencing has an enormous impact, for instance, it makes identification of a risk of genetic diseases possible.

In the time of a pandemic, which is exceptionally relevant at the point of writing this paper, usage of biotechnology for vaccine deployment could have a vital significance. The potential is that through the identification of the markers of an illness, a vaccine can be synthesized, what could potentially prevent or

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[1] https://www.ntnu.edu/ibt/about-us/what-is-biotechnology - last accessed 31 May 2020.

help dealing with a pandemic or a widely-spread disease[2]. At the point, the application of Artificial Intelligence becomes a game-changer in the processes of searching and fining the cure.

Undoubtedly, there are numerous complications throughout the stages of vaccine deployment, among which time-consuming clinical trials could be listed. In such circumstances AI becomes an essential element. For instance, due to the application of AI, development of a drug for obsessive-compulsive disorder during the exploratory research phase[3] took only 12 months to get to clinical trial, whereas normally, it is assumed to take 5 years. Recently, in February 2020, this drug, DSP-1181, has entered the stage of human clinical trial[4].

In health-related areas, one of the main aims of application of AI is similar to the objectives of biotechnology: analysis of outcomes that would be experienced by a patient when prevention or treatment methods are used. In other words, AI is applied in disease diagnostics, development of medicaments, and other areas of medicine. One of the purposes is to make a "personalised" treatment and care for a patient.

1.1 What is AI and how does it work?

Artificial Intelligence is very often spoken of, especially in our world of developing technologies. We hear about its application in various fields of our lives, and debate on its importance and influence. However, it might be found unreasonable to talk about the concept without describing it. The essence of understanding an issue is to realise what is being dealt with.

Artificial intelligence is not a new concept, even though its certain application is undoubtedly innovative. The formulation of the definition belongs to John Mccarthy, who developed it in 1956, within the framework of the workshops at Dartmouth College, as following: «Every aspect of learning or any other feature of intelligence can in principle be so precisely described that a machine can be made to simulate it. An attempt will be made to find how to make machines use language, form abstractions and concept, solve kinds of problems now reserved for humans, and improve themselves»[5].

The application of artificial intelligence essentially aims at problem-solving; the ultimate goal might be considered as making computer programmes to solve the problems in the way as humans do. The observation of people's behaviour and methods is an important step in order to design the algorithm with the above-mentioned goal in mind; and yet, the problem-solving task shall not be drawn out of the picture,

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[2] *One of the examples is a polio vaccine developed with biotech in 1952 - https://www.bharatbiotech.com/biopolio.html .*

[3] *Developed by an Oxford-based AI start-up, Exscientia, in collaboration with the Japanese pharmaceutical firm Sumitomo Dainippon Pharma: https://www.ft.com/content/fe55190e-42bf-11ea-a43a-c4b328d9061c .*

[4] *Balfour, H. (2020, February 4). DSP-1181: drug created using AI enters clinical trials. Retrieved May 9, 2020, from https://www.europeanpharmaceuticalreview.com/news/112044/dsp-1181-drug-created-using-ai-enters-clinical-trials/.*

[5] MCCARTHY, JOHN. HUBERT DREYFUS*, What Computers Still Can't Do. Artificial Intelligence*, vol. 80, no. 1, 1996, pp. 143–150.

thus, imitation of human behaviour does not appear to be the sole purpose of AI; certain methods which involve more computation, than humans can do, are preferable in certain situations[6].

It is crucial to remember that AI does not represent a wonder-machine which is capable of resolution of every existing problem that humans have faced. Rather, AI is based on the utilisation of various mathematic algorithms which aim to learn from the huge amount of data in order to solve the problems that are considered to be solved only by humans. And the strong side of AI is its capability to solve such problems with high accuracy.

As Figure 1 displays, machine learning and deep leaning could be found under the AI umbrella. Artificial Intelligence can be defined as a technique that enables machines to mimic human behaviour, sense, reason, act and adapt. Machine learning, generally refers to algorithms whose performance improves with experience learnt from data over time. And deep learning as a subset of machine makes the computation of multi-layer neural network feasible[7].

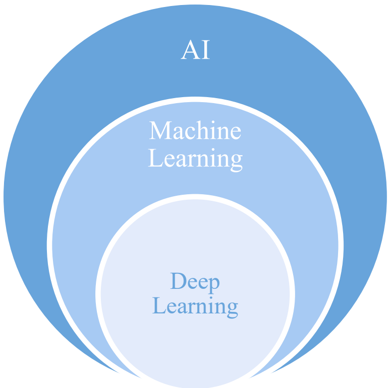

Figure 1. *Inspired by the figure provided by https://www.researchgate.net/post/AI_vs_Machine_Learning_vs_Artificial_Neural_Network_vs_Deep_Learning*

There are variously designed algorithms that are applied within different projects, for the sake of an example and further purposes, let's have a short look on how an Artificial Neural Network (ANN) operates. ANNs are designed on the basis of neurones in the human brain (or at least how we assume those neurones work), which enables it to recognize patterns in data, hence to learn from it. To teach such a network to differentiate among images (for instance, between images of cats and dogs), a huge number of tagged examples (like "cat" or "dog" for images containing the respective animal) needs to be fed to the algorithm. The network then is able to also classify input data that it has not "seen" before (test data) through the parameters it derived from processing these examples (training data).

[6] *For example, hand-writing recognition.*

[7] A detailed distinction is presented here: https://sonix.ai/articles/difference-between-artificial-intelligence-machine-learning-and-natural-language-processing - last accessed 26 May 2020.

Figure 2 depicts an illustration of such model; it helps to understand the concepts behind the algorithm. “Input Layer” refers to the data as given to the algorithm. Through “Hidden Layers” containing parameters and weights, the algorithm is searching for combinations best suited to identify the image. “Output Layer” refers to the result as provided by the algorithm e.g. the probability for an image to be displaying a cat or a dog.

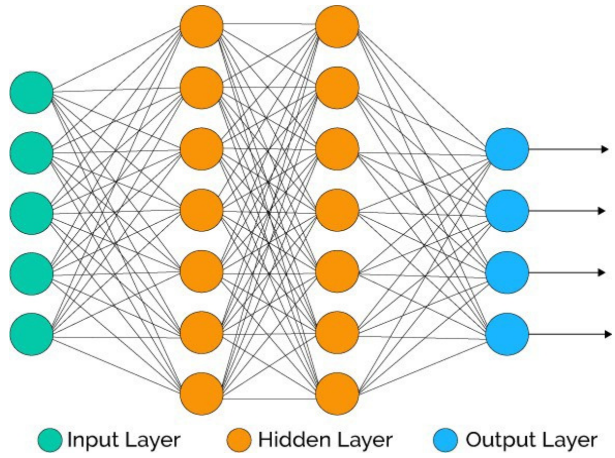

Figure 2. *Work of an Artificial Neural Network*
Source:[*https://towardsdatascience.com/machine-learning-fundamentals-ii-neural-*](https://towardsdatascience.com/machine-learning-fundamentals-ii-neural-)

When identifying whether a patient, whose scanned image (e.g. X-Ray) is fed to the ANN, has a particular disease or anomaly, e.g. whether or not a patient in question has tuberculosis, whether a tissue is cancerous or healthy, the same principle is used. ANNs are widely used for medical applications in diagnosis, electronic signal analysis, medical image analysis and radiology[8].

2. Exemplary Projects of Cooperation Between Health- and Tech- Sectors

There are many AI applications to medicine and healthcare. Assistance in making prognosis and diagnosis, early illness detection, imaging scans analysis, treatment search and development, health monitoring, medical data management and the list is not exhaustive[9]. The following examples are only a few out of many practical utilisation of the AI driven tools in the healthcare sector.

2.1. InnerEye Microsoft Project

Microsoft, as well as other big tech corporations, has been involved in a number of projects through which it aims to integrate the available technology as assisting tools for medical specialists. The ultimate goal is to

[8] PATEL JL, GOYAL RK, *Applications of artificial neural networks in medical science.*, in *Curr Clin Pharmacol*. 2007;2(3):217-226.
[9] See, among others: TOPOL, E. (2019). *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again*. BASIC BOOKS.

make the treatment, and most importantly, prevention of a disease, time and cost effective, and essentially save lives.

Let's consider an example of how an AI assistant tool is effective through looking at clinical workflow for image guided radiotherapy[10]. The patient is scanned in three dimensions; the clinician then needs to delaminate the tumour and the organs around it (that are potentially at risk) to build a 3-D model and plan further dosage required for treatment of a particular patient. The outlining procedure is exceptionally complicated and time-consuming, moreover, the probability of inaccuracy is high. A clinician uses a click-based tool to outline the tumour. These operations are necessary to be done in 3-D, meaning that the outlining needs to be repeated for each of multiple dozens of horizontal slices wherever the tumour is visible[11].

Looking at Figure 2, for a moment, imagine that with the help of a computer mouse, it is necessary to highlight the areas of a brain tumour, and not only on one of the displayed images but on all. Even assuming high qualifications and professionalism that a certain clinician might have, the manual process is still exceptionally complicated.

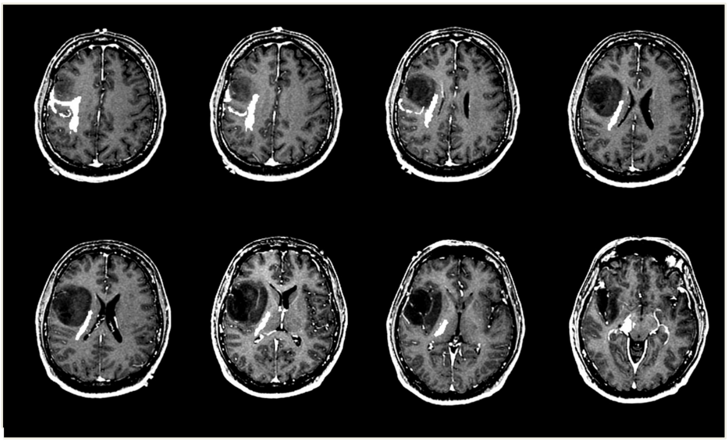

Figure 3 *Source: S. Cha "Update on Brain Tumor Imaging: From Anatomy to Physiology", American Journal of Neuroradiology March 2006, 27 (3) 475-487*

InnerEye applies auto segmentation of the organs in a scanned part of the body and can visually identify and display potential tumours or anomalies[12]. The InnerEye highlights the areas that it identifies as potentially tumorous, which enables a clinician to look closer at the obtained result[13]. Throughout the entire procedure,

10 More details on the workflow for image guided radiotherapy: GUPTA, T., & NARAYAN, C. A. (2012). *Image-guided radiation therapy: Physician's perspectives*, in *Journal of medical physics*, *37*(4), 174–182.

11 Dr. R. Jena, neuro-oncologist of the University of Cambridge Cancer Centre, UK, on the operation of the InnerEye project: https://www.microsoft.com/en-us/research/video/five-minute-overview-innereye-research-project/.

12 https://www.microsoft.com/en-us/research/project/medical-image-analysis/ - last accessed 26 May 2020.

13 MATT B, *From gaming to healthcare: Microsoft's approach to visualizing cancer*, https://digital.hbs.edu/platform-rctom/submission/from-gaming-to-healthcare-microsofts-approach-to-visualizing-cancer/ - last accessed 26 May 2020.

clinician supervises the process, by for example providing hints to an algorithm of where the tumour is located.

However, to reach this result the algorithm should go through the huge number of scans of different parts of patients' bodies in order for the algorithm to be able to recognise presence or absence of tumour in a new scan[14]. Through learning processes the network gets adapted, its diagnostic analysis improves, and so does the accuracy of the result[15].

2.2 DeepMind & Google Health

Similarly, the integrated projects of DeepMind application Streams and Google Health aim at finding the most effective way of dealing with cancer at different stages of its development.

DeepMind (to be more precise, its part - DeepMind Health) is a platform, that was founded in London in 2010 for the purposes of assisting in identifying cancer in neck and head areas (originally). The algorithm was designed to automatically differentiate between cancerous and healthy tissues through the comparison of the set of parameters and is currently applied not only to the areas of head and neck[16].

In 2014, it was acquired by Google in order to have access to the technology that would improve patients' treatment; it was welcomed with a lot of controversy and criticism concerning protection of patients' data (it is going to be covered in a subsequent part)[17].

The merge resulted in a huge impact on the prediction of cancer. One might wonder, why prediction is so important. In fact, when a disease (whatever it might be) is detected at an early stage, there is a higher probability (unfortunately, still, no certainty) that a patient would recover with the lower dosage of treatment.

According to the International evaluation of an AI system for breast cancer screening, published online on 1 January 2020, the algorithm which was initially trained on over 90,000 mammograms of the American and British women resulted in approximately 6% fewer incorrect diagnosis and 9% fewer falsely determined negative results than standard clinical practice[18].

2.3 Tracking Parkinson's Disease with an app

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[14] EIT Health (European Institute of Innovation & Technology) , McKinsey & Company (2020), *Transforming healthcare with AI – The impact on the workforce and organisations*, https://eithealth.eu/wp-content/uploads/2020/03/EIT-Health-and-McKinsey_Transforming-Healthcare-with-AI

[15] https://healthcare-in-europe.com/en/news/artificial-intelligence-diagnoses-with-high-accuracy.html - last accessed 26 May 2020

[16] https://www.techworld.com/startups/deepmind-timeline-history-of-uks-pioneering-ai-firm-3775364/

[17] https://deepmind.com/blog/announcements/scaling-streams-google - last accessed 26 May 2020

[18] McKinney, S. M., Sieniek, M., Godbole, V., Godwin, J., Antropova, N., Ashrafian, H., Shetty, S. (2020). *International evaluation of an AI system for breast cancer screening,* in *Nature*, 577(7788), 89-94.

Advancement in technology opens new doors to the researchers. Many people nowadays are attached to their smartphones, and use numerous apps to be assisted in everyday life: tracking activity, heart rate, night sleep, etc. It, therefore, does not come as a surprise to witness development of apps which could make the diagnosis of a particular disease and its tracking possible, even outside a hospital.

One of the diseases that is exceptionally complicated to be diagnosed is Parkinson's disease (PD). Its symptoms and development vary from patient to patient, thus, there cannot be one treatment plan applicable to all[19]. The costs of the treatment and diagnostics are very high; according to the study involving 486 PD patients in six countries (Austria, Czech Republic, Germany, Italy, Portugal, Russia), the total costs per patient might vary from EUR 2,620 to EUR 9,820[20]. Such difference in costs is explained by the specificities of economy and healthcare system of each state. However, in either way, the costs are huge.

Introduction of smartphone apps that can track and analyse patient's data[21] have become a game-changer in many different ways. For example, a PD patient might have a test conducted while following their daily routine. Essentially, this spares time and cost as compared to going to the hospital, and the probability of missing certain details is diminished. The testing procedure via app is conducted through active tests and passive monitoring.

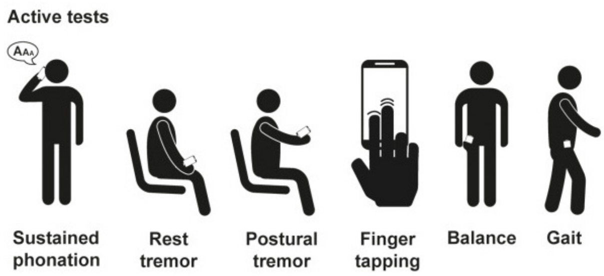

Figure 5
Source: https://onlinelibrary.wiley.com/doi/full/10.1002/mds.27376

Figure 4 displays the elements of an active test as required by Roche PD Mobile Application v1[22]. This subsequently is supplemented by the data collected passively: patients are asked to carry their smartphones with them while proceeding with their daily routine.

[19] XIA R, MAO ZH. *Progression of motor symptoms in Parkinson's disease*, in *Neurosci Bull*. 2012;28(1):39-48.
[20] *Campenhausen, Sonja & Winter, Yaroslav & Silva, Antonio & Sampaio, Cristina & Růžička, Evžen & Barone, Paolo & Poewe, Werner & Guekht, Alla & Mateus, Ceu & Pfeiffer, Karl-P & Berger, Karin & Skoupa, Jana & Boetzel, Kai & Geiger-Gritsch, Sabine & Siebert, Uwe & Balzer-Geldsetzer, Monika & Oertel, Wolfgang & Dodel, Richard & Reese, Jens. (2010). Costs of illness and care in Parkinson's Disease: An evaluation in six countries. European neuropsychopharmacology : the journal of the European College of Neuropsychopharmacology. 21. 180-91. 10.1016/j.euroneuro.2010.08.002.*
[21] *The ability of an app to quantify severity of PD has been studied and confirmed by several research studies, one of which is -* ZHAN A, MOHAN S, TAROLLI C, *et al. Using Smartphones and Machine Learning to Quantify Parkinson Disease Severity: The Mobile Parkinson Disease Score,* in *JAMA Neurol, 2018;75(7):876–880.*
[22] *As developed by Roche, the pharmaceutical company.*

The application of AI has also made it possible for a number of projects [23] to analyse through a specifically designed vision system recorded videos of patients' movements in order to identify PD symptoms. It is specifically relevant for those patients who experience difficulties in accessing medical specialists (for instance, because of living in a remote area, having no assistance, etc). Such technology makes it possible to work with the patient remotely. And it is particularly significant during the time of a pandemic.

3. Risks and Challenges

The abovementioned projects are only a few examples out of many developing or already operating. The advantages and potential of the technology implementation in healthcare are enormous, however so are the risks. When speaking of risks and challenges, one cannot avoid making speculations, some of which are inspired by vivid imagination of film directors. What first comes to mind is superiority of AI machines and subsequent elimination of humanity. Surely, this claim is relevant for a dramatic fictitious plot rather than the real world. And yet, threats do exist. Moreover, a continuous success could be misleading and a missed potential failure, thus, might bring about devastating consequences.

This section is going to outline some of the obstacles that prevent effective implementation of AI in healthcare or threats which emerge from having the technologies fully integrated into the system.

3.1. Algorithmic bias

Starting with trivial examples of risks connected with AI application, particularly in healthcare (since this sector is the scope of the paper) it is necessary to refer back to the work of an algorithm as described in section 1.1.

The observed in the abovementioned section algorithm learns from the given data, and on its basis subsequently makes suggestions. Biases refer to prejudices and inclinations for or against a person or group of people, particularly in the way that is considered to be unfair. In line with the word's definition[24] "bias" implies an attitude or a feeling, both of which cannot constitute an AI characteristic. If the algorithm is incapable to feel and thus create an attitude, what do we mean by an "algorithmic bias". The idea is that the unfair result is anyways produced, however, in the case with algorithms, it happens due to systematic and repeatable errors[25].

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[23] For example, a web app for detecting PD launched by an Australian start-up Lookinglass – see more https://www.healthcareit.com.au/article/startup-launches-ai-app-detecting-parkinson's .

[24] See common definitions provided by the dictionaries: https://www.oxfordlearnersdictionaries.com/definition/english/bias_1?q=bias; https://dictionary.cambridge.org/dictionary/english/bias; https://www.macmillandictionary.com/dictionary/british/bias_1

[25] https://towardsdatascience.com/algorithmic-bias-explained-for-beginners-79b1aa778fe6 - last accessed 01 June 2020.

For example, facial recognition algorithms, which do not identify or recognise faces of particular races, leading to potential harm towards minorities regarding the access for equal opportunities. As a consequence, certain accusations of AI being racist and/or sexist have been put forward[26].

One of the reasons for the emergence of such problem is "not quality" training data provided to an algorithm. The biases might be potentially avoided, if an algorithm is "fed" with more extensive and diversified data set. A simple example, that could be easily tried with Google search engine, displays the issue. If the word "nurse" is typed in, the images that appear, display predominately female medical staff, whereas if "programmer" is searched for, the results would show mostly male. It does not mean that the algorithm behind is sexist by its decision and developed attitude, rather that it is biased based on the data set it learnt from (or actually the limited scope of the data). The algorithm does not have a goal to discriminate, it merely fulfils the aim which it was programmed to do.

In the healthcare sector, algorithmic biases (particularly racial biases) have a high potential of affecting access to care for a huge number of people. The research on the dissenting racial bias in an algorithm[27] revealed that a software programme, that identifies those who would get access to high-risk health care management programmes, favours access to the white patients as compared to black. Additionally, the study highlighted that "remedying this disparity would increase the percentage of Black patients receiving additional help from 17.7 to 46.5%"[28]. The bias occurred because the healthcare costs (rather than illness itself) were used as a determining measure for health needs; the algorithm underestimated the risk for black patients based on their lower spending on healthcare[29].

Undoubtedly, discrimination is a significant concern, however, eliminating correlations between, for instance, race and other features, might be harmful, particularly in the health system. Considering that certain diseases are more likely to emerge among the representatives of a particular race[30] or are more common to one sex[31] [32], a diagnosis system shall not be negligent to the differences that would influence its outcome and following treatment. Yet, the issue of potential unequal treatment (when any causal link to the necessary biological differentiation is absent) needs to be treated with particular attention, especially when development or maintenance of algorithms for healthcare are in question.

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[26] Among others: Zou, J., & Schiebinger, L. (2018). *AI can be sexist and racist — it's time to make it fair.* in *Nature,* 559(7714), 324-326.

[27] Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). *Dissecting racial bias in an algorithm used to manage the health of populations*, in *Science*, 366(6464), 447-453.

[28] ibid.

[29] https://healthitanalytics.com/news/ehr-data-reveals-racial-disparities-in-emergency-pain-treatment - last accessed 01 June 2020

[30] Sickle-cell anaemia is considered to be prevailing among the Latin-American, Middle Eastern and sub-Saharan African, whereas cystic fibrosis is more common among Northern Europeans.

[31] For example, systemic lupus erythematosus (a kind of skin inflammation) predominantly occurs in females: Ngo, ST; Steyn, FJ; McCombe, PA (August 2014). *Gender differences in autoimmune disease.* Frontiers in Neuroendocrinology. 35 (3): 347–69.

[32] Peripheral artery disease occurs at similar rates in both males and females, but reveals itself differently according to sex: Committee on Understanding the Biology of Sex and Gender Differences; Theresa M. Wizemann and Mary-Lou Pardue (2001), *Exploring the biological contributions to human health : does sex matter?* Washington, D.C: National Academy Press.

3.2. Legal issues

Apart from practical obstacles, challenges emerge in the legal field. The issues listed below are only a few from the plurality of challenges faced worldwide.

3.2.1 Data protection

Throughout this paper, the notion of collecting data for the research purposes has been mentioned several times. Though, undoubtedly, it is an important part in generating an algorithm which might provide a higher degree of certainty, the issues emerge on the legal scale. The data is being collected, assessed, and shared with various actors. Introduction of data protection laws such as GDPR in the EU, has provided the set of principles that are designed to protect individuals in the age of big data. Art 5 of the Regulation lists these principles as following: lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy; storage limitation; integrity and confidentiality; accountability. GDPR requires a consent of an individual to be provided as one of the legal basses to have data shared. In practice, however, the consent for data sharing does not necessarily constitutes the protection of individuals, taking into consideration the vast majority of users of apps, websites, etc, skip reading terms and conditions to get faster access to the service. Moreover, if an individual is willing to use a particular service, which has no competitive alternative, privacy becomes a metaphorical price to be paid for the comfort and convenience. It is crucial for the consumer to be aware of what they agree for, and the provider of the service to be transparent in its usage of the data. Additionally, when considering “consent”, it is important to draw a line between ethical and legal requirements. Consent widely constitutes one of several legal or lawful bases (not The legal basis) for the processing of personal data[33].

Data concerning health is regarded as a special category, taking into consideration how sensitive this data is. Processing of such personal data is not prohibited when, in accordance with Art 9(2) of GDPR, the “processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional”, or when public interest in the area of public health is concerned.

It is true that data is required to train an algorithm to produce a more accurate result, nevertheless, an AI algorithm does not require to receive an identity of a patient (ID, for instance) in order to make its

[33] Art 6 defines lawfulness of processing as a situation when at least one of the requirements is fulfilled (among these requirements is consent); See also Art 9 as an example of processing for specific purposes and under specified conditions without the consent.

assessment. The data may remain anonymous when shared between the actors, for example, between a hospital and a tech company. By doing so, the privacy of a patient is protected, and even in a situation of a cyber-attack, this identity would not be revealed, simply because the data input is not affiliated with an exact person. Unfortunately, even if not fed to an algorithm, the personal data could be revealed from exposed databases. Not only patients' data is then at stake, but also the data of medical personnel.[34]

GDPR provides limitation to the usage of personal data for the research purposes (such as health related research) making pseudonymisation a requirement[35]. Pseudonymisation is referred to data processing conducted in the way, "that personal data can no longer be attributed to a specific data subject without the use of additional information"[36]. Moreover this additional information is necessarily to be stored separately and shall be ensured to have no attribution to an identified or identifiable natural person.

GDPR is not the sole data protection legal regime, EU Member States can and do legislate in the field of data protection as long as their laws are compliant with the Regulation rules. Moreover, GDPR has an impact outside the EU, for instance, it (particularly, the earlier version) is considered as a source of inspiration for South Africa's Protection of Personal Information Act[37]. Nonetheless, legal regimes vary, so do the requirements for and specificities of data protection. Additionally, cross-border data exchange plays a significant role for international medical studies and research projects; due to the varying level of data protection, GDPR allows data transfer under strict conditions. According to Art 45, the European Commission is entitled to assess what third countries or international organisations have appropriate level of data protection. So far, Andorra, Argentina, Canada, the Faroe Islands, Guernsey, Israel, the Isle of Man, Japan, Jersey, New Zealand, Switzerland, and Uruguay have recognised as such countries[38]. Regarding the USA, only companies registered under EU-US Privacy Shield programmes are concerned[39].

Nevertheless, technical aspects shall not be ruled out. AI is a tool rather than a legal actor. When an algorithm has no access whatsoever to the data that would identify a specific individual, the probability of a leak or threat imposed to an individual is drastically reduced. With health data it is, however, more problematic, because the data used for research is often linked to a patient's medical file or history[40]. In order to build effective prediction, not only people suffering from a disease are within the research interest, but also those who might potentially suffer from a particular condition in the future. In such cases, the link between health

[34] *The additional threat of data exposure is that, even when a party who negligently or maliciously shared the data contrary to the legal provisions is punished, the harm is irrevocably done, and the remedies might hardly cover the damages.*
[35] Art 89(1) GDPR.
[36] Art 4(5) GDPR.
[37] *Linda Nordling, 'South African Law May Impede Human Health Research' (2019) 363(6429).*
[38] *Communication from the Commission to the European Parliament and the Council, Data protection rules as a trust-enabler in the EU and beyond – taking stock, Brussels, 24.7.2019 COM(2019) 374 final*
[39] *European Commission Implementing Decision (EU) 2016/1250 of July 2016, 2016 O.J. (L 207) 11.*
[40] Consulting Report (2018). Cole, A. and Towse, A. *Legal Barriers to the Better Use of Health Data to Deliver Pharmaceutical Innovation*.

and non-health data might play an important role[41]. Among complications, however, is collection of the consent that could permit such linkage among the types of data.

Additionally, technical requirements (e.g. cybersecurity, potential errors analysis, etc) need to be monitored and updated in order to protect sensitive data which is not supposed to be accessed by any party who is not entitled to have admission. The balance between privacy, right to data protection and research for the purposes of common good shall be found. In the situation of global health emergency, detailed results of research are essential to find the solution. An adaptable legal framework, neither rigid nor loose, is a pivotal instrument, which, however, shall not become an obstacle for the use of medical data as a tool for preventing dangers for the public good or the weapon against privacy of individuals.

3.2.2 Liability

If something goes wrong – how is liability allocated between a physician, the hospital which provides access to the technology and the maker of the algorithm? In other words, who is liable? This frequently asked question is in fact very complicated to answer. Perhaps, it is more relevant to look at the rationale behind lability regimes rather than identification of a particular actor who would bare the liability.

The purpose of a liability regime is to compensate damages of the injured party. Fault based liability is driven by causation, the blame could be assigned to a party if the link of causation is established. In the non-fault regime, for instance, consumer protection liability, existence of a defect is a requirement.

When AI is concerned, a causal link is more problematic to be established. Fault is much more complicated to be linked to the algorithms which operate on the basis of machine learning, for example, when there could be no trace to human error, due to autonomous AI operation[42]. And the question arises whether the liability should be assigned to the developer, data provider, programmer, manufacturer or user of a particular device. In the EU, the laws of the Member States do not yet provide specific rules for damages that emerge from the use of digital technologies such as AI, even though, there exist some attempts to harmonise the law of tort[43].

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[41] ibid.

[42] Hannah R. Sullivan and Scott J. Schweikart, *Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?* , in *AMA J Ethics*, 2019;21(2):E121-124.

[43] *For example, Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p 29), as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999, OJ L 141 20 4.6.1999. See also infra B.III.6. Directive 2009/103/EC of the European Parliament and of the Council of 16 September 2009 relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability, OJ L 263, 7.10.2009, p. 11–31. The Directive is currently under review, see Proposal COM(2018) 336 final.*

Within the health sector, the GDPR and Regulation (EU) 2017/745 on medical devices provide for the producer's liability to the extent of ensuring products safety[44], however only if the product falls under the definition of a medical device[45]. GDPR sets also an obligation for the producer to adopt "privacy by design", and thus, if damages occur, would be held liable. The uncertainty arises when an entity produces software that processes personal data, but this entity itself is not qualified as either the data controller or processor. Then, the matter would most likely enter the contractual relationship[46], and thus, shift the liability regime to the obligations established by the contract.

The suggestion of the EU Committee on Legal Affairs is to alter the liability regime based on the risk-profile of the AI system[47]: strict liability for high-risk systems[48], and fault-based liability for low-risks[49] for the damages to life, health, physical integrity or the property of a natural or legal person[50].

Some Member States approach this issue through obligatory insurance requirements. For example, in Italy (similarly in Spain), a sufficient liability insurance cover is a requirement for a person willing to test an automated vehicle on public roads[51]. Other countries, such as Germany, rely on the strict liability regime[52]. This legislation (though fragmented across the EU) is the source of inspiration for the further possible legislative proposals at the EU level. In its report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, the European Commission seeks a possibility to find compromise among the regimes, that exist in national laws, for the AI risks that the public is exposed to, in order to achieve effective compensation for victims[53].

In either way the objective is to compensate damages and protect the victims who suffered them. Moreover, the answer to the liability question would still marginally depend on case-by-case basis and a relevant legal regime, particularly when falling out of the scope of the EU driven rules.

3.3. Other challenges

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[44] Holder C. (ed.), Iglesias, M. (ed.), Triaille J.-P., Van Gysegnem J.-M., *Legal and regulatory implications of Artificial Intelligence. The case of autonomous vehicles, m-health and data mining*, Publication Office, Luxembourg, 2019.

[45] In accordance with Art 2 of the Regulation (EU) 2017/745 on medical devices

[46] Holder C. (ed.), Iglesias, M. (ed.), Triaille J.-P., Van Gysegnem J.-M., *Legal and regulatory implications of Artificial Intelligence. The case of autonomous vehicles, m-health and data mining*, Publication Office, Luxembourg, 2019.

[47] European Parliament, Committee on Legal Affairs*. Draft Report with recommendations to the Commission on a Civil liability regime for Artificial Intelligence.* 2020/2014 (INL)

[48] Art 4(1) ibid.

[49] Art 8 (1)

[50] Art 2(1)

[51] *Modalità attuative e strumenti operativi della sperimentazione su strada delle soluzioni di Smart Road e di guida connessa e automatica, 18A02619, GU n° 90 (Article 19 of the Italian Decree of 28 February 2018 on the testing of connected and automated vehicles on public roads of 18 April 2018).*

[52] *§ 7 of the German Road Traffic Act (Straßenverkehrsgesetz) - strict liability of the keeper of the vehicle*

[53] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee. *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics.* Brussels, 19.2.2020. COM(2020) 64 final

There is an urge to balance AI benefits and its threats; integrating AI technology into the healthcare system constitutes a possibility to improve efficiency and quality of patients' care and treatment[54] and at the same time, the risks of violating privacy, confidentiality and patients autonomy need to be minimised. The success rate of a specific AI programme might also be overrated, (for instance, if AI generated results are compared to the work of one pathologist only), thus, complete reliance on the outputs of an AI programme might be misleading and instead require expertise in order to have results evaluated in a more proper way[55].

Other concerns relate to AI becoming a replacement for human specialists, fostering the latter to lose their jobs[56]. However, considering the outlined issues, such scenario is less likely, since AI nevertheless remains an assisting tool. And yet, such concerns become particularly relevant when medical education is in question. Rather than replacing human medical specialists, AI integration into healthcare fosters necessity to adapt and reframe education and training with a particular focus on interaction with and management of the AI devices[57].

Additionally, to the already mentioned challenges arising in the legal field, one particular element could be added. Current liability regimes are not yet adapted to fully respond to the emerging and fast-developing technologies, particularly when addressing incomprehension of how an algorithm reached a particular conclusion (the so-called, "black-box")[58]. Consequently, there is a lot of effort to be put in order to create a decent foundation for safe and effective use of AI driven technology in healthcare[59].

4. Attempts to Regulate: EU

The abovementioned sections, in the way or the other, depict attempts of certain legal regimes to establish a framework which would constitute a valid response to the rapid technological developments. This section is going to look in some detail on the EU strategy regarding AI technology.

In April, 2019, the European Commission published Ethics Guidelines for Trustworthy AI, which set specific requirements for an AI system to be considered trustworthy. According to these guidelines, developers, deployers and end-users, as well as the broader society, have to ensure that the requirements are followed. Figure 5 displays the key requirements set by the guidelines and their interconnectivity. Essentially, it shows

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54 *AMA J Ethics.* 2019;21(2):E121-124.

55 MICHAEL ANDERSON, AND SUSAN LEIGH ANDERSON, *How Should AI Be Developed, Validated, and Implemented in Patient Care?* in *AMA J Ethics.* 2019;21(2): E121-124.

56 JANDRIĆ, P. (2017), *Will robots take your job? Prometheus, 35*(3), 240-241.

57 STEVEN A. WARTMAN, AND C. DONALD COMBS, *Reimagining Medical Education in the Age of AI,* in *AMA J Ethics.* 2019;21(2):E121-124.

58 HANNAH R. SULLIVAN AND SCOTT J. SCHWEIKART, *Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?*, in *AMA J Ethics*, 2019;21(2): E121-124.

59 ibid.

that all of these elements are equally important and necessary to be implemented and subsequently evaluated throughout the lifecycle of an AI system (from development to utilisation).

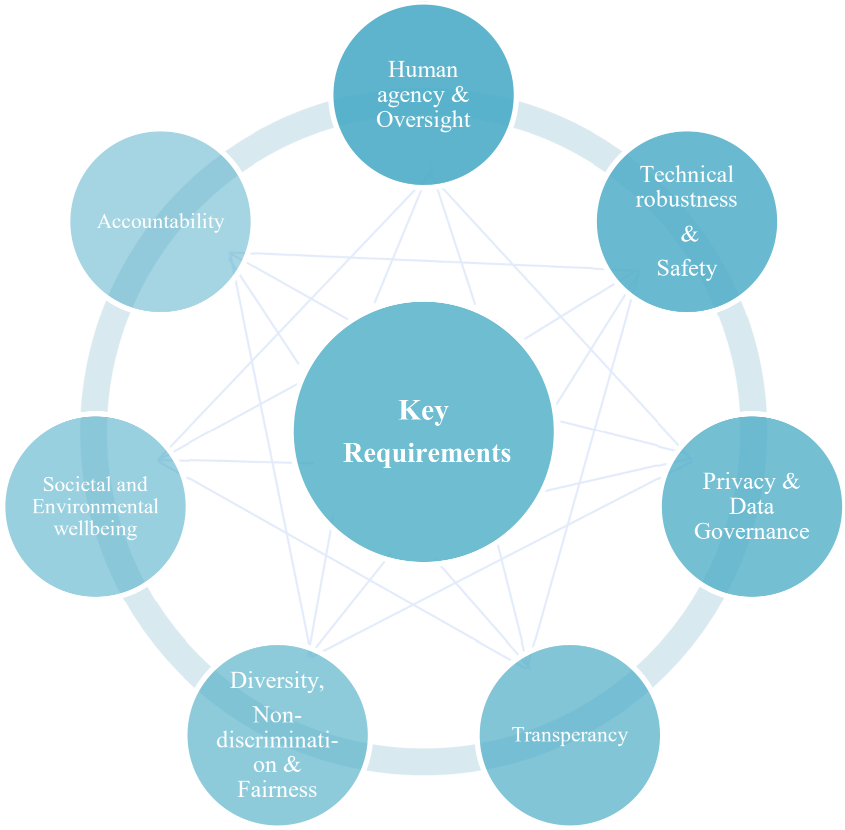

Figure 6
Inspired by https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines/1#Human%20agency

These guidelines constitute an example of non-legal instrument becoming a leading light in the application of AI for various relevant actors. As it was discussed earlier, technical aspects and capabilities are necessary to be considered rather than solely focus on the rigidity of legal framework. And the guidelines of such kind seem to successfully achieve the goal.

More recently, in February 2020, the European Commission has issued White Paper On Artificial Intelligence, in which it «invites Member States, other European institutions, and all stakeholders, including industry, social partners, civil society organisations, researchers, the public in general and any interested party, to react to the options [provided by AI] and to contribute to the Commission's future decision-making in this domain».

The main adopted approach is centred around necessity to have human control over every critical decision taken by an AI system. Any system that potentially can affect rights of an individual, including the right to life, has to be thoroughly tested, and even then AI shall remain an assistant tool rather than a decision-maker.

Imposing quality standards on the AI systems, that could enter the healthcare sector, seems to be a rational solution. However, the element of probability that something might go wrong is always present, and should not be forgotten. In this case, potential risks might be identified at an early stage and dealt with in a more efficacious manner.

One of the most recent legislative initiatives has been presented by the European Parliament Legal Affairs Committee (see reference to the liability regime discussion in subsection 3.2.2) on the design of the legal frameworks to address emerging digital technologies[60]. In order to avoid an overlap and conflict with already existing legal provision (consumer protection, data protection, etc), the initiative covers only the harm to life, health, physical integrity and property[61] and pursues a uniform approach across Member States. While building strong safeguards, the objective is to exploit the positive sides of AI[62]. The EU, additionally, aims at imposing requirements to ensure conformity with safety, fairness and data protection standards[63]. How successful and goal-reaching such approaches would be, could be seen only with a passage of time. It is crucial, though, that the new liability regime responses to the rapid technological development, and when enforced, is not outdated and obsolete to tackle the emerging issues.

5. Conclusion: Relevance to Covid-19

The conclusion of the paper could be drawn by looking at the application of AI during the covid-19 pandemic. Essentially, the opportunities, risks and challenges that have been outlined are relevant for the current events. As Eric Horvitz, Microsoft's Chief Scientific Officer, highlights: «Data and computation [could] help light the path to mitigating the pandemic»[64].

During the covid-19 pandemic, AI has become an essential tool in the fight against the virus. AI systems are used to predict the spread and evolution of the disease, to identify the groups which are more likely to be affected by the virus, to contribute to research and development of a vaccine and treatment (it has already significantly speeded up the process by generating prediction of the virus structure). Moreover, coupled with judgement and assessment of human medical experts AI has shown higher accuracy[65].

For example, DeepMind (one of its projects was described in a previous section) has published its predictions of coronavirus protein structures in the open databases, which is a crucial element for the search of

[60] European Parliament, Committee on Legal Affairs. *Draft Report with recommendations to the Commission on a Civil liability regime for Artificial Intelligence.* 2020/2014 (INL).
[61] ibid. Explanatory Statemen.t
[62] ibid.
[63] https://www.lawfareblog.com/eus-white-paper-ai-thoughtful-and-balanced-way-forward - last accessed 01 June 2020.
[64] https://blogs.microsoft.com/on-the-issues/2020/04/09/ai-for-health-covid-19/ - last accessed 01 June 2020.
[65] https://enterprisetalk.com/covid-19/covid-19-how-ai-can-improve-healthcare-decision-making/ - last visited 01 June 2020.

treatment[66]. By understanding the structure of different types of proteins, it is possible to develop a drug that would "turn-off" the type of proteins on the surface of so-called T-cells (which are essential for the work of the immune system) which are capable of preventing the response to infection[67], and, thus, stimulate the entire immune system and its resistance to such infection[68].

Existing projects that employ AI in image diagnostics have served as a ground for the adjustment of the technology to the covid-19 crisis. In Europe, for instance, an international collaboration between the European Society of Medical Informatics and the companies Robovision and Quibim, *Imaging COVID-19 AI,* aims at automating covid-19 diagnosis based on imaging[69] (see other projects described in section II). And rapid monitoring and tracking of the spread of the virus has become essential to effectively quarantine and reduce transmission[70].

The risks, legal issues and challenges, that were outlined in the previous sections, are also relevant to the ongoing pandemic. In fact, some are aggravated in the face of the crisis. For instance, compliance with data protection requirements becomes more complicated when the necessity to fight against the virus emerges as a prevailing public concern of a global scale[71]. The overlaps do occur and bring about more legal concerns. Different regulatory authorities and governmental bodies on the domestic, supranational and international levels, have issued guidelines[72] in order to ensure compliance with data protection laws.

In the rush to resolve the crisis, some crucial elements might be missed out. The risk of biases and certain groups being missed out when clinical trials of a potential vaccine are conducted and risk of future deterioration are nevertheless present. It is crucial to find the treatment for the virus, however not merely in the short-term perspective. A universal panacea seems to be a part of a utopian novel; realistically speaking, numerous elements need to be taken into consideration. The covid-19 pandemic should not become a justification for unnecessary interference into private life and stricter governmental control, and yet a stronger cooperation is the key to overcome the crisis.

AI is not a wonder-machine capable of magical miracles. Not only shall the AI technologies develop, the ways of their utilisation need to be reconsidered. Absence of transparency and rigor in AI programming, application

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[66] J. JUMPER, K. TUNYASUVUNAKOOL, P. KOHLI, D. HASSABIS *et al, Computational predictions of protein structures associated with COVID-19,* DeepMind .

[67] BREDA A, VALADARES NF, NORBERTO DE SOUZA O, et al. *Protein Structure, Modelling and Applications*. 2006 May 1 [Updated 2007 Sep 14]. In: GRUBER A, DURHAM AM, HUYNH C, et al., editors. *Bioinformatics in Tropical Disease Research: A Practical and Case-Study Approach* [Internet]. Bethesda (MD): National Center for Biotechnology Information (US); 2008. Chapter A06.

[68]Among others: https://www.nature.com/scitable/topicpage/protein-structure-14122136/ - last accessed 01 June 2020.

[69] https://www.ie.edu/building-resilience/knowledge/digital-health-ai-time-covid-19/ - last accessed 01 June 2020 .

[70] BAIDU, *How Baidu is bringing AI to the fight against coronavirus*, MIT Technology Review, 11 March 2020.

[71] https://www2.deloitte.com/al/en/pages/legal/articles/data-protection-covid-19.html - last accessed 30 May 2020.

[72] *European Data Protection Board, Guidelines on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, 21.04.2020, https://edpb.europa.eu/our-work-tools/our-documents/usmernenia/guidelines-042020-use-location-data-and-contact-tracing_en - last accessed 17 May 2020.*

and maintenance would worsen already complicated aspects of healthcare system (and other sectors), instead of improving them.

A global health crisis inevitably causes changes, among which there would most likely be an even faster development of digital and AI technologies and their integration into the healthcare sector. These changes consequently become a foundation of the strong response system for potential new outbreaks.