ISMR ACADEMY

Simple (?) question

We learned that the world is made of atoms from a philosopher, robots were created by an artist, and the first Internet users were heroes of fantasy novels. It is difficult to bring into reality what was created in the imagination. All functional, economic, legal and ethical aspects of robotics or artificial intelligence are created by the method of trial and omission, because we cannot afford mistakes. As with an atom. But it is worth asking simple questions and trying to answer them. Medical robotics is a field that has already taken its first steps, so you can also infer something from experience. It does not change the fact that the sentences, opinions and sometimes controversial decisions presented below may be modified many times. Like all organisms, they evolve and... their offspring also.

#AI

AI – what is it?

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Artificial Inteligence

In my opinion, **artificial intelligence is a part of robotics**. The source of the word robot is associated with the figure of an artificial man introduced by Czech Karel Čapek 100 years ago to the scene; R.U.R. Rossumovi Univerzální Roboti (Rossum's Universal Robots). Robotics is a technical discipline which deals with the synthesis of certain human functions through the use of mechanisms, sensors, executive assemblies and computers. Because human have a brain – artificial intelligence is an integral part of robotics.

Generally, artificial intelligence was created to link machinery communication with human intelligence. A robot is an artificial man or part of it, a humanoid robot, artificial organs or artificial intelligence.

The traditional definition of robot means artificial man. From this point of view, the robot should have the ability to move (the ability to perform mechanical work) and the ability to make decisions based on information provided by its senses (intelligence).

In medicine, artificial intelligence can definitely play a positive role in developing strategies and controlling tactic solutions for operations and generally health services.

The art of robotics is based on an intelligent combination of mechanical work and information management obtained by sensors.

AI & robotics transforms medicine. Intelligence is a way of drawing conclusions from the analysis of data obtained from sensors, signals or images.

ISO/IEC 22989:20201 contains the following definition of AI: 'AI – **capability to acquire, process, create and apply knowledge, held in the form of a model, to conduct one or more given tasks'**.

In June 2022, the Coalition for AI in Health prepared – the White Book of AI in clinical practice. Basically the document shows how much there is to be done.

Let's start with the fact that The legal definition of AI has not yet been adopted (although legislative work related to it is in progress at the level of EU law). There are many definitions of **AI, in simplified terms, 'it can be assumed that it is software that is based on previously collected knowledge, and on the basis of the obtained data, performs the assigned tasks, his task, while perfecting himself**'. 'The legal framework for the use of AI is still in the process of being developed. Currently, AI can be legally used in clinical practice, but one should remember to comply with the rules resulting, inter alia, from patient's rights and the requirements related to the performance of medical professions'. [1]

'The obligation to respect patients' rights applies to, among others, medical professionals and healthcare entities. Although AI may help, for example, in the process of admitting patients to treatment, suggest its optimal course, and even provide the patient with advice, it does not replace a doctor, other medical workers or a medical entity. Thus, AI does not have to follow patient's rights, but the person who uses them does.'[1]

'The patient has the right to information, inter alia about the proposed and possible diagnostic and treatment methods and the foreseeable consequences of their use or omission. This means, in particular, the right to information about the availability and use of AI in the provision of health services.' [1]

'AI should be treated as a tool in the hands of a medical professional, which may provide support for many processes, not only diagnostic and therapeutic, but also scientific, research, organizational and management. AI does not replace a medical professional, does not make decisions for them, does not provide health services for them, and does not make a judgment on his / her own health.' [1]

'**Education** in the field of AI is of key importance from the perspective of the development and popularization of this technology, as it can potentially shape realistic opinions of medical professionals with regard to AI, improve their competences in this field and translate into an increase in the safety of using the technology in question'[1]

Like any tool, it must be used in the right way. AI learns from examples. The more repetitive situations analyzed, the better the reaction to the discovered pattern. AI will not make us immune to stupidity. We have to educate it in the right way, on the right data, and we ourselves – we humans – have to learn to use it.

Control. 'Man should remain in control of AI systems. Human beings, in particular, should make the final medical decisions.' [1]

What is important? Transparency, explainability, understandability. Responsibility.

Inclusiveness. AI in health care should be designed in a way that encourages the widest and fair use and access possible, regardless of age, gender, income, race, ethnicity, sexual orientation, abilities or other characteristics protected under human rights codes.

Responsiveness. Designers, developers and users should continuously and transparently evaluate AI applications during their actual use to determine whether AI is adequately and appropriately responding to expectations and requirements. In our opinion, the responsiveness of AI systems should be subject to further clarification and standardization

Following the White Paper, we provide an overview the proposal for a regulation of the European Parliament and of the Council on harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts [2].

The definition of AI used in the Artificial Intelligence Act project is very broad. It includes not only **software based on machine learning mechanisms, but also e.g. knowledge bases and search methods.** In April 2022, a new version of the Artificial Intelligence Act project appeared, introducing changes e.g. in terms of the definition of AI. Originally, such a system means **software, developed using one or more of the techniques and approaches listed in Annex I, that can generate results for a given set of human-defined purposes.** A change was proposed whereby the results would not need to be determined by humans. Moreover, the hypothesis was added to the catalog of potential results for the operation of AI systems.

On May 26, 2021, the application of new and extensive legal changes resulting from Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices began, amending Directive 2001/83 / EC, and Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC – hereinafter MDR (Medical Device Regulation).

For any advisory sytems the key concepts are input and output. 'According to the guidelines of the Medical Device Coordination Group [3], any data provided to the software can be considered input data in order to obtain an output after it has been computed.

According to the guidelines of the Medical Device Coordination Group [3], any data generated by the software can be used as output.

The central rule relating to software that is a medical device in MDR Appendix VIII is Rule 11/185.

185 Rule 11:

Software designed to provide information to be used in making decisions for diagnostic or therapeutic purposes is in Class IIa, except where the consequences of such decisions are likely to result in: death or irreversible deterioration of the person's health, in which case the software is class IIa. III, or there is a serious deterioration of the individual's health or the need for surgical intervention, in which case the software is class IIb. Software designed to monitor physiological processes is in class IIa, except where it is intended to monitor vital physiological parameters, where a change in these parameters is likely to present an immediate risk to the patient in which case the software is in class IIb. All other software belongs to class I.

The problem is certification – especially important for AI, which is a medical device. In this context, attention should be paid to the different situation where AI software is introduced as a 'frozen', 'trained' tool in full (in fact, we use a ready-made tool) and when AI software is used with continuing learning from the data obtained during the process of providing health services (decision algorithms will develop additionally). The European legislator sees this as a problem, which is reflected in the Artificial Intelligence Act (cf. point 7.1.2.). Issue on the certification of artificial intelligence systems (but here it only refers to the assessment and confirmation of compliance with regard to the so-called quality assessment systems and technical documentation). [1]

The proposed regulation of the Artificial Intelligence Act may have significant consequences for producers. For example, in the case of high-risk AI systems, it will be necessary to introduce an additional risk management system (Art. 9 of the Artificial Intelligence Act) or to meet more stringent requirements regarding technical documentation (Art. 11 of the Artificial Intelligence Act), registers (Art. 12 of Artificial Intelligence Intelligence Act), human oversight of the product (Art. 14 of the Artificial Intelligence Act) and cyber security (Art. 15 of the Artificial Intelligence Act) [1].

AI, on the other hand, is great for helping when the doctor has less information than usual – e.g. he has an X-ray image and no specialist's description, he performs operations using a less invasive method, that see less, cannot touch, and operates through small openings in the patient's body. After all, we know the human body, we know the anatomy, physiology, pathology, we have diagnostic data, we know the patient's interview, so we have the data that AI can analyze.

AI IN MEDICAL ROBOTS

AI and medical robots are a dream couple. They match themselves. Why? Because of communication: fast, accurate and digital. Full synergy and process optimization. It is somewhat anachronistic to use robots as telemanipulators, just as it makes no sense to steer a vehicle if it can drive itself to a destination. Of course, the key is the security criterion.

Autonomous robots, autonomous vehicles require an artificial brain and its education on examples. The world, its architecture, nature or man and his diseases are variable, determined and verified data in a given time and place. They need updating. That is, access to information sources. So sensors – sensitive, stable, reliable, resistant to various changes in the environment.

The **robot** is not a machine but an **IT device** that creates a great opportunity for the integration of an entire diagnostic system with the operator. This is a challenge for creating new tools, and both artificial intelligence and robots are one of them. The less invasive the surgery, the less visual and sensory information we have – the more the role of AI increases [4].

AUTONOMY OF MEDICAL ROBOTS

The autonomy of medical robots on a five-point scale (modeled on the SAE J3016 standard).

0. The lowest level, 0, is a lack of autonomy.

1. Level 1 is telemanipulation (remote control) with support. In these type of robots, some elements have been introduced to support operation automatically. It can be, for example, an emergency stop system for a robot in a hazardous situation. Surgical robots such as da Vinci and Robin Heart are currently in this group.

2. Level 2 presents robots with the option of partly automated work. A robot that can perform one of the tasks in an automated manner, e.g. tying a node or orientation of the cam-vision track to a tool.

3. Level 3 is highly automated work. The system moves independently in the work space and scope of tasks but is able to assess the limits of its freedom. It notices that if the working conditions are outside the defined area, the operator must immediately take control of the robot. In the absence of such a reaction, the robot stops. Such robots are self-propelled robots for tele-presentation and so-called robotic nurses for communication and transport of various products and materials in hospitals.

4. Level 4 is fully automated work. The robot works independently but should be supervised, e.g. by a doctor, rescuer or physiotherapist. An example of a vehicle – a robot – included in this level is the autonomous Volvo XC90 used in Uber tests (in the vehicle there is a driver – a human verification element that can take over steering, after warnings from the control system). Such machines are currently computer tomography or robotic radio-surgical knives that move and operate in accordance with the planned trajectory and tasks specified before the surgery.

5. Level 5 means a robot working fully autonomously. The medical robot works independently, sharing space with the patient and medical staff, makes independent decisions and performs tasks provided for in its specialization. The robot has no tele-manipulation system. An example is the city car prototype developed by Google, Waymo Firefly, a car without a manual control system, including the steering wheel, gear lever or pedals. There are currently no such medical robots.

An evolutionary trend moves toward progressive automation. Medicine is the greatest challenge for this, the most difficult, but also the most important.

Let's add – there is a lot to do ahead of us, but ... it will pay off. According to analysts: AI in the healthcare market has been valued at $ 8.23 billion in 2020 and is projected to reach $ 194.4 billion by 2030. Due to the growing demand for minimally invasive surgeries, in which artificial intelligence technologies are supported, the widely used robot-assisted surgery segment will be characterized by an extremely high dynamic of 36.6% y / y.

For those interested in the role of AI in surgery, I recommend the book: 'Artificial Intelligence and the Perspective of Autonomous Surgery', which will be published this year by Springer, prepared by Gumbs / Karcz / Nawrat with the world's most distinguished representatives of medicine and AI technology as chapter authors.

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#Diagnostic Robots

A diagnostic robot – what is it?

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A **medical diagnosis** is the process of determining which disease or condition explains a person's symptoms with medical data.

Diagnostic methods are used to collect information in the form of a patient's history (interview), medical data (blood condition, secretions, ...), medical signals (blood pressure, ECG, EMG, ... – uses the measurement of physical signals), medical images (photography, ultrasobography, Tomography, MRI ... – uses the physical phenomena of interaction with the body).

The **medical diagnostic robot** is

1) a doctor's tool in performing measurements and / or collecting information (interview, questionnaire, data collection review) and / or data acquisition (storage + easy access = creation of personalized and cataloged files), and / or analysis, inference (proper diagnosis) and / or forecasting (predictive advisory programs)

2) replacing a doctor-diagnostician.

The robot is an intelligent combination of sensorics with mechanical work and decision-making skills.

The diagnostic robot can therefore perform part of the measurement work independently on site or remotely in a controlled setting, but it is also a computer (smartfon) program (software) drawing conclusions regarding the evaluation of the collected data, observations, and measurements for a given patient.

Diagnostic robots are diagnostic tools in the form of a physical robot or any device with software in the form of an expert system.

The algorithm itself, the recipe itself, is not a robot, just as a book or a mathematical formula is not human. The key to distinguish them is interactivity, intelligence, and the ability to react appropriately to input data – that is, just like a specialist (who uses textbook knowledge), a robot is a properly programmed device. In the best version, both can learn, i.e. modify their knowledge base and decision-making (deep learning).

We can also use the term **diagnostic robots** for measuring devices with mechanical parts and **diagnostic bots** – if they only have an intellectual, analytical part.

An example of diagnostic robots: tomography; diagniostic bots: Watson. In February 2013, IBM announced that Watson software system's first commercial application would be for utilization management decisions in lung cancer.

Medical diagnosis is the identification of the cause of a a disease, injury, or abnormal physiological state. In a **physical examination, medical examination,** or **clinical examination**, a medical practitioner, diagnostician *(physician, physiotherapist, dentist, podiatrist, optometrist, nurse practitioner, healthcare scientist or physician assistant)* examines a patient for any possible medical signs or symptoms of a medical conditio using **medical tests** (physical and visual exams, **diagnostic** imaging, genetic testing, chemical and cellular testing).

Robotic tools use sensors (visual, audible, electro-magnetic, mechanical, temperature, radiation...) and programmable precise movements, kinematics, signal analysis and signal transmission technologies to perform a physical examination of the patient. Unlike the basis of physical examination used by medical team: inspection, palpation (feel), percussion (tap to determine resonance characteristics), and auscultation (listen), robotic tools can also use other physical phenomena such as x-ray or nuclear radiation, magnetic resonance of hydrogen nuclei, etc., to make millions of spatially ordered observations, assembling them into a computer spatial image of the patient's body and gathering information about local processes taking place in organs and cells obtained non-invasively (controlled harmfulness of the organism). Due to the fact that the applied physical phenomena are also harmful to the personnel – precisely the robotization of these diagnostic systems – also protects medical teams.

I propose to divide the diagnostic robots and diagnostic tools according to the physical / chemical / biological **phenomena used:**

1.visual (observation in visible light, eye examination),

2. laser

2. nuclear radiation

3. infrared radiation (thermal cameras, temperature measurement)

4. X-ray (X)

5. acoustic (auscultation, hearing test)

6. ultrasonic (ultrasound)

7. magnetic resonance imaging (NMR, MRI)

8. mechanical (pressure, strength and range of motion of the musculoskeletal system, chest movement while breathing, stress tests ...)

9. electric / magnetic (EKG, EMG, ..)

10. chemical (analysis of the composition of the exhaled air, etc.)

11. genetic

12. biochemical examination of secretions (urine, ...)

13. blood chemistry tests

14. bacteriological and virological tests ...

15. ....

The method of organizing diagnostic robots according to their **method of control**:

1. automatic measurement (e.g. X-ray control gates at airports, measuring medical boxes, measuring temperature of people, photos, cameras analyzing movement, e.g. falls in hospitals or nursing homes..., devices for long-term measurements, e.g. holters) with a computer part diagnosis of observed people and creating information sets and possibly making decisions, e.g. alarm ...

2. programmable measuring and diagnostic devices (computer tomographs, NMR, capsules for observation of the digestive system, a bed or chair using a specific sequence of movement for diagnostic measurements, etc.) with computer processing and presentation of data

3. diagnostic devices controlled at a distance by a specialist (e.g. making measurements by remotely controlling the movement of the ultrasound probe, remotely controlled devices for assessing the movement system in the rehabilitation process, biopsy robot etc.)

4. autonomous external diagnostic robots – specialized testing devices that independently select and evaluate patients with a specific disease state

5. autonomous internal diagnostic robots – diagnostic implants, mini-, nano-diagnostic robots for diagnostics of organs and cells, lab-on-chip with a system for collecting, evaluating, and transmitting data

Mix – Diagnostic-therapeutic and diagnostic-rescue medical robots:

1. rescue robots for artificial respiration and heart massage

2. robots for medical transport with patient diagnostics (e.g. medical robots for the army and space expeditions or for saving people at sea, in caves or mines or in urban infrastructure, used during war, pandemic, catastrophes)

3.Diagnostic systems of continuous measurements operating in the loop of automatic supervision of executive systems, e.g. for patients with diabetes (external)

4.Implantable diagnostic devices that also have the ability to activate vital functions (pacemakers with cardioverters – heart diagnosis, analysis and specific action)

5.Artificial organs with an extensive diagnostic part (respirators, artificial lungs or an artificial heart responding to the patient's condition, orthopedic prostheses diagnosing the patient's condition, e.g. muscle spasticity and triggering a specific action).

Division of diagnostic AI robots according to the **time horizon**:

– diagnostic robots assessing the current state on the basis of current research

– prognostic robots assessing the future state on the basis of diagnostic tests

The diagnosis is at the beginning of the treatment process; it has a decisive influence on the patient's fate and the achievement of a positive result, as well as, the cost of the medical service. We have more and more data from more and more perfect measuring and imaging devices, and an insufficient number of specialists who can analyze this data, in addition, clinicians are sometimes wrong, so now there is a struggle to automate diagnostics. It is, in a sense, an experimental field for AI-based robot systems – the progress of all medical robotics depends on the success or failure of diagnostic robotics. If we succeed, we will have a paradigm shift in medical services from patient-technology-doctor to patient-technology system, i.e. to full health technology, in which devices will communicate with each other on the patient's path during the next stages of their treatment.