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Legal challenges for robots and autonomous artificial intelligence systems in the healthcare context with special reference to Covid-19 health crisis*

DESAFÍOS JURÍDICOS PARA LOS ROBOTS Y LOS SISTEMAS AUTÓNOMOS DE INTELIGENCIA ARTIFICIAL EN EL CONTEXTO SANITARIO CON ESPECIAL REFERENCIA A LA CRISIS SANITARIA COVID-19

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ABSTRACT

It is no longer far from reality that machines will not only help, but in many cases replace humans in their roles as caregivers, healthcare professionals, doctors and specialists, as well as in the decision-making process in the healthcare sector. Indeed, the field of health and care is an undisputed arena for the spread of robotic innovation. Artificial Intelligence has changed the architecture of the world, and this extends to the world of healthcare. This status quo will generate - or rather is already generating, given that robotics is not the future, but is already a reality - a series of multiple and multidisciplinary novel issues for health law and policy. This paper focuses on exploring the main legal considerations that arise, highlighting the need for various reforms of legal doctrine and regulatory structures. Given that

KEYWORDS

Artificial Intelligence
Healthcare robot
COVID-19 health crisis
Health Law

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robots and Artificial Intelligence are an emerging rather than an established component of healthcare delivery, this paper aims to provoke, challenge and inspire critical thinking about what is likely to be one of the highlights for health law and policy debates in the coming decades.

RESUMEN

No es ya lejano a la realidad que las máquinas no sólo ayudarán, sino que, en muchos casos, sustituirán a los seres humanos en sus funciones de cuidadores, profesionales sanitarios, médicos y especialistas, así como en lo que atañe al proceso de toma de decisiones en el sector sanitario. Y es que, el ámbito de la sanidad y los cuidados constituye un indiscutible escenario de propagación de la innovación robótica. La Inteligencia Artificial ha cambiado la arquitectura del mundo y esto alcanza al mundo sanitario. Este status quo generará —o mejor está ya generando, habida cuenta la robótica no es el futuro, sino que es ya una realidad—, una serie de múltiples y multidisciplinares cuestiones novedosas para el Derecho y la política sanitarias. Este artículo se focaliza en la exploración de las principales consideraciones jurídicas que surgen, destacando la necesidad de diversas reformas de la doctrina jurídica y las estructuras reguladoras. Dado que los robots y la Inteligencia Artificial son un componente emergente más que establecido en la prestación de asistencia sanitaria, este artículo pretende provocar, desafiar e inspirar a pensar de forma crítica sobre lo que seguramente será una de los puntos álgidos en los debates sobre legislación y políticas sanitarias en los próximos decenios.

PALABRAS CLAVE

Inteligencia Artificial
Robot sanitario
Crisis sanitaria COVID-19
Derecho Sanitario

I. Open issues

It is erroneous to think that Artificial Intelligence is some sort of futuristic science or that machines will not only assist, but in many cases, will substitute for humans as caregivers, medical service providers, diagnosticians and expert decision-makers. In fact, the health sector is an undeniable area for the propagation of robotic innovation (Palmerini, 2017: 55). Artificial Intelligence has changed the world's structure, and this has reached healthcare.

This *status quo* will generate —or is already generating, taking into account that robotics is not the future, but already a reality (Minero Alejandre, 2020: 55-56)— a number of novel and multidisciplinary issues for health law and policy. Among these issues, liability for damage generated by robots and the processing of personal data are particularly relevant, and we will address these matters in this paper.

Adequate enforcement of existing regulations, the need for new laws and the formulation of appropriate health policy alternatives requires sufficient attention to ensure the beneficial use of robots and Artificial Intelligence.

In this regard, robots are already automating various physical tasks traditionally carried out by health care professionals, such as: delivering goods; monitoring vital signs, administration and distribution of medication among patients, monitoring to determine whether the patient is taking the prescribed medication, assistance with mobility, among other functions.

An example is ROBEAR. This is a human-sized robot, specialised in nursing auxiliary care (commonly called "nurse robot") with which a patient can be lifted out of a wheelchair. These types of robots would be classified as care robots (García Portero, 2018: 208), which are in full expansion in view of the growing ageing of the population. Indeed, the over-65s are a group with a growing demographic and economic weight in European society.

We have to qualify that these care robots arise not only for the care of the elderly, but also for people with a certain type of disability. They have a greater potential regarding physical tasks, but they can also have their transcendence regarding tasks of a psychological nature.

So, beyond the physical, Artificial Intelligence is indeed achieving a measurable success in carrying out various intellectual tasks in the field of psychotherapy, medical diagnosis and decision making. Aspects of health care that were historically within the domain of human clinical experts.

It is very encouraging in these days of global health crisis to see an example of an Artificial Intelligence system capable of making medical diagnoses: we are talking about the robot that is capable of diagnosing the COVID-19. The main advantage of these platforms based on Artificial Intelligence is to accelerate the process of diagnosis and treatment of COVID-19 disease, a real threat to the global health system (Tsikala Vafea *et ál.,* 2020: 249-257). This is the case of the robot, called OPENTRONS that allows the processing of samples to make PCR tests massively and diagnose the largest number of people affected by COVID-19. In this sense, The Biomedical Diagnostics Centre (CDB) at the Hospital Clínic de Barcelona has incorporated a new robot to perform mass PCR tests. The arrival of the robot has been made possible thanks to the collective effort of several private and public entities in the framework of the Covichain Robots initiative. The incorporation of the robot responds to the need to streamline coronavirus testing and solve the bottleneck of sample processing. The robots are equipped with the latest technology under open source characteristics, which allows them to be adapted to the protocols established in each hospital. The robot, called OPENTRONS, allows the processing of samples for mass PCR testing and diagnosis of the largest number of people affected by COVID-19.

These early successes anticipate the expected impact that robotics and Artificial Intelligence will have in the coming decades on the healthcare system, its many industries, professionals and caregivers, as well as on the patients and families subjected to their use. At the same time, several features of robots and AI will create new challenges for healthcare, requiring careful reflection on the appropriate limits of delegating human tasks and decision-making to machines. In addition to their potentially huge impact on labour markets, robots and AI are forcing us to rethink several traditional ethical and legal (Romeo Casabona, Guillén & Jerez, 2020) concepts, including the system of liability and redress.

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Since automation is advancing, it is worth taking stock of the various robots and artificial intelligences currently deployed and under development in the health sector. This will help us to identify, anticipate and better understand some of the ethical, legal, political and social challenges that these technologies are creating.

All in all, this article focuses on exploring the main legal considerations that arise in this area. It also highlights the need for various reforms of legal doctrine and regulatory structures. Given that robots and Artificial Intelligence are a well-established emerging aspect of healthcare delivery, this paper aims to provoke, challenge and inspire the reader to think critically about what is likely to be one of the highlights of health law and policy debates in the coming decades.

II. Distinction between related concepts

1. Robots (bots and cobots), machines, Artificial Intelligence and Robotics

We have alternatively used the terms machines, Artificial Intelligence, Robotics and robots. It is useful to qualify each of these concepts.

Robots are a classic of science fiction, both in literature and film. Ever since the Czech writer Karel Capek coined the term in the first decades of the 20th century to describe working or servile machines, they have been the protagonists of countless novels and films in different roles -from faithful human squires like the mythical C3PO, who sometimes acted as a robot surgeon in Star Wars (Van Wynsberghe, 2015:1-4), to annihilators of humanity, see Blade Runner or Terminator-. In fact, "Robot", which could be translated as "slave" or "forced labourer", was taken up decades later by cinema and literature, and became the most widely accepted and popularised term.

However, it is worth mentioning that it is not "robot" that is the oldest term, but rather the word "android", which was first used by St. Albert in 1270, and popularised by the French author Auguste Villiers in his novel *L'Ève future* in 1886. When we refer to "android" we are referring generically to a mechanical entity with an anthropomorphic appearance.

In a subtly more precise term, we find the term "cyber-physical systems" (CPS), defined by the European Union (EPRS-European Parliamentary Research Service Scientific Foresight Unit-STOA, 2016) as: "intelligent robotic systems, linked with the Internet of Things, or technical systems of networked computers, robots and artificial intelligence that interact with the physical world". It should be noted that this definition provides a further step by indicating that these are not isolated autonomous machines, but those that interact directly with the world around them, either through sensors (interaction with environmental factors) or with people (interaction with human factors).

As stated in the previous paragraph, robot is a term used, therefore, to describe a machine that interacts with the physical world to perform specific tasks. It is, in short, a programmable machine that can automatically perform a series of complex actions, a series

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of mechanical functions (Ercilla García, 2020: 61). With respect to related versions that respond to the neologism such as "bots", the essential difference between a bot and a robot lies in the existence of a physical part. Just as a bot is essentially software, a robot requires hardware. While robots are programmable machines that can execute actions automatically, bots are programmes that can execute actions automatically. Very close to robots are "cobots", a term that refers to the contraction between "collaborative" and "robot". These are collaborative robots that complement human work or collaborate with it to carry out a task (Ercilla García, 2020: 64-66).

Finally, the formula "Artificial Intelligence or AI" defines a reality capable of analysing data and acting accordingly in pursuit of a pre-programmed goal. In other words, in addition to the features we have already seen (mobility, submission to orders and interaction with the physical world, or capturing information from the environment), we add the capacity to analyse, develop reasoning and act in accordance with them. In the most modern definition of the term proposed by the European Union (European Commission - High-Level Expert Group on Artificial Intelligence, 2019) it is defined as follows: "Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions".

As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems).

The starting point of Artificial Intelligence allows us to construct progressions, also terminological of itself. Thus, it is commonly accepted to use concepts such as "strong Artificial Intelligence" and "narrow Artificial Intelligence" to refer to that which can carry out actions traditionally assigned to human beings, in the first case, and to that which is designed only to perform a very limited range of actions, in the second.

2. And what about "cybors"?

I believe the issue on this should be pursued within sport law context (Atienza Macías, 2020).

In relation to the different classes or typologies of doping, we consider it appropriate to mention that, at present, the following classification is usually made:

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On the one hand, we can refer to "chemical or pharmacological doping" and "blood doping". No less popular is the so-called "gene doping", to which we have alluded in previous pages and which is linked to the recently fashionable concept of human enhancement. Doping by chimerisation also stands out, and a possible extension of doping by cyborgisation (Navas Navarro & Camacho Clavijo, 2019) or robotisation (Barrio Andrés, 2019) is also advocated as another form of doping in sport.

Indeed, genetic science not only assures us that we can know the code in which human nature is written, but also promises us that we will be able to improve and modify it as we choose. However, the scientific and biotechnological developments that will have an inescapable impact on sport do not end there, i.e. with genetic engineering. In addition to gene doping (Miah, 2004), we will also have to watch out for physiological improvements brought about by prostheses and body implants that may lead to the creation of cyborg athletes (Pérez Triviño, 2013), as well as the creation of hybrids and chimeras.

In fact, within bodily improvements of physical characteristics, the field of sport is a paradigmatic example, being one of the social spheres in which these genetic transformations on the human body are contemplated with the greatest intensity. And this is without taking into account the improvements that may be made in other aspects of sporting performance, such as the cognitive and emotional aspects, areas in which neuroscience and pharmacology are advancing by leaps and bounds.

On the other hand, we cannot ignore certain reflections that go so far as to discuss the possibility of a so-called "technological doping" connected to the impact of Big Data in the sporting context. The hypothesis is that huge amounts of data collected in the field of sport are used in an efficient and targeted manner to achieve defined objectives, in order to shed light on those aspects linked to sporting performance (Mayer-Schönberger *et ál.,* 2013: 139-141 and 145).

Thus, while we are no longer perplexed by the proliferation of Big Data technologies in sectors such as health, education, finance, logistics, marketing, public administration and even food, we find their impact on professional sport even more shocking. Indeed, although Big Data is usually associated with the scientific, business or commercial spheres, this concept is becoming increasingly present in sport and, in particular, in top-level competition. Thus, it is not unusual in Formula 1 broadcasts to hear talk of telemetry - through which data processed by computers is basically interpreted - in relation to the analysis of some aspect linked to the drivers, the engines or even the weather conditions. However, the origin of the use of Big Data technology in sports goes back to baseball, as can be seen in the field of fiction with the film Moneyball (directed by Bennett Miller in 2011) based on a book of the same name (published by Michael Lewis in 2003), which analyses how the team's general manager (Brad Pitt) managed to relaunch his team (the Oakland Athletics), thanks to the intensive use of baseball player statistics, and thus began to apply sabermetric principles when making signings.

Data analysis is a revolution for professional sport, allowing for improved decision-making in areas as diverse as transfer management, match tactics and so on. Indeed, there are increasingly sophisticated means to collect and subsequently analyse

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huge amounts of data related to any aspect of any sport: cameras, sensors record every detail of an athlete's performance.

Likewise, the wearables –in this sense, the Golden State Warriors, the NBA basketball team, have pioneered the use of wearables in training. The players' equipment contains no less than sixteen sensors that collect data on heart rate, breathing, and the activity of the main muscle groups. A small device in the trousers collects all this information and sends it to a smartphone from which the player's activity can be analysed in real time (Ranadivé, 2014) – boom is spreading unstoppably in professional sport: small sensors in bandages or sports clothing collect data, such as the athlete's speed or heart rate, which subsequently allow scientists, nutritionists and physical trainers to design personalised training programmes and get to know how training is affecting their health or if they are dangerously increasing the risk of injury. In this way, "smart" watches and bracelets that monitor heart rate, exercise, calories and even sleep patterns are the latest big bet of the big brands of electronics, telephony and sport, whose applications include improving physical performance. It seems that, nowadays, sports training is no longer conceivable without the use of apps that measure and record the athlete's physical activity. The most advanced athletes also use sensors and performance enhancement devices, and in elite sport they go even further, with the constant search and exploration of the latest technologies. With this data, trainers and coaches can polish defects in technique, improve their positioning on the pitch, or adjust the amount of calories the athlete should ingest depending on the effort and wear and tear they make of them, or the levels of training they can withstand without risk of injury.

All these developments are aimed at achieving the best possible performance. This is where the question arises as to whether the application of these modern data techniques to sport could be considered a type of doping that we could call "technological doping" insofar as it provides certain athletes with advantages from outside the track or the field of play.

The combination of big data and wearables in sport already seems to be a reality or a paradigm shift, so that this technological advance and the rise of wearables raises the question of whether we will soon be talking about cyborg athletes.

Finally, we cannot fail to mention here the current spread of a type of doping involving so-called "cyber athletes" within the so-called "eSports" (electronic sports), which applies to all video games played competitively. These are events that take place all over the world and include a variety of genres and competitions, from fighting games to strategy titles or sports simulators. This is a clear example of the spread of new technologies in the field of sports, given that eSports have been booming in recent years thanks to the massification of competitions over the internet. In this regard, the first organisations date back to the 1990s, with the formation of the Cyberathlete Professional League in the United States. The popularity of the competitions led to the creation of other organisations, including today's Major League Gaming and the World Cyber Games, which are considered the electronic equivalent of the Olympic Games (Bogost, 2013).

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As in traditional high-performance sports, today's professional gamers and teams are immersed in a highly competitive and demanding industry. The organisational plan of the most prominent clans is top-notch, where the relationship with sponsors is paramount. Likewise, their players are treated in a manner befitting their status as elite e-sportsmen, with training facilities equipped with all the amenities. The explosion in popularity of eSports has given rise to a new discussion: is it right to consider professional video gamers as sportsmen and women? The community seems somewhat polarised: some personalities such as John Skipper, President of the Entertainment and Sports Programming Network (ESPN) have been against considering it a sport insofar as there is no physical activity involved (Woods, 2015: 95) on this issue, although disciplines such as chess set a precedent for de-branding sports as a purely physical activity. And if so, can the use of stimulant substances, by the way, be considered as sports doping?

In view of the seriousness of the situation, the Electronic Sports League (ESL) and a group of experts are working together to put an end to the problem. To this end, the ESL has published a regulation that includes a list of banned substances. In order to control the illegal use of these drugs, saliva tests and skin tests will be carried out, trying to be as non-invasive as possible while maintaining the privacy of the players (Chikish, *et ál.,* 2019: 294-313). To this end, it is planned to create an area away from the competition for this purpose. Players who are taking any of the banned substances by medical prescription will have to provide sufficient evidence prior to the competitions. They have announced that there will be no retroactive penalties, but players found to be taking banned substances from now on will be sanctioned with a reduction of winnings, deduction of points, disqualification from the tournament, and up to two years' ban from registering for tournaments in the sports league. As we can see, the parallels with the mechanisms for dealing with doping in "conventional" sports are clear.

III. Robots in healthcare. Definition and typology

The EU's health sector is facing increasing demand for services due to an ageing population, a rise in chronic diseases, budgetary constraints and shortages of skilled workers.

Technological advances in the fields of robotics and AI can offer countless opportunities to meet these challenges, resulting in significant cost savings. Together with the integration of digital technologies, the application of robotics and AI could lead to improvements in medical diagnosis, surgical interventions, disease prevention and treatment, and rehabilitation and long-term care support (Fosch-Villaronga, 2020). AI and digital solutions could also contribute to more efficient and automated work management processes, while providing continuous training for health and care workers (Dolic, 2019).

Care robots have been defined in the literature as robots designed for use in the home, hospital or other settings to assist, support or provide care to the sick, disabled, elderly or vulnerable (Vallor, 2011: 251-268) or in the care of people in general (Van Wynsberghe, 2015: 61-62).

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Before we refer to the typology of sanitary robots, we must make an observation. It has been claimed in the legal literature (Barrio Andrés, 2019) that the law is obliged to provide advanced regulation to stimulate the development of robotics and artificial intelligence while ensuring that development is in line with the values of the constitutions and the Charter of Fundamental Rights of the European Union. Among the various regulatory initiatives, it is noteworthy the European Parliament Resolution of 16 February 2017 with recommendations to the Commission on civil law rules on robotics. In this regard, on the 20 January 2015 the JURI Committee decided to establish a Working Group (WG) on legal questions related to the development of Robotics and Artificial Intelligence (AI) in the European Union. The WG primarily aimed at drafting civil law rules linked to this subject-matter. Besides Members of the Committee on Legal Affairs the Working Group also included Members representing the Committee on Industry, Research and Energy (ITRE), the Committee on the Internal Market and Consumer Protection (IMCO) and the Committee on Employment and Social Affairs (EMPL). Robotics and AI have become one of the most prominent technological trends of our century. The fast increase of their use and development brings new and difficult challenges to our society. The road from the industrial sector to the civil society environment obliges a different approach on these technologies, as robots and AI would increase their interaction with humans in very diverse fields. The JURI Committee believes that the risks posed by these new interactions should be tackled urgently, ensuring that a set of core fundamental values is translated into every stage of contact between robots, AI and humans. In this process, special emphasis should be given to human safety, privacy, integrity, dignity and autonomy. Other important aspects addressed in this resolution are: standardisation, intellectual property rights, data ownership, employment and liability. It is crucial that regulation provides predictable and sufficiently clear conditions to incentivise European innovation in the area of robotics and AI (European Parliament resolution of 16 February 2017 with recommendations to the Commission on civil law rules on robotics [P8_TA(2017)0051]. The European Parliament's Resolution on robotics of February 2017 has received special attention from the doctrine and has been the subject of two monographs. Thus, based on this resolution, the choral work coordinated by Rogel Vide proposes a journey through issues such as creativity by robots or androids, the consideration of these as persons, artificial intelligence, the control and failures of robots and their civil responsibility (VV.AA. 2018).

It is precisely this European Parliament Resolution of 2017 that has identified three major areas of application of robotics in the field of health sector: surgical, rehabilitative/prosthetic and healthcare. Thus, some of the most interesting applications for the health and healthcare sectors include the following:

1. *Surgical robots*. Robotic surgery allows for more precise, less invasive and remote interventions, based on the availability and evaluation of large amounts of data. We refer, specifically, to the existence of robots designed for surgical practice. Given its initial commercial success, a paradigmatic example is the DA VINCI robot, distributed by the company of the same name, at the time the owner of a

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multitude of patents protecting the robot technology designed to assist in surgical operations (García-Prieto Cuesta, 2018: 43) (Douissard *et ál:* 2019: 13-27).

2. *Prosthetic and rehabilitative robots*. Rehabilitation systems that support patients' recovery as well as their long-term treatment at home rather than in a health care facility. The first includes a wide range, such as rehabilitation of damaged body functions or replacement of limbs, cognitive rehabilitation, and would also include exoskeletons or other wearable or implantable elements and, where appropriate, advanced bionic prostheses (Andreu Martínez, 2019: 81).
3. *Care robots.* Care and social assistance robots that make it possible to meet the growing demands for long-term care of an ageing population affected by multiple morbidities

IV. Robots and COVID-19

1. Robots for virus disinfection and medicine delivery

As we all know, a new coronavirus (SARS-CoV-2, causing Covid-19 disease) was identified for the first time in December 2019 in Wuhan City, Hubei Province, China, and has spread rapidly around the world. The Covid-19 pandemic has caused an unprecedented health and economic crisis. The magnitude of the crisis has demanded an immediate response from government actors, scientists and medical professionals. With limited resources and the immediate need for medical supplies, health support and treatment, the crisis has demanded innovative solutions. New uses of emerging technologies have been proposed to meet the growing demands. With limited resources and the immediate need for medical supplies, health support and treatments, the crisis has demanded innovative solutions. New uses of emerging technologies have been proposed to meet growing demands. Emerging technologies have contributed to the study of COVID-19 (Atienza Macías & Vieito Villar, 2020), the development of advanced diagnostic tools and treatments, and the response to medical supply shortages. Innovative use of emerging technologies continues to have a profound impact on our ability to respond to this global crisis and should continue to be used to help improve outcomes. Technologies include robots. Robots are a promising technology to perform many tasks such as spraying, disinfecting, cleaning, treating, detecting too high a body temperature or the absence of a mask, and delivering medical goods and supplies in the event of a COVID19 pandemic (Sikala Vafea *et ál.* 2020) (Alsamhi & Lee, 2020)

During the 2015 Ebola outbreak, three major areas were identified where robotics can make a difference clinical care (e.g. telemedicine and decontamination); logistics (e.g. delivery and waste handling) and recognition (e.g. monitoring compliance with voluntary quarantines) (Yang *et ál.,* 2020).

All in all, recent events have shown that collaboration between medical researchers and engineers is essential for the development of rapid and less costly ways to tackle the pandemic.

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2. Healthcare robots and COVID-19: accompanying and non-transmission of the virus

Many of the robots used in health care will have social attributes, interacting with patients to provide companionship, therapy and an extended ability to monitor vital signs and other health-related functions. As robots become more capable of imitating human facial gestures, voices, expressions, language and emotions, people will increasingly develop social bonds with them. This, in turn, will establish the kind of trust needed for the delegation of certain tasks and decision-making previously carried out by human caregivers and doctors. Robots are already being designed to optimise interaction with dementia and autism patients, providing the optimal level of social engagement to facilitate learning, companionship and, in some cases, increase the capacity for independence of these patient populations (Kerr *et ál.,* 2017: 257-280) (Henkel *et ál.,* 2020).

Another strategy to imbue robots with sociability is telepresence. Telepresence robots are semi-autonomous robots that can be operated remotely but can also perform some operations themselves. The purpose of these robots is to give a sense of presence to both the teleoperator and those in the same place as the robot. For example, THE GIRAFF is famous, a telepresence robot aimed at older populations that uses a variety of intelligent home sensors to measure changes in patients' blood pressure and detect when they faint. In parallel, it has a skype-like interface to connect the patient to their caregivers and family members.

These types of social robots that provide "companionship" have had and will have a crucial role in times of COVID-19 with the long periods of quarantine required, especially counterproductive for the mental health of older and more vulnerable people who, because they are people at risk, have had to be more rigorous in their confinement. Their potential lies in the fact that they carry out accompanying tasks and, given their non-human characteristic, the non-transmission of the virus seems to be guaranteed.

V. The legal role of the robot

It is extremely likely that delivering care using robots will, in some instances, cause some kind of harm. In fact, in the United States there have already been cases of damage following surgery with the Da Vinci robot mentioned above. Establishing liability in such cases will present novel legal issues. The da Vinci Surgical System is designed to enhance minimally invasive surgeries by providing surgeons with greater precision and visualisation and enabling procedures that would otherwise be considered too difficult without a robotic instrument. When expertly performed, these minimally invasive robotic procedures can help provide patients with optimised recoveries compared to traditional open surgeries. Robotic surgery, specifically with devices such as the da Vinci Surgical System, has experienced rapid expansion and growth since the early 2000s. However, as the frequency of robotic procedures increases, so do complaints of system malfunction and reports of patient injuries that can, in effect, lead to lawsuits

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against stakeholders including the device manufacturer, the hospital or institutions and their staff, as well as surgeons and their associates. Each of these stakeholders involved in robotic surgery has a responsibility to maintain the highest level of training and care available to help a patient achieve a good outcome (Hechenbleikner & Jacob, 2019:27-34) (García Micó, 2014).

One of the most common problems in the regulation of robotics in the health care context is to find a harmony between promoting technological innovation and at the same time ensuring that new robotic technologies do not pose unreasonable risks to health and safety or to the protection of fundamental rights and values (Leenes *et ál*., 2017: 14). In this respect, special precautions are needed in the interaction of artificial intelligence systems and robots with particularly vulnerable people, i.e. the elderly, children, the disabled.

What helps to achieve this balance is the liability regime, which must deal with possible adverse effects on the use of robots (García Portero, 2018:218).

They stand out as key legal aspects of this sector, together with the institute of liability, secondly, safety and commercialisation and thirdly, everything concerning privacy and data protection.

1. Responsibility of robots and Artificial Intelligence

The question of liability when a robot causes damage or injury is a radial issue that concerns all robots used in healthcare.

In accordance with the classification criteria for healthcare robots followed in the third section on Robots in healthcare. Definition and typology:

Firstly, the introduction of robots in surgery generates a new risk: the real possibility that a patient may be injured by the robot regardless of the actions of the surgeon.

A second level refers to prosthetic robots. The risks associated with the use of robotic prostheses can be particularly high, since they are extremely technologically sophisticated systems, are used in a large number of everyday activities and can be employed in ways that the manufacturer did not originally envisage.

Thus, in the case of care robots, it is not risky to think that a robot that moves an elderly person from a bed to a wheelchair, for example, could injure this elderly person if it does not function properly. If this were to happen, who would be responsible for compensating the injured person? The person responsible for the damage could be the developer of the robot, the manufacturer, the seller, the company in charge of its maintenance, or even the user himself for interacting with the robot in a way prohibited by the manufacturer.

In this respect, it is the institution of product liability - as a "special civil liability regime" - that we find most appropriate in the context of damage caused by robots (Ataz López, 2020: 34). The legal framework for product liability in Europe is included in 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

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products, amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999.

There may also be occasions when a user has been injured by a misuse of a care robot or a prosthetic robot, rather than by a defect in the robot, and in these cases the way to redress the damage will be through the imposition of compulsory civil liability insurance, which should be taken out by the owner of the robot.

It should be noted that there are other factors to be considered in the production of any harmful action. Taking robotic surgery as an example, in it the surgeons, the hospital, the maintenance teams, the software developers and those responsible for the computer systems could have a possible role or participation in causing the damage to the patient.

From the above it follows that the liability for incorporating technological devices into the human body is divided into two: on the one hand, that resulting from incorrect surgical intervention and, on the other, that resulting from a defective product.

Whether it is a claim under product liability or an action under contractual or non-contractual civil liability in the case of damage to third parties, it can often be difficult to prove the defective nature of complex robotic technology.

In this area, the European Union and EURON (EUropean RObotics research Network) are considering the tracking and recording of robot activity (black box) and also the provision of a "unique identification" for each robot. In this respect, it has been proposed that medical robots should *ex lege* be equipped -in an aeronautical simile- with a "black box" in which all data relating to the movements of the robot, environmental data, orders given by the operator, etc., would be perfectly recorded.

This mechanism would allow manufacturers to intuit how the robot's learning algorithm caused changes in the system's behaviour. Given the high processing capacities and the processing of big data, it is very difficult for people to know how the robot has taken a certain decision and what the basis is.

2. Safety and commercialisation aspects

At the present time, we already have a normative that regulates the manufacture and marketing of robots in the health sector and, to this end, two main directives were issued at European context.

1. Firstly, Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. This directive harmonises national legislation on active implantable medical devices in order to ensure universally applicable, redundant safety standards for patients. It also allows products to be used in any EU country.
2. Secondly, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. This standard harmonizes national legislation on medical devices by promoting public confidence in the system. It also allows products to be used in any EU country.

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Currently, the key regulation in force in the European area is included in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

3. Privacy and protection of health-related data (sensitive or specially protected)

It is very likely that robots used for health purposes will collect large amounts of very intimate personal data. This type of data, in the context of data protection legislation, is referred to as sensitive or specially protected data, in which health data is subsumed.

Of course, the data that may involve the most information are those obtained for social assistance purposes, insofar as they refer to all types of data on the lifestyle or habits of the person in his or her daily life. This could include geolocation data, monitoring of vital signs, management of medical alarms, monitoring to determine whether the patient is taking the prescribed medication, voice recognition, sound recording, storage of information as the user gives it through dialogue with the robot and, eventually, could include in the future, an affective computing system (e.g. analysis of the person's gestures for recognition, management and generation of emotions).

At the same time, it should be noted that in the context of these new robotic systems, data on the patient's condition and illnesses will have to be stored, as well as the much-needed "medical history", medicines and other data concerning health, in order for the robot to carry out its task.

Nevertheless, aspects relating to privacy and data protection at European level are regulated in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).

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