Regulating Healthcare Robot and AI Technologies

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1. The rise of healthcare robot and AI technologies

The insertion of robots and artificial intelligent (AI) systems in healthcare settings is accelerating. Healthcare robots offer the possibility of assisting patients in ways that seemed far-fetched time ago and freeing caregivers from doing tedious tasks. Typical healthcare robots include socially assistive robots for therapy, lower/upper-limb exoskeletons for rehabilitation, robots for the blind, feeding robots, companion robots, surgery robots, or delivery robots. Healthcare AI applications promise safer, more efficient, and personalized care. Typical applications of such systems include personalized diagnosis, early disease detection, hospitalization risk prediction, and drug discovery.

Although recent studies support the adoption of robotic technologies for care purposes, these technological developments interact with children, elderly or disabled, socially and physically, and may raise concerns that range from physical to cognitive safety, to discrimination, data protection, transparency, responsibility, or dignity. Research in other fields also suggests that technology may have a profound and alerting impact on us and our human nature in the long run, as the more time we spend with technology, the less time we spend on learning the abilities and skills that real-life requires. Moreover, European Institutions worry that the insertion of robots could dehumanize caring practices as human contact is an essential aspect of personal care.

These technologies also process vast amounts of data - often using cloud services, can learn from experience and self-improve their performance, which challenges the applicability of existing regulations that were not designed for progressive, adaptive, and evolutionary systems. Static regulations are not ready for the automated processing of data evaluating, analyzing, and predicting health-related outcomes, affecting not only data protection rights but, ultimately, the overall safety of the individual. Even new regulations such as the General Data Protection Regulation may prove ineffective in AI environments. Moreover, legislation establishing safety requirements was mostly designed for things working in isolation, mostly in industrial environments. In this sense, it comes without surprise that there

[1] The views expressed in this paper are those of the author and do not necessarily reflect the views or policies of the Knowledge Center Data & Society or CiTiP. The paper aims to contribute to the existing debate on AI.

are no specific laws for interconnected robots in healthcare but a complex mosaic of different regulations that may (or may not) apply to robot technology.

This policy paper comes as a result of the fellowship that the author Dr. Fosch-Villaronga had at the Flemish Knowledge Center for Data & Society (CDS) at Centre for IT & IP Law (CiTiP) of the University KU Leuven, in Belgium during December 3-8, 2019. The vision paper maps some of the potential benefits and adverse effects of healthcare robots and AI technologies to help steer the development and use of policies concerning AI and robot technologies in care settings in the appropriate direction. Some thoughtful policy recommendations geared towards ensuring effective healthcare robot legal oversight and the promotion of the responsible development of these technologies close the vision paper in the hope that this will inform the policy debate surrounding the regulation of AI in Flanders.

2. Definitions and potential applications

A robot is a movable machine that performs tasks either automatically or with a degree of autonomy. Movable, because it has the capacity for movement, within its environment or on its own. A machine, because it is an apparatus using mechanical power. Performing tasks, either automatically or with a degree of autonomy, because it works by itself with or without human control.

A robot has a physical body. Typical embodiments include anthropomorphic, zoomorphic, caricatured, and functional. The embodiment of the robot plays a crucial role in many applications: children feel stronger friendship bonds with a physical robot compared to a virtual avatar, the use of physically present robot tutors produces better learning results, and individuals with cognitive impairments find the interaction more "efficient, natural, and preferred" with a physical robot than with a simulated one. Robot embodiment enhances presence, helps with the allocation of social-interactional intelligence typically via gaze and facial expressions, and makes robot task capabilities intelligible from the user perspective. The intelligibility of robot tasks may enhance the transparency of robot intentions and actions and promote trust.

The European Foresight Monitoring Network (EFMN) (2008) defined healthcare robots as systems able to perform coordinated mechatronic actions (force or movement exertions) based on processing information acquired through sensor technology, to support the functioning of impaired individuals, medical interventions, care and rehabilitation of patients and also individuals in prevention programs. In 2019, the Policy Department for Economic, Scientific, and Quality of Life Policies of the European Parliament identified robotic surgery, care, and socially assistive robots, rehabilitation systems, and training for healthcare workers as the *most interesting* applications of healthcare robots:

Table 1. Most interesting *healthcare robot applications according to the Policy Department for Economic, Scientific, and Quality of Life Policies of the European Parliament*.

Most interesting healthcare robot applications	
Robotic surgery	allowing more accurate, less invasive and remote interventions relying on the availability and assessment of vast amounts of data
Care and socially assistive robots	allowing to meet the expanding demands for long-term care from an aging population affected by multi-morbidities
Rehabilitation systems	supporting the recovery of patients as well as their long-term treatment at home rather than at a healthcare facility
Training for health and care workers	offering support for continuous training and life-long learning initiatives

The European Parliament also highlighted that 'possible applications of AI and robotics in medical care (*are)* managing medical records and data, performing repetitive jobs (analysing tests, X-rays, CT scans, data entry), treatment design, digital consultation (such as medical consultation based on personal medical history and common medical knowledge), virtual nurses, medication management, drug creation, precision medicine (as genetics and genomics look for mutations and links to disease from the information in DNA), health monitoring and healthcare system analysis, among other applications,' although none of those applications seem to relate to *robotics*, only AI.

Other robot applications on the rise are in the field of assistive robotics, those robots that assist users to perform a task or perform a task for users. Recent projects focus on physical assistant robots, also called 'exoskeletons,' those wearable robots that augment or supplement users' physical capabilities. Others on clothing assistants, also known as robot-assisted dressing, those robots that help users to dress up; and feeding robots, which may help people with disabilities live more independently and participate in social life in a more inclusive manner. Guiding robots could be mass-produced and available for the blind and improve this way users' confidence, autonomy, and independence, and avoid punished-based training for assistive dogs, the negative impacts of which is largely underexplored.

Other applications are socially assistive robots, those robots that assist socially users. Typical applications include robots for neuro-rehabilitation, for children with autism, robots that help patients monitor chronic illnesses at home, or for dementia. Although it is unclear what safeguards apply at the social or psychological level, it is a growing area of interest.

Prospective areas of interest may include the potential use of sexual robots for care purposes, or sex care robots. The World Health Organization (WHO) defines sexual health as the "state of physical, mental, and social wellbeing concerning sexuality. It requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence." Although every human should be able to enjoy physical touch, intimacy, and sexual pleasure, however, disabled people are often not in the position to fully experience the joys of life in the same manner as abled people. Similarly, older adults may have sexual needs that public healthcare tend to ignore as an essential part of their wellbeing.

In 1993, the United Nations stated that persons with disabilities should enjoy family life and personal integrity, and should 'not be denied the opportunity to experience their sexuality, have sexual relationships and experience parenthood' (Rule 9, para. 2). However, after more than 20 years of discussion, the universal access to sexual and reproductive health remains an unfinished agenda, as if society failed in recognizing people with disabilities as sexual beings.

Robot technology may have moral implications, contribute to the loss of human contact, reinforce existing socio-economic inequalities or fail in delivering good care, and there is no proof that care robot technology is going to be any different. Moreover, these technologies might have long term catastrophic or existential risks and might have to 'be subject to planning and mitigation efforts commensurate with their expected impact.' Still, robot technologies may also benefit a large part of the population, and that is what we tried to understand in this article.

3. Areas of concern

Since the use of healthcare robots and AI technologies are fairly new, the understanding of their associated impacts is still under exploration, and the literature lacks a comprehensive understanding of the positive or negative impacts of healthcare care robots.

This part of the vision paper brings together some studies that have reflected upon the implications of care robots that could anticipate some of the implications these technologies might have. The next table below summarizes some of the main legal, ethical, and regulatory implications of the use and development of robots for care purposes:

Care-related considerations	**Explanation**
Human-robot safe interaction	Robots may challenge the physical and mental integrity of the users. Both physical and cognitive safety should be protected.
Human responsibility	Depending on the degree of control a user has, the question of who is responsible if something goes wrong may abound. Technology complexity should not be a reason to avoid human responsibility.
Privacy and data protection loss	Always-on robotic devices that monitor the activities of elders may challenge the protection of their data protection and privacy rights.
Autonomy and independence restriction	Task delegations from the human to the machine risk overriding the autonomy and independence of a person.
Deception and infantilization	Mimicking life-life and human states may lead to questioning the authenticity of the relationship and deceive of the user. Robots may

	encourage the idea elders (with dementia) go through a second childhood
Dignity, objectification, and loss of control	Insensitive use of robots risks treating elders as if they were not sentient beings.
Human-human interaction decrease	Human-robot interaction may exacerbate existing elder loneliness and increase neglection by relatives and society.
Long-term consequences	Technology, including robots and AI, may have long-term consequences that might be difficult to foresee before mass-adoption and continuous use.
Effects on education	The insertion of robot and AI technologies in the healthcare sector may affect the learning and educational processes of medical doctors, nurses, and practitioners that may have to re-skill and also familiarize themselves with areas geared towards reflection.
Discrimination, bias	Robots and AI could reinforce and exacerbate existing socio-economic inequalities. Attention to not only gender and race but also minorities like LGBTQ+ community, religion or political orientation is essential to avoid discrimination.
Access	Fair distribution to advances in healthcare technology that can potentially benefit society at large should be not reserved for a minority, but for everyone.
Transparency, explainability	Having machines or algorithms that 'decide' without oversight, without being intelligible to humans should be avoided. Do not forget that machines are man-made, and the decisions nor the responsibility should be shifted in favor of the machine.
Cyber-physical systems require cyber-physical security	As cyber-physical systems, robots need safeguards relating to the physical and digital parts to be safe.

Moreover, power dynamics between private standards and public policymaking confuse robot classification and their subsequent governance. While public policymakers tend to put all healthcare robots in the same basket, the industry pushes for new 'in-between' categories not recognized in legal texts. The ISO 13482:2014 standard on safety requirements for 'personal care robots,' for instance, defines this category as 'service robot that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications.' The standard does not define *personal care*, although it excludes robots with medical purposes, and includes physical assistants such as exoskeletons, 'wheeled passenger carriers' reminding of wheelchairs, and 'mobile servant robots' that may work as socially assistive robots

These confusions blur the understanding of which requirements roboticists have to meet to be compliant with binding regulations. In turn, this ultimately affects their safety, as it is not clear what is the minimum safeguard baseline that needs to be, by law, respected.

4. Policy recommendations

Develop a comprehensive framework for Healthcare Robots and AI Technologies

Our legal system works in a horror vacui or, preferably, horror lacunae mode. We regulate everything: since we are conceived until we die, even after legal entities, nature, and we avoid the existence of legal lacunas. The regulation provides legal certainty, establishing to-be-respected boundaries, consequences for violations. In light of new development, therefore, there might be already many laws that apply to a particular thing. Healthcare robots, for instance, might not be regulated per se. However, a mosaic of existing regulations that range from the Directive 2001/95/EC on general product safety and Directive 85/374/EEC on liability for defective products, to the Medical Device Regulation 2017/745 or including the General Data Protection Regulation 2016/679, may apply to it. It comes without surprise, thus, that before developing a new law, regulators make sure the legal system already responds to any associated issue.

Still, after a thorough legal assessment, regulators and scholars might find out that technological developments call into question the existing legal framework. For instance, not all healthcare robots might be considered 'medical devices,' and maybe new emerging rights such as 'the right to a meaningful contact' developed by the Parliamentary Assembly of the Council of Europe should have to be realized.

Since the art of progress is to preserve order amid change and to preserve change amid order, a comprehensive framework for healthcare robots is needed. Such a framework should identify the stakeholder ecosystem surrounding these robots, and related rights and obligations, recognize the specificities of different robot types, and also potentially applicable legislation. Moreover, policymakers may also want to identify lacunae, parts in the legislation demanding clarification, and take action to provide robot developers with further guidance.

Promote healthcare robot and AI technologies that truly benefit the patient

Often, nurses report that they would not like to have a robot that talks to their patients but a robot that makes the bed instead. Freeing nurses from such a task would improve the quality time they have to assist patients. However, not all the 'saved time' is directly applied to a 'meaningful contact' with the patient.

In other occasions, we insist on having a human caregiver to assist patients to avoid the dehumanization of care. However, feeding robots (robotic arms incorporated on the table or in a wheelchair) would allow for increased privacy and intimacy during mealtime, helping this way people with disabilities live more independently and participating in social life without the need of having a human carer.

There should be in place mechanisms and methodologies to promote reflection on whether the investment in the AI or the robot is the best solution. In the case of the healthcare sector, sometimes hiring new professionals and improving the working conditions of health practitioners at large would reduce many of the issues associated with the development and implementation of robots. In this sense, education and re-training skills will be soon deemed necessary for those environments likely to adopt robotics and AI technologies.

Robotic ecosystems' complexity should not, in itself, be a reason for removing human responsibility

One of the reasons why the legal community has discussions on holding the robot responsible for its actions maybe because of the "prevalence-induced concept change" phenomenon. This phenomenon suggests that "people often respond to decreases in the prevalence of a stimulus by expanding their concept of it." In their article, Levari et al. explain that "when blue dots became rare, participants began to see purple dots as blue; when threatening faces became rare, participants began to see neutral faces as threatening; and when unethical requests became rare, participants began to see innocuous requests as unethical."

Levari et al. suggest that the prevalence-induced concept change can be a problem depending on the context of the application. For instance, they explain "When yellow bananas become less prevalent, a shopper's concept of "ripe" should expand to include speckled ones, but when violent crimes become less prevalent, a police officer's concept of "assault" should not expand to include jaywalking." In the context of robotic systems this phenomenon may read as follows: *when direct human actions become less prevalent, the policymaker's concept of "responsibility" should not expand to include robot actions*.

Develop the methodology Robot Impact Assessment to promote legal compliance

Instead of developing one assessment for every impact a particular robot technology may pose, technology assessments (TA) focus on "forecasting, at least on a probabilistic basis, the full spectrum of possible consequences of technological advance, leaving to the political process the actual choice among the alternative policies in the light of the best available knowledge of their likely consequences."

Beyond privacy, surveillance, robot technology differ in context, type, and can have several impacts. A Robot Impact Assessment describing the context of the use of the robot, the characteristics of the robot, the current regulatory framework, and the possibility to address the related risks may not only promote compliance, but it may also inform policies from a bottom-up perspective on the impacts of such technology. It is essential to configure legal and regulatory assessing mechanisms that go beyond ethics guidelines or other instruments relating to algorithmic impact assessments that overlook the intrinsic relationship between the cyber and the physical aspects of these aspects.

Robot Impact Assessment data repositories for policy-making purposes

Impact assessments in the legal domain are currently seen merely as an accountability tool, i.e., a way to show that, for instance, a roboticist is compliant with the data protection legal framework. The knowledge generated by these impact assessments does not feedback the legal system per se nonetheless. In this sense, there is no data collection mechanism oriented towards a repository format for evidence-based policymaking purposes. In other words, the law does not learn from these assessments (yet); they are just standalone and static instruments. A mechanism that could extract relevant knowledge from these accountability tools could help to build evidence of what technologies exist, what risks arise, and how these risks are mitigated.

In the future, policymaking could take advantage of the data/knowledge generated by accountability instruments. The generated data/knowledge could be inserted in a shared data repository to help evidence-based policymaking in matching different types of technology, with threats and risks, and also with mitigations. A first step towards automating this process would be to create a software-based accountability system that helps roboticists developing a robot to identify which legislations they have to follow. The tool could gather dissonances or unregulated areas and policymakers could react to that. Over time, guidelines and clarifications could be released to set precedents for future developers.

Robots are cyber-physical systems and may demand cyber and physical safeguards, also psychological

In a healthcare setting, robots interact in close, direct contact with children, older adults, and persons with disabilities. If an attacker can compromise the controlling of the machines or have effects on the production chain, any malfunctioning or any cybersecurity attack to a healthcare robot may affect the health and well-being of people.

As cyber-physical systems, robots need safeguards relating to the physical and digital parts to be safe. Robots represent an interface to the physical world, making security concerns particularly salient because, unlike traditional computers, they can have an immediate physical effect on their environment. Acknowledging such a link is essential in the healthcare domain, as 'vulnerabilities could allow unauthorized users to remotely access, control, and issue commands to compromised devices, potentially leading to patient harm.'

As robots also interact with users *socially*, it is often the question of what is the safeguard baseline to be respected for robot developers to ensure that there is not going to be any psychological harm associated with their technology.

Start thinking about iterative regulatory processes for robot and AI governance

What lacks in robot and AI governance is a backstep mechanism that can coordinate and align robot and regulatory developers. The mere evolution of both regulatory and robot development does not assure harmony in respect of the legal boundaries to be respected by roboticists, or to the concrete issues to be addressed by regulatory bodies. Moreover, evolutionary systems, either AI-driven or robot technologies do not fit in existing categories and challenge subsequent certification processes.

Previous literature stresses the need for an *issue manager* or the creation of a European Robotics Agency. However, it is important to think about what is going to be the *modus operandi* of those managers. And that is why it is important to start thinking about iterative regulatory processes for robot and AI governance involving Robot Impact Assessment, Shared Data Repositories, and Regulatory Impact Assessments, that can serve as a backbone in coordinating and aligning robot and regulatory developers, for healthcare purposes.