




Article

Implementing Ethical, Legal, and Societal Considerations in Wearable Robot Design

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Abstract: Ethical, legal and societal implications (ELSI) in the development of wearable robots (WRs) are currently not explicitly addressed in most guidelines for WR developers. Previous work has identified ELSI related to WRs, e.g., impacts on body and identity, ableism, data protection, control and responsibilities, but translation of these concerns into actionable recommendations remains outstanding. This paper provides practical guidance for the implementation of ELSI in WR design, development and use. First, we identify the need for domain-specific recommendations against the context of current ELSI guidance. We then demonstrate the feasibility and usefulness of taking a domain-specific approach by successively transforming currently identified ELSI into an action-guiding flowchart for integration of ELSI specific to the different stages of WR development. This flowchart identifies specific questions to be considered by WR development teams and suggests actions to be taken in response. By tailoring ELSI guidance to WR developers, centring it on user needs, their relation to others and wider society, and being cognizant of existing legislation and values, we hope to help the community develop better WRs that are safer, have greater usability, and which impact positively on society.

Keywords: wearable robot; exoskeleton; ethical, legal, and societal issues; ELSI guidance; ELSI implementation; user-centred design; responsible research and innovation; value-sensitive design



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1. Introduction

Wearable robots (WRs) have a high potential impact on users, their social environment and society at large [1]. WR technical and programming education is being integrated into engineering curricula [2], but non-technical potential impacts have only been modestly addressed in curricula to date. While guidance and benchmarking for WR developers regarding electrical and mechanical safety is being developed, see [3,4], ethical, legal and social implications (ELSI) have not been translated into actionable goals. There is a general awareness in robotics development of some legal and regulatory aspects, such as health and safety or data security, but WR developers are often unsure of the relevance of other ELSI concerns for their professional practice.

The purpose of this paper is twofold: first, to give an overview of documents, processes, and initiatives that offer *general* information and guidance on the integration of ELSI into the development of new technologies. Second, and most importantly, we aim to provide the first *practical*, domain-specific guidance on ELSI matters in the development of

WRs. The paper builds on prior work conducted by the Working Group of the H2020 COST Action 16116 on ELSI of WRs, including expert consultations and a literature review [5]. The results of this theoretical analysis are now translated into a specified flowchart directed at WR engineers and is designed to help them include ELSI considerations into the development process of WRs.

Education about, and consideration of, ELSI in WR design help to prepare the ground-work for engineers and designers to comply with the current, and yet to be developed, legal frameworks [6]. Integrating legal and ethical considerations into WR design may not only ease market entrance, but also facilitate the building of trust and ultimately user acceptance of the device. Such acceptance is paramount because it leads to faster adoption of WRs in daily practice [7–9], making WRs more commercially successful. Considering ELSI also helps researchers think through their projects with a broader lens, which may also facilitate faster ethical approvals for testing and consecutive prototyping [10].

Including ELSI in guidance and education for WR developers is also in line with the broader shift in engineering education from technology-only skills towards the development of transdisciplinary “21st-century skills”, such as critical/creative thinking, social skills, collaboration, and communication [11,12]. It is not sufficient to focus on technical and standardization issues [5,13–15]. Engineers also need to recognise the wider impact of their technologies, e.g., by addressing questions regarding expectations, understanding, and behavior by various stakeholders, which may impact the societal reception of WRs. It is also important to be cognizant of current legal and regulatory requirements as well as impending developments with potential future impact on the field [16,17].

This paper starts by outlining various existing international guidance documents that propose important elements of good ELSI practices. While these documents outline general procedures and principles, it will be argued that insufficient attention has so far been paid to the need for practical domain-specific ELSI guidance for WR developers (Section 2). To close this gap, we first provide a condensed summary of important ELSI for WRs in Section 3 and then use this knowledge to devise a flowchart tailored for WR engineers in Section 4. We hope that our practical guidance can convey to WR developers that the consideration of ELSI does not have to be an obstacle to their work, but that it can be an opportunity to increase their chances of developing a successful product.

2. Process, Principles and Domain-Specificity: The Challenge of Targeting Ethical, Legal and Social Implications (ELSI) Guidance Effectively

Over the last decade, there has been increasing awareness of the importance of paying attention to ELSI in robot development [18–20]. ELSI considerations have also received significantly increased attention from governance bodies and professional organisations, in various guises. While sometimes ELSI work is identified as a distinct, primarily citizen-oriented engagement approach, distinguished from Responsible Research and Innovation (RRI) as a later approach that is more oriented towards researchers and developers [21], in this paper we consider the ELSI umbrella to be wide, referring to all attempts to engage stakeholders in an inclusive and critical reflection process on novel technology development, ideally inculcating an attitude of humility among innovators [22]. This includes most prominently in the European context RRI initiatives funded by the European Commission as well as recent guidance documents targeted at technology developers [17,23]. Despite receiving widespread attention, such instruments’ impact on practice has previously been limited. The primary challenge for any attempt at providing ELSI guidance to robotic engineers appears to be finding the appropriate balance between:

- i. The need for a clear process of integrating the consideration of ELSI in WRs development, as exemplified by process models for ethical design, such as value-sensitive design (VSD) or ethics-by-design, the procedural focus of some RRI approaches, or the use of design flow-charts, for example, the Assessment list in the High Level Expert Group (HLEG) on AI [17];

- ii. The need for “top-down” guidance, by providing specific sets of substantive ELSI guidance, often based on general principles that can cover many application areas and be applicable to as yet unknown innovations, as exemplified by HLEG AI [17], IEEE [23], privacy by design, universal design, equality, diversity and inclusion (EDI), standards, and professional ethics codes;
- iii. The need for “bottom-up” guidance, in the sense of achieving sufficiently domain-specific guidance that allows robot developers to easily apply relevant concerns to their practice, including attention to specific use cases and stakeholder involvement.

This section will provide a brief overview of how a variety of proposals guiding the integration of ELSI considerations into the technology development process respond to that challenge.

2.1. ELSI Design Tools That Focus on Process

The integration of ELSI into the technology development process calls for attention to where in the process of development these aspects should be taken into account. There is generally agreement that ELSI need to inform technology development from the earliest point at which goals and values underpinning the technology are being defined, through the process of identifying and selecting desired functionalities and features, to the implementation of the technology in practice settings [24–27].

Procedural aspects are core features of VSD, a technology development methodology that aims to integrate value consideration as an integral part. It is based on the idea of embedded values [28], the assumption that value concerns become inevitably embedded in technologies through design decisions. Friedmann, Kahn and Borning [29] present VSD as an iterative process with an initial analysis of value considerations for a new technology that is revisited periodically in light of new knowledge about stakeholder views and the specific demands of the technical implementation. VSD has inspired other approaches focused on the deep and early integration of values into the technology development process, such as privacy by design [30], ethics by design [31], or, specifically for the field of care robots, care-centred value-sensitive design [19].

RRI is an approach to socially responsible innovation within the framework of research funded by the European Commission that covers a wide range of design tools and considerations meant to bring together innovators and societal stakeholders. According to Schomberg [26], RRI is “a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (to allow a proper embedding of scientific and technological advances in our society)” (p. 9). For example, the AREA/4P Framework for the responsible development of ICT technologies, developed as part of the ORBIT project [32] helps technology developers through a structured reflection process by identifying issues relating to each of the four procedural categories of anticipation, reflection, engagement and action (AREA), and specifying for each of these categories the four aspects of process, product, purpose and people (4P). The AREA/P4 Framework provides questions to help technology developers adapt and integrate ELSI considerations for their specific technology domain. Other RRI projects, such as RRI Tools [33], provide generic reflection tools that help developers elicit relevant considerations, for instance by focusing on the importance of diversity and inclusion of stakeholders, anticipation of impacts and reflection on implicit values, openness and transparency for public scrutiny, and responsiveness to changing circumstances or emerging knowledge.

Universal design is a design approach that is specifically focused on the inclusiveness of technologies for diverse users. It requires (i) equitable use for persons with diverse abilities, (ii) flexibility in use, accommodating different user preferences, (iii) simplicity and intuitiveness of use, (iv) easily perceptible essential information, (v) tolerance for error, (vi) low physical effort for device use, and (vii) facilitating easy use through providing appropriate size and space for users. Universal design is generally closely associated with

the disability rights perspective which, as a procedural requirement, demands consultation with stakeholders, following the principle of “nothing about us without us”. EDI, endorsed by many funding bodies, similarly requires the inclusion of a wide range of stakeholders in the research and development process, as a means to achieve better quality results through bringing together people with different experiences, ways of thinking and sensitivities, that allows the creation of a wider range of potentially valuable ideas, methods and solutions.

2.2. ELSI Design Tools That Identify Substantive Principles

Generally, design tools that include a set of substantive principles tend to be less focused on the specifics of the design process. Yet, procedural elements can merge to some extent with substantive principles, when certain procedural elements (such as stakeholder engagement) also embody substantive values (such as equality and fairness). In recent years, various high-level publications have provided guidance that focuses specifically on establishing a set of fundamental normative principles for the field of information technology, especially with regard to robots and AI.

In 2019, an expert group convened by the European Commission published their *Guidance on Trustworthy AI*, requiring compliance with laws and regulations, adherence to ethical principles and values, and system robustness to avoid unintentional harm. They identified a list of seven essential principles: (1) human agency and oversight, (2) technical robustness and safety, (3) privacy and data governance, (4) transparency, (5) diversity, non-discrimination, and fairness, (6) environmental and societal well-being, and (7) accountability [17]. These principles were further specified and operationalised, to facilitate their application in diverse contexts. While these principles were developed with regard to AI, many of them appear applicable to data-intensive information technologies in general.

The IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems published a guidance document on *Ethically Aligned Design* [23] outlining core principles. The document is based on three “pillars”, including an anthropological dimension by focusing on universal human values, a political dimension by focusing on political self-determination and data agency, and a technical dimension by focusing on technical dependability. These are complemented by the identification of a set of eight general principles that are partly cutting across the three pillars. These principles include (i) ensuring human rights, (ii) fostering human well-being, (iii) empowering human data agency, (iv) effectiveness and fitness for purpose, (v) transparency, (vi) accountability, (vii) awareness of risks of misuse, and (viii) specification of operators’ competence requirements. The discussion of the realisation of these principles in practice operationalises these principles further, including extensive reference to relevant standards in the field.

ELSI have also found their way into standards for robotics in recent years to mitigate the ELSI posed by robotics [34]. The British Standard Institute (BSI) has developed the British Standard (BS) 8611:2016 “Robots and Robotic Devices. Guide to the ethical design and application of robots and robotic systems” [35] which identifies 20 moral hazards and risks grouped on societal, application, commercial/financial, and environmental categories. It provides guidelines to mitigate or reduce risks associated with these categories. The standard builds on existing safety requirements for industrial, personal care, and medical robots and provides engineers with the tools to conduct an ethical risk assessment.

2.3. Desiderata for the Translation of ELSI Guidance into Domain-Specific Practice

However, what all the approaches and guidance documents outlined in the previous sections have in common is that their ELSI recommendations remain at a fairly high level of generality. As discussed, they focus predominantly on (i) identifying procedural elements for the integration of ELSI considerations in tech design and (ii) providing a framework of general normative guidance. Making principles practically meaningful is challenging. While all approaches discussed here make substantial efforts towards operationalising the process elements and normative principles to make them more practical, the generality of their application comes with the cost of lower applicability to specific domains.

The successful creation of domain-specific guidance requires more than a straightforward top-down application of general principles to a specific application domain. Instead, it needs to be informed and shaped by the particular characteristics of that domain that give rise to unique constellations of concerns. Whether domain-specific guidance can be created frequently depends on whether a meaningful dialogue has taken place between those with substantial experience of robot development in the field and those with a broader understanding of ELSI concerns, for example, through a careful review of ELSI literature, through standardization processes or other forms of direct engagement with stakeholders and policymakers [36,37]. Such a process does not just involve the selection of relevant principles from a pre-existing set of principles but frequently also includes the emergence of considerations that may not have been part of the prior conceptual framework.

Domain-specific guidance is significantly more developed in some robotics domains than in others. The interests of ELSI scholars and practitioners in a field are not always aligned, insofar as theoretically interesting ethical concerns may appear unrealistic and therefore not practically relevant to technology developers. Attention has also tended to be drawn towards societally more prominent uses, such as the use of self-driving vehicles, or overtly ethically challenging domains, such as the use of social robots for the care of vulnerable people. This has led to the comparative neglect of others that may appear less intuitively problematic but may nevertheless raise important ELSI questions, such as industrial robots or WRs. Guidance on specific aspects, such as guidance on the autonomy levels of robots, can also be well developed in certain domains, for example for driving automation, while still lagging behind on others, for example, medical robotics [38,39]. ELSI-sensitive design guidance for WRs has received particularly low levels of attention in the literature so far. As an exemption, exoskeletons received attention in a guidance document for research that possibly facilitate human enhancement [40]. However, ELSI of WRs conform to more than implications for possible human enhancement, as the next section will demonstrate.

3. ELSI Considerations for Wearable Robots: Methods Followed for Selecting Domain-Specific Principles and Core Concepts

While the above methodologies, documents, and resources provide general guidance on ELSI considerations' inclusion into the technology development process, they may appear somewhat removed from WR development's specific characteristics and challenges. This section provides a brief overview of relevant ELSI considerations for WRs, as developed in more detail in Kapeller and colleagues [5] (It should be noted that the funders' requirements required that military applications be excluded from consideration).

Using findings from both expert opinion (from three separate workshops) and a literature review, the authors classified 12 important ELSI into subjective (WR and the self), interpersonal (WR and the other), and social dimensions (WR and Society). These findings resulted from different workshops organized under the Cost Action 16116 on Wearable Robots. The authors conducted three consultations during 2017–2018 with experts with different backgrounds: ethicists, philosophers, social scientists, legal scholars, medical professionals, and engineers. The first meeting was held in Porto, Portugal in 2017 and gathered 30 experts and students from engineering, healthcare and rehabilitation, philosophy, and the regulatory field. The second meeting, held in Leiden, The Netherlands, in 2018 under the WeRob Conference, had a more ethical and philosophical focus, as it gathered 30 experts in robot ethics and wider ELSI regarding robots and the philosophy of technology. The last consultation was held in Pisa, Italy, in 2018 during the H2020 CSA INBOTS Conference. This meeting included a pool of 20 experts in engineering, philosophy of technology, robot ethics, technology law, and other mixed backgrounds.

During the workshops, the organizers asked the experts to brainstorm about the particular ELSI that wearable robotics bring forward on individual Post-It notes. After this individual exercise, the organizers pre-clustered them and introduced them to the audience in the second phase. In the third phase, the participants discussed in multidisciplinary groups and selected their three central and most pressing ELSI surrounding the use and de-

velopment of wearable robots. Finally, the workshops concluded with a plenary discussion on the topic. Due to time constraints, the workshop in Italy skipped phase two.

The workshop organizers transcribed all the notes and findings into a list. They also clustered the recurring issues, produced a mind-map of wearable robot ELSI, and identified common themes. The organizers conducted a non-systematic literature research on these themes, which complemented and supported the experts' perspectives, and published an article in *Science and Engineering Ethics* on the main findings [5]. The main goal of the analysis was to create a map of ELSI particular to WR technologies that could provide structure and context to the concerns identified in those discussions.

These ELSI for WR are now explained in Table 1 below, using colour coding to highlight the dimensions: blue for WR and the self, green for WR and the other, and orange for WR and society (the colours are chosen for their accessibility). Within these dimensions, the individual issues are presented in tones of the main colour of the dimension. Adding to the original paper, we also provide short explanations and illustrate the ELSI with concrete examples.

Table 1. Brief overview of relevant ethical, legal and societal implications (ELSI) considerations for wearable robots (WRs).

Dimension	Issue	Explanation	Examples (Non-Exhaustive List)
Wearable Robots and the Self	Benefits, Risks and Harms for Self	WRs are considered within the context of the key ethical principles of beneficence and non-maleficence [41]. Harm-benefit analyses usually seek to determine benefit profiles and justifiable risks connected to the development and use of WRs [42], but these can be user dependent. The recent work by Bessler et al. [43,44] showed that there are multiple adverse effects and safety hazards linked to the use of robotics and their interaction with the human body.	Harms: functional restrictions, limited ease of use and battery life, intrusive appearance, data hacking, malware, or risk of falling. harmful physical interaction between the user and the WRs. Benefits: being able to stand erect supported by a lower limb WR, reducing incidence of back strain within working environments, or using the upper limb to manipulate the immediate environment.
	Body and Identity Impacts	WRs may affect a user’s self-perception and identity; they are likely to change not only the users’ functional abilities but also how their self is experienced [45,46].	Identity: WRs, like wheelchairs, can become incorporated into their users’ identities, necessitating a conceptual re-evaluation of the body [45,47]. This may include considering cosmetic [48] or also emotional aspects [49]. Dependence: Dependence on WR for essential activities of daily life including holding things, walking or working has potential impacts on the user’s identity if the technology is withdrawn without adequate replacement [42,50].
	The Experience of Vulnerability	WRs could cause or ameliorate a user’s experience of vulnerability, defined as the ‘capacity to suffer that is inherent in human embodiment’ [51].	Vulnerability: Vulnerability, resulting from reduced mobility with concomitant health and social risks, could be ameliorated by the WR, or increased if it resulted in dependence on the WR which was then withdrawn.
	Agency, Control and Responsibility	Training is required so that WR users can co-ordinate their shared bodily and WR movements. Especially to start with, users might feel that they are not entirely in control of the combination of their body and the machine, as there are still limited solutions for successfully translating users intent to robotic movement.	Safety and Control: The WR user could experience unplanned and possibly harmful movements, generating ‘destructive forces whose controlled output behavior may not always be in agreement with the user’s intent’ [48]. Users might try to move in a way that is incompatible with the WR’s programming, or may not want to use the WR’s automatically generated movements.
Wearable Robots and the Other	Ableism and Stigmatization in the Perception of the WR-Supported Body with Disabilities	WR may strengthen the ableist viewpoint that disabilities are intrinsically bad, create stigma, reduce the socially acceptable range of bodies, decrease the focus on improving accessibility and not be suitable for all users.	Accessibility: Claims for accessible devices such as ramps and door openers [52] could be undermined by increased use of WRs. Intersectional approach: WRs have weight and height limitations, and will be built around expected shapes. Anyone who does not meet these will be excluded [37,53] unless WR developers account for these differences [53].
	Overestimation and Alienation in the Perception of the WR-Enhanced Professional Body	Different regulations currently apply depending on the context of use i.e., whether within the healthcare field or not [15]. However, the boundaries can be indistinct—when does healthcare supporting use change into non-health related enhancement [47,50], and so which regulations apply [15].	Dehumanisation and Discrimination: Changing expectations of the work a WR-enhanced worker can achieve might lead to extra risks, unequal treatment, and exploitation [54]. Increased negative feelings, including alienation, may be experienced by WR-enhanced workers from people unfamiliar with WRs. Work environments which include significant public-facing contact may face more challenges.

Table 1. Cont.

Dimension	Issue	Explanation	Examples (Non-Exhaustive List)
	Care-Giving, Dependencies and Trust	Care relationships may be significantly affected by the use of WRs as they are characterised by various dependencies. Their complexity and ethical significance have been extensively explored in bioethics e.g., [55,56]. Families may also be impacted by patients' WR use.	<p>Trust: WRs can be used by caregivers, to assist patients' movements, so reducing bodily strain, or by care-receivers to enhance movement. Both contexts can be either for short periods of rehabilitation or longer-term options. Trust in the device and its role in care may be potentially precarious and easily disrupted.</p> <p>Left-behind: A perceived, and potentially inappropriate, reduced need for human care may result from patients' increased physical independence from using WRs.</p>
Wearable Robots and the Society	Technologisa-tion, Dehumanisation and Exploitation	'Turning workers into machines' has been connected to the dehumanisation of work and the possible exploitation of workers [50].	<p>Dehumanisation: The reasons for imposing the use of WRs on workers might be an act of domination and subjugation for financial reasons, rather than being targeted to improve workers' health. If workers' become stronger or more efficient owing to WR use, employers may raise task performance targets instead of balancing efficiency benefits holistically against the broader impacts of intensified work practices on workers</p>
	Social Justice, Resources and Access	Access is likely to be limited by cost and physical dimensions.	<p>Accessibility: WRs may exacerbate social inequality by only being available to wealthy patients in developed countries [50,57]. WRs for growing children need to be adaptable and have a life-based design approach [58].</p>
	Data Protection and Privacy	WR specifications will control the nature, sensitivity and volume of processed data. For a human-exoskeleton interaction this may include data on kinematics and kinetics from training and use, exoskeleton performance, environment, as well as a user's health data.	<p>Data Management: Much of this biometric data will be in the sensitive data category of the General Data Protection Regulation (GDPR), requiring enhanced protective measures to ensure the rights of the WR users as data subjects.</p> <p>Cybersecurity and safety: Exploitation of technological vulnerabilities could permit remote unauthorized people to access, control, and issue commands to compromised devices, potentially leading to patient harm [59]. For robotic devices directly attached to the user's body the implications may be greater and so deserve particular attention [37,50].</p>

Table 1. Cont.

Dimension	Issue	Explanation	Examples (Non-Exhaustive List)
	Accountability and Responsibility	Responsibility and accountability for robot actions arise from an individual through to a societal level.	<p>Responsibility: Challenges include:</p> <ul style="list-style-type: none"> (i) distributed responsibility i.e., identifying who is responsible if a problem emerges. The issue is caused by the complexity of various agents’ input into the WR design, development, deployment, and decision-making, when various parties have a causal impact on the robot’s output [60], (ii) potential ‘responsibility gaps’ identified for systems with autonomous features. Is it appropriate to hold human agents responsible for the WR’s autonomous actions [61]? (iii) dual-use. While a WR might be developed with the ethical aim of assisting rehabilitation it might also be used for potentially harmful purposes in different contexts [50]. (iv) risks for therapists and bystanders. During the use of WRs in uncontrolled environments (outside of the lab), there may be situations where people other than the users are at risk. A lack of knowledge within the general population on how to interact with users of WRs or unforeseen WRs behaviours may lead to hazardous situations.
	Legislation and Regulation for WRs	Legal frameworks governing WR use are not clear. At the same time, legislation is complex and the status of WR as medical devices is unclear. Some regulations are binding (MDR) while others (ISO standard) are not.	<p>Compliance with existing regulations: WRs, whether worn in a healthcare setting for patient rehabilitation, or in a factory setting for worker support, may present similar risks to the user’s health and, thus, have to follow the Medical Device Regulation [15,62].</p>

4. Implementing ELSI Considerations in Wearable Robotics: From Principles to Actionable Guidance

A classification of ELSI distinctive to the WR domain is likely to be informative for those designing and implementing WRs, for people wearing them, and for those caregivers working with people using these devices. Eventually, this information could even benefit those providing guidance and regulation around WRs such as policy or standard makers. WR developers may also benefit from having a translation mechanism capable of offering actionable guidance.

The flowchart in Figure 1 below provides WR developers with suggested guidance concerning the most suitable stage to answer these questions (some of which are deliberately repeated in various stages). These recommendations follow from problems with ELSI identified in the previous section, best practices, and the authors’ experience with WR developers and stakeholders. Despite the recommendations’ chronological order, WR developers are encouraged to keep the questions in mind throughout all development stages. The proposed flowchart should be taken as a set of suggestions that could be followed, depending on available resources within each development context. It is acknowledged that doing justice to all the included questions may be overly demanding for many development teams—we want to facilitate engagement but not impose unrealistic demands on WR developers. At the same time, we hope that providing a comprehensive set of considerations may foster reflection within development teams on the integration of a wider range of concerns into current practices, many of which can be easily implemented or at least approximated.

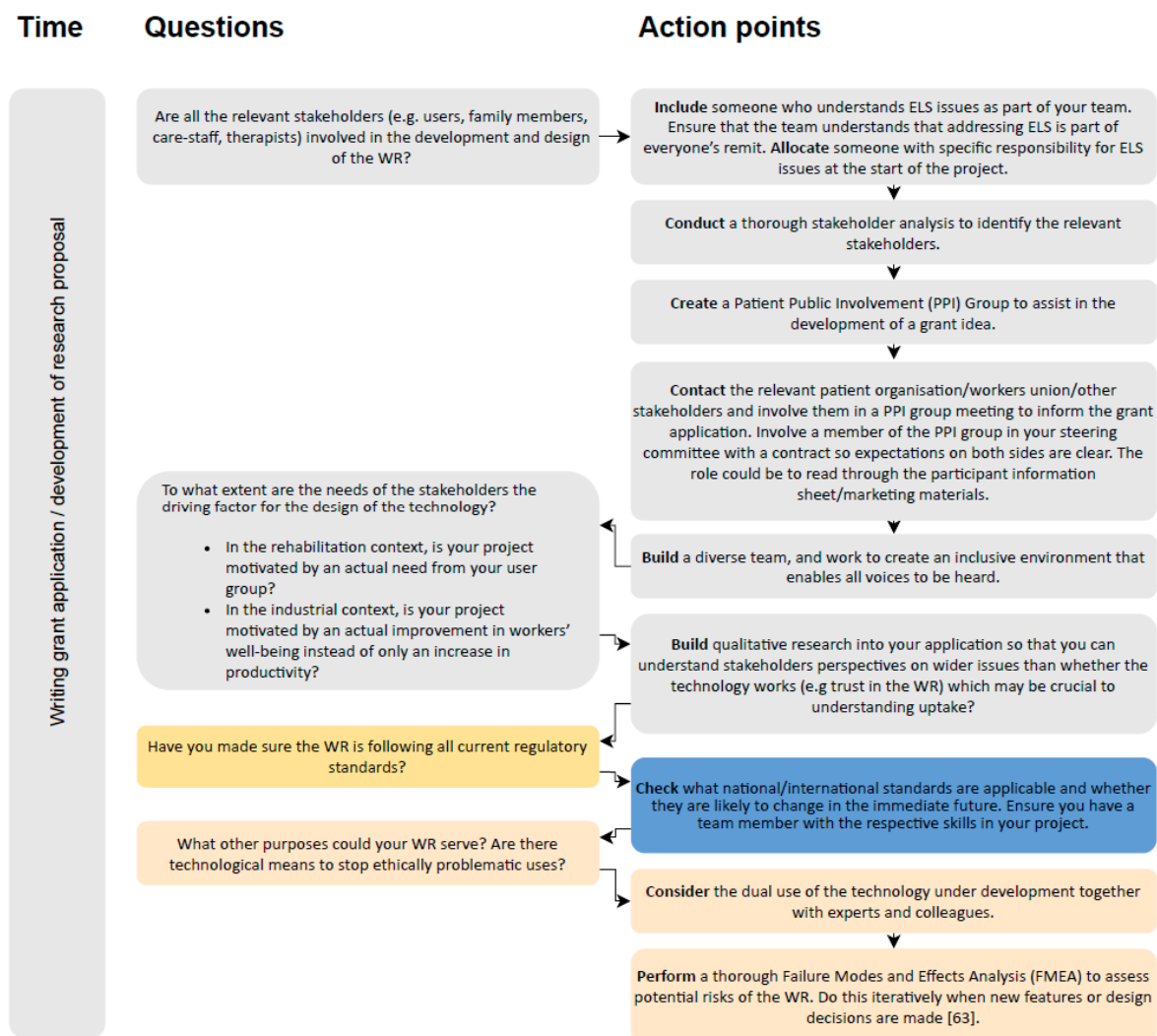


Figure 1. Cont.

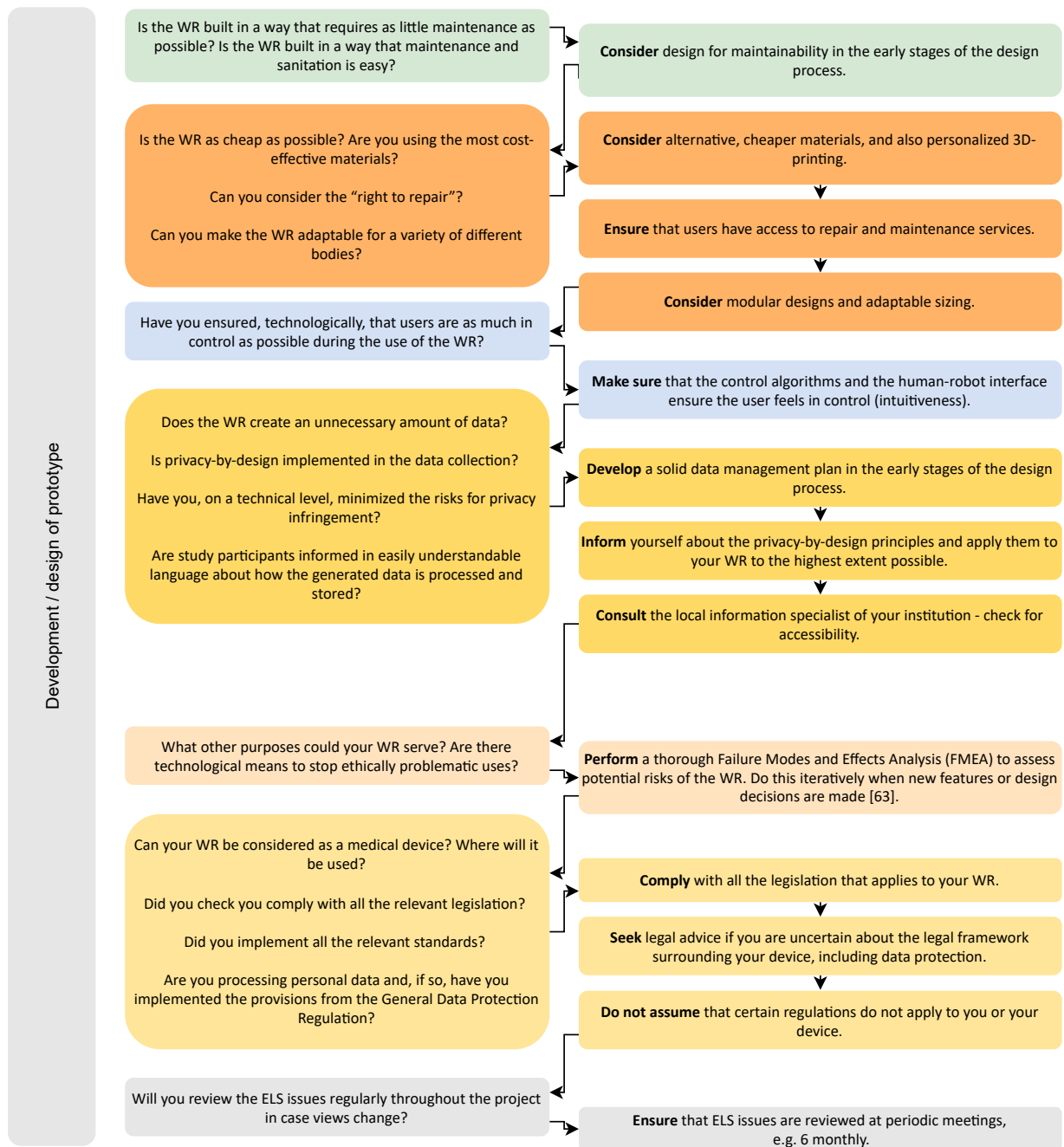


Figure 1. Cont.



Figure 1. Cont.

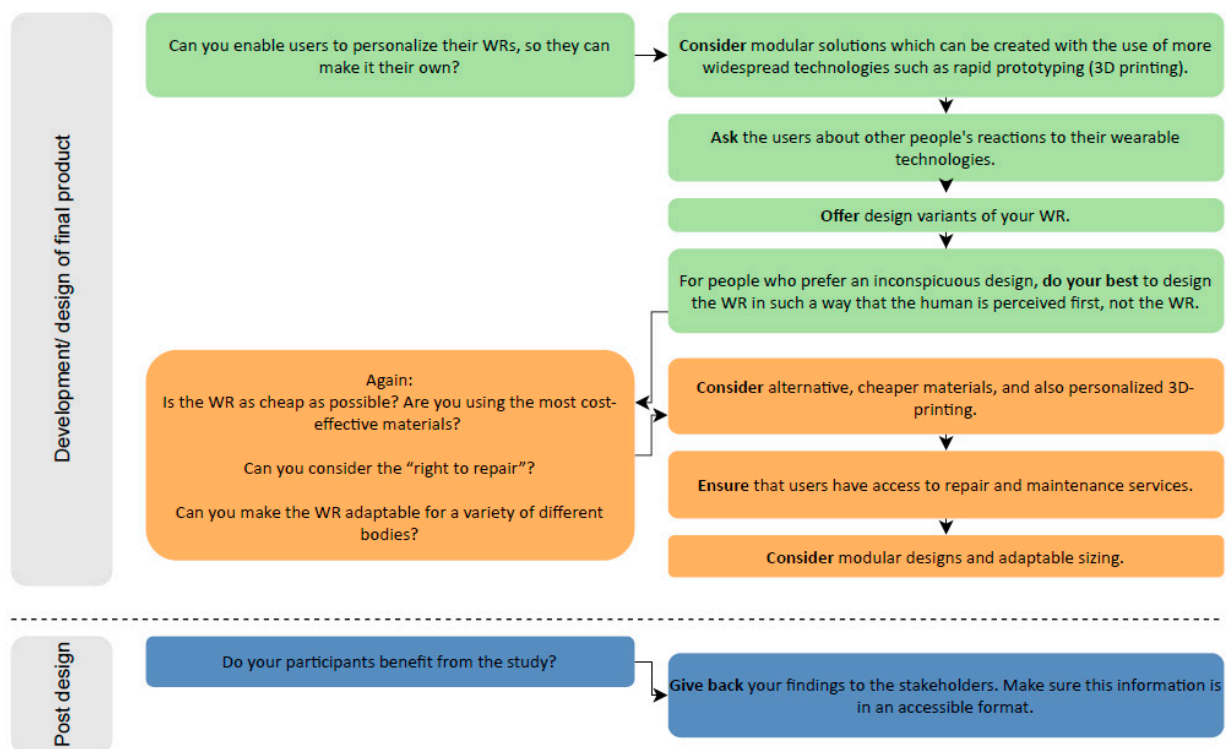


Figure 1. Questions and action points for implementing ELSI in WR development, with a reference to [63]. 2003, American Society for Quality.

The colour coding is continued from Table 1 above, allowing the developer to link the questions and action points with the dimensions and issues. The grey colour represents many dimensions and issues. This colour coding could be helpful to ensure that developers are not missing out on covering issues for grant or ethics applications as well as in the WR development process.

5. Conclusions

WRs which assist, train, and augment human motor functions are being deployed rapidly, while often relatively little reflection is given to the resultant impact on users and their social environments. WRs entail technical and safety aspects that need consideration and specific complex ethical, legal, and social implications. This is due to different application domains and stakeholders, possible design applications, their close interaction with the human body, and cognitive aspects relating to the control of their function, making them different from other robots. The profound consequences of the close intertwining of the machine and the human body for users, the people around them, and society at large demand specific guidance at the ELSI implementation level. This paper provides the first practical ELSI-sensitive design guidance for WR developers.

In this respect, this paper examined existing ELSI design tools (focusing on process and the identification of principles) and their limitations for the WR specific domain. We also summarised previous work [5], which created a taxonomy of ELSI considerations in WRs. A classification of these ELSI is likely to benefit many, including academics, those guiding the integration of ELSI considerations in the design process, policymakers, people wearing and working with people using these devices as well as those designing and implementing devices, and those providing guidance and regulation around them.

To help operationalize these considerations for WR developers, the key part of this paper revolved around transforming these principles into actionable guidance. To this end, we investigated timing and pressing questions in the development of a WR, and incorporated detailed action points, linking these to the three dimensions, subjective (WRs and the Self), interpersonal (WRs and the Other), and social dimensions (WRs and Society)

identified in the taxonomy. We displayed them in the form of a flowchart covering all development stages from the proposal design/grant application to the post-design phases, with reference to the table of action points. The provision of this comprehensive set of considerations is meant to support reflection on the inclusion of ELSI considerations in WR development within the scope of what is feasible in each context, without being unduly demanding. The next desirable step would be to conduct an empirical trial with WR developers using this flowchart, to evaluate the validity and practicality of this proposed guidance.

We hope that the adoption of this approach would improve the ELSI-sensitive management of potential challenges in the development and deployment of WRs as part of a value-led design process, ultimately leading to more acceptable, safer, and successful wearable robots.

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References

1. COST Action 16116 Wearable Robots. Augmentation, Assistance, or Substitution of Human Motor Functions. 2017. Available online: <https://wearablerobots.eu/> (accessed on 20 July 2021).
2. Van Laar, E.; Van Deursen, A.J.; Van Dijk, J.A.; De Haan, J. Measuring the levels of 21st-century digital skills among professionals working within the creative industries: A performance-based approach. *Poetics* **2020**, *81*, 101434. [CrossRef]
3. Benchmarking Locomotion: Benchmarking Bipedal Locomotion. Available online: <http://www.benchmarkinglocomotion.org/new/> (accessed on 20 July 2021).
4. Eurobench: European Robotic Framework for Bipedal Locomotion Benchmarking. Available online: <https://eurobench2020.eu> (accessed on 20 July 2021).
5. Kapeller, A.; Felzmann, H.; Fosch-Villaronga, E.; Hughes, A.-M. A taxonomy of ethical, legal and social implications of wearable robots: An expert perspective. *Sci. Eng. Ethics* **2020**, *26*, 3229–3247. [CrossRef] [PubMed]
6. European Parliament and the Council of Europe ‘Leaked’ EU Regulation on AI. Available online: https://drive.google.com/file/d/1ZaBPsfors_aHKNeeyXxk9ujfTru747EOn/view (accessed on 14 April 2021).
7. Hill, D.; Holloway, C.; Ramirez, D.Z.M.; Smitham, P.; Pappas, Y. What are user perspectives of exoskeleton technology? A literature review. *Int. J. Technol. Assess. Heal. Care* **2017**, *33*, 160–167. [CrossRef] [PubMed]
8. Almpani, S.; Mitsikas, T.; Stefaneas, P.; Frangos, P. ExosCE: A legal-based computational system for compliance with exoskeletons’ CE marking. *Paladyn J. Behav. Robot.* **2020**, *11*, 414–427. [CrossRef]
9. Ármannsdóttir, A.L.; Beckerle, P.; Moreno, J.C.; Van Asseldonk, E.H.F.; Manrique-Sancho, M.-T.; Del-Ama, A.J.; Veneman, J.; Briem, K. Assessing the Involvement of Users During Development of Lower Limb Wearable Robotic Exoskeletons: A Survey Study. *Hum. Factors J. Hum. Factors Ergon. Soc.* **2020**, *62*, 351–364. [CrossRef] [PubMed]
10. Kapeller, A.; Nagenborg, M.H.; Nizamis, K. Wearable robotic exoskeletons: A socio-philosophical perspective on Duchenne muscular dystrophy research. *Paladyn, J. Behav. Robot.* **2020**, *11*, 404–413. [CrossRef]
11. Beers, S. *Teaching 21st Century Skills*; ASCD: Alexandria, VA, USA, 2011.
12. Kilic-Bebek, E.; Nizamis, K.; Karapars, Z.; Gokkurt, A.; Unal, R.; Bebek, O.; Vlutters, M.; Vander, P.E.B.; Borghesan, G.; Decré, W.; et al. *Discussing Modernizing Engineering Education through the Erasmus + Project Titled “Open Educational Resources on Enabling Technologies in Wearable and Collaborative Robotics (WeCoRD)*, 3rd ed.; Accepted/In Press; International Instructional Technologies in Engineering Education Symposium IITEE: Izmir, Turkey, 2020.
13. Arntz, M.; Gregory, T.; Zierahn, U. ELS Issues in Robotics and Steps to Consider Them. Part 1: Robotics and Employment. Consequences of Robotics and Technological Change for the Structure and Level of Employment; Research Report; ZEW-Gutachten und Forschungsberichte: 2016. Available online: <https://www.econstor.eu/bitstream/10419/146501/1/867017465.pdf> (accessed on 12 March 2021).
14. Vandemeulebroucke, T.; de Casterlé, B.D.; Gastmans, C. The use of care robots in aged care: A systematic review of argument-based ethics literature. *Arch. Gerontol. Geriatr.* **2018**, *74*, 15–25. [CrossRef]

15. Fosch-Villaronga, E. *Robots, Healthcare, and the Law: Regulating Automation in Personal Care*; Routledge: Abingdon, UK, 2019.
16. Holder, C.; Khurana, V.; Harrison, F.; Jacobs, L. Robotics and law: Key legal and regulatory implications of the robotics age (Part I of II). *Comput. Law Secur. Rev.* **2016**, *32*, 383–402. [[CrossRef](#)]
17. High Level Expert Group (HLEG) on Artificial Intelligence, HLEG AI. Ethical Guidelines for Trustworthy AI. European Commission. Available online: <https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai> (accessed on 12 March 2021).
18. Vallor, S. Carebots and Caregivers: Sustaining the Ethical Ideal of Care in the Twenty-First Century. *Philos. Technol.* **2011**, *24*, 251–268. [[CrossRef](#)]
19. Van Wynsberghe, A. Designing Robots for Care: Care Centered Value-Sensitive Design. *Sci. Eng. Ethics* **2012**, *19*, 407–433. [[CrossRef](#)]
20. Palmerini, E.; Bertolini, A.; Battaglia, F.; Koops, B.-J.; Carnevale, A.; Salvini, P. RoboLaw: Towards a European framework for robotics regulation. *Robot. Auton. Syst.* **2016**, *86*, 78–85. [[CrossRef](#)]
21. Felt, U.; Fochler, M.; Sigl, L. IMAGINE RRI. A card-based method for reflecting on responsibility in life science research. *J. Responsible Innov.* **2018**, *5*, 1–24. [[CrossRef](#)]
22. Felt, U. “Response-able practices” or “New bureaucracies of virtue”: The challenges of making RRI work in academic environments. In *Responsible Innovation 3: A European Agenda?* Asveld, L., van Dam-Mieras, R., Swierstra, T., Lavrijsen, S., Linse, K., van den Hoven, J., Eds.; Springer: Cham, Switzerland, 2017; pp. 49–68.
23. IEEE. Ethically Aligned Design. 2016. Available online: https://standards.ieee.org/news/2016/ethically_aligned_design.html (accessed on 14 April 2021).
24. Sutcliffe, H. A Report on Responsible Research and Innovation. MATTER European Commission. 2011. Available online: <https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.226.8407&rep=rep1&type=pdf> (accessed on 20 July 2021).
25. Owen, R.; Macnaghten, P.; Stilgoe, J. Responsible research and innovation: From science in society to science for society, with society. *Sci. Public Policy* **2012**, *39*, 751–760. [[CrossRef](#)]
26. Schomberg, R.V. Technikfolgen abschätzen lehren: Bildungspotenziale transdisziplinärer Methode. In *Prospects for Technology Assessment in a Framework of Responsible Research and Innovation*; Dusseldorp, M., Beecroft, R., Eds.; Springer: Wiesbaden, Germany, 2012; pp. 39–61. Available online: <https://app.box.com/s/f9quor8jo1bi3ham8lfc> (accessed on 18 May 2021).
27. Burget, M.; Bardone, E.; Pedaste, M. Definitions and conceptual dimensions of responsible research and innovation: A literature review. *Sci. Eng. Ethics* **2017**, *23*, 1–19. [[CrossRef](#)] [[PubMed](#)]
28. Nissenbaum, H. How computer systems embody values. *Computer* **2001**, *34*, 119–120. [[CrossRef](#)]
29. Friedman, B.; Kahn, P.H.; Borning, A.; Hultdtgren, A. Value sensitive design and information systems. In *Early Engagement and New Technologies: Opening up the Laboratory*; Springer: Dordrecht, The Netherlands, 2013; pp. 55–95.
30. Cavoukian, A. Privacy by design: The definitive workshop. A foreword by Ann Cavoukian, Ph.D. *Identity Inf. Soc.* **2010**, *3*, 247–251. [[CrossRef](#)]
31. Cummings, M.L. Integrating ethics in design through the value-sensitive design approach. *Sci. Eng. Ethics* **2006**, *12*, 701–715. [[CrossRef](#)]
32. ORBIT Project. AREA 4P Framework. Available online: <https://www.orbit-rri.org/about/area-4p-framework/> (accessed on 18 May 2021).
33. RRI-Tools Project. Self Reflection Tool. Available online: <https://rri-tools.eu/self-reflection-tool> (accessed on 18 May 2021).
34. Winfield, A. Ethical standards in robotics and AI. *Nat. Electron.* **2019**, *2*, 46–48. [[CrossRef](#)]
35. British Standard Institute, BS 8611: Robots and Robotic Devices. Guide to the Ethical Design and Application of Robots and Robotic Systems. United Kingdom. 2016. Available online: <https://shop.bsigroup.com/ProductDetail?pid=00000000030320089> (accessed on 20 July 2021).
36. Salvini, P.; Laschi, C.; Dario, P. Do Service Robots Need a Driving License? [Industrial Activities]. *IEEE Robot. Autom. Mag.* **2011**, *18*, 12–13. [[CrossRef](#)]
37. Fosch-Villaronga, E.; Heldeweg, M. “Regulation, I presume?” said the robot—Towards an iterative regulatory process for robot governance. *Comput. Law Secur. Rev.* **2018**, *34*, 1258–1277. [[CrossRef](#)]
38. Yang, G.-Z.; Cambias, J.; Cleary, K.; Daimler, E.; Drake, J.; Dupont, P.E.; Hata, N.; Kazanzides, P.; Martel, S.; Patel, R.V.; et al. Medical robotics—Regulatory, ethical and legal considerations for increasing levels of autonomy. *Sci. Robot.* **2017**, *2*, eaam8638. [[CrossRef](#)] [[PubMed](#)]
39. Fosch-Villaronga, E.; Khanna, P.; Drukarch, H.; Custers, B.H.M. A human in the loop in surgery automation. *Nat. Mach. Intell.* **2021**, *3*, 368–369. [[CrossRef](#)]
40. Erden, Y.E.; Brey, P. *Ethical Guidance for Research with a Potential for Human Enhancement (Version V1)*; Zenodo: Genève, Switzerland, 2021. [[CrossRef](#)]
41. Beauchamp, T.L.; Childress, J.F. *Principles of Biomedical Ethics*; Oxford University Press: Oxford, UK, 1979.
42. Bissolotti, L.; Nicoli, F.; Picozzi, M. Domestic use of the exoskeleton for gait training in patients with spinal cord injuries: Ethical dilemmas in clinical practice. *Front. Neurosci.* **2018**, *12*, 78. [[CrossRef](#)]
43. Bessler, J.; Prange-Lasonder, G.B.; Schaake, L.; Saenz, J.F.; Bidard, C.; Fassi, I.; Valori, M.; Lassen, A.B.; Buurke, J.H. Safety assessment of rehabilitation robots: A review identifying safety skills and current knowledge gaps. *Front. Robot. AI* **2021**, *8*, 33. [[CrossRef](#)] [[PubMed](#)]
44. Bessler, J.; Prange-Lasonder, G.B.; Schulte, R.V.; Schaake, L.; Prinsen, E.C.; Buurke, J.H. Occurrence and type of adverse events during the use of stationary gait robots—A systematic literature review. *Front. Robot. AI* **2020**, *7*, 158. [[CrossRef](#)] [[PubMed](#)]

45. Barfield, W.; Williams, A. Cyborgs and enhancement technology. *Philosophies* **2017**, *2*, 4. [CrossRef]
46. Breen, J.S. The exoskeleton generation–disability redux. *Disabil. Soc.* **2015**, *30*, 1568–1572. [CrossRef]
47. Palmerini, E.; Azzarri, F.; Battaglia, F.; Bertolini, A.; Carnevale, A.; Carpaneto, J.; Warwick, K. Guidelines on Regulating Robotics: Deliverable 6.2 (Regulating Emerging Robotic Technologies in Europe: Robotics facing Law and Ethics). 2014. Available online: http://www.robolaw.eu/RoboLaw_files/documents/robolaw_d6.2_guidelinesregulatingrobotics_20140922.pdf (accessed on 20 July 2021).
48. Tucker, M.R.; Olivier, J.; Pagel, A.; Bleuler, H.; Bouri, M.; Lambercy, O.; Gassert, R. Control strategies for active lower extremity prosthetics and orthotics: A review. *J. Neuroeng. Rehabil.* **2015**, *12*, 1–30. [CrossRef]
49. Sawh, M. Getting all Emotional: Wearables that are Trying to Monitor How We Feel. Wareable. Available online: <https://www.wareable.com/wearable-tech/wearables-that-track-emotion-7278> (accessed on 18 May 2021).
50. Greenbaum, D. Ethical, legal and social concerns relating to exoskeletons. *ACM SIGCAS Comput. Soc.* **2016**, *45*, 234–239. [CrossRef]
51. Mackenzie, C.; Rogers, W.; Dodds, S. *Vulnerability: New Essays in Ethics and Feminist Philosophy*; Oxford University Press: Oxford, UK, 2014.
52. Klein, E.; Nam, C. Neuroethics and brain-computer interfaces (BCIs). *Brain Comput. Interfaces* **2016**, *3*, 123–125. [CrossRef]
53. Søraa, R.A.; Fosch-Villaronga, E. Exoskeletons for all: The interplay between exoskeletons, inclusion, gender and intersectionality. *Paladyn J. Behav. Robot.* **2020**, *11*, 217–227. [CrossRef]
54. Vrousalis, N. Exploitation: A primer. *Philos. Compass* **2018**, *13*, e12486. [CrossRef]
55. Kittay, E.F. *Love's labor: Essays on Women, Equality and Dependency*, 2nd ed.; Routledge: New York, NY, USA, 2020.
56. Kittay, E.; Feder, E. (Eds.) *The Subject of Care: Feminist Perspectives on Dependency*; Rowman & Littlefield Publishers: Lanham, MD, USA, 2002.
57. Manning, J. *Health, Humanity and Justice: Emerging Technologies and Health Policy in the 21st Century*; An Independent Review Commissioned; Conservative Party: London, UK, 2010.
58. Fosch-Villaronga, E.; Čartolovni, A.; Pierce, R.L. Promoting inclusiveness in exoskeleton robotics: Addressing challenges for pediatric access. *Paladyn J. Behav. Robot.* **2020**, *11*, 327–339. [CrossRef]
59. Food and Drug Administration. FDA Cybersecurity. 2019. Available online: <https://www.fda.gov/medical-devices/digital-health/cybersecurity> (accessed on 20 July 2021).
60. Floridi, L. Faultless responsibility: On the nature and allocation of moral responsibility for distributed moral actions. *Philos. Trans. R. Soc. A Math. Phys. Eng. Sci.* **2016**, *374*, 20160112. [CrossRef] [PubMed]
61. Matthias, A. The responsibility gap: Ascribing responsibility for the actions of learning automata. *Ethics Inf. Technol.* **2004**, *6*, 175–183. [CrossRef]
62. Fosch-Villaronga, E.; Özcan, B. The progressive intertwining between design, human needs and the regulation of care technology: The case of lower-limb exoskeletons. *Int. J. Soc. Robot.* **2019**, *12*, 959–972. [CrossRef]
63. Stamatis, D.H. *Failure Mode and Effect Analysis-FMEA from Theory to Execution*; 2nd Edition Revised and Expanded; American Society for Quality (ASQ): Milwaukee, WI, USA, 2003.