# Clinicians' Perspectives on Safety, Ethical, and Legal Considerations for Home-Based Physical Rehabilitation Robots

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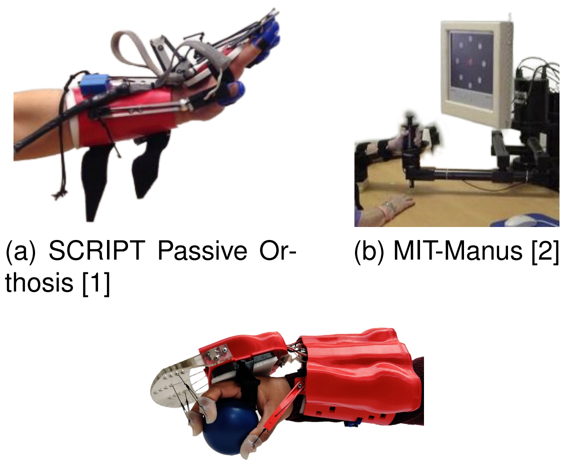
***Abstract*—The growing demand for neurorehabilitation is driving the development of innovative, home-based robotic solutions, offering a promising approach to alleviate the strain on healthcare systems burdened by limited resources and workforce shortages. Despite significant technological advancements in rehabilitation robotics, adoption remains limited due to unresolved safety, legal, and ethical concerns. This study provides a comprehensive analysis of these three aspects from the perspective of experienced neurorehabilitation clinicians, offering valuable insights into the challenges surrounding home-based rehabilitation robots. Using a qualitative approach, we identified eight key themes derived from clinicians' feedback. These themes underscore critical areas, including the need for robust safety measures, regulatory clarity on liability and data privacy, and the ethical imperative of ensuring equitable access to technology for diverse user populations. Our findings highlight the need for a multifaceted approach to overcome these challenges, including user-centred design, rigorous testing, comprehensive user training, and necessary updates to regulatory frameworks to ensure the safe, effective, and equitable deployment of these technologies.**

***Index Terms*—Rehabilitation Robots, Ethics, Legal, Safety, Clinicians, Therapists.**



(a) SCRIPT Passive Orthosis [1]   (b) MIT-Manus [2]

(c) WiGlove [3]

Fig. 1. Rehabilitation devices used for post-stroke therapy

## I. Introduction

With the rising incidence of neurological conditions, the demand for neurorehabilitation care has placed increasing strain on healthcare systems, which are constrained by limited resources and workforce shortages. Home-based robotic devices are gaining significant impetus as a promising solution to these challenges [1]. These devices empower patients to independently engage in rehabilitation exercises while enabling therapists to remotely monitor their progress, optimising the use of their time and expertise. Beyond easing the burden on healthcare systems, these robots offer additional advantages, including persistent availability and the delivery of objective and quantifiable measures of patient progress, thereby supporting evidence-based practices and enhancing the overall quality of care.

The approach of using robots for physical rehabilitation has been around since the 1990s, when the first device was developed for upper-limb therapy [4]. Since then, numerous robotic systems have been created to support both upper-limb and lower-limb rehabilitation [5]. Early designs were predominantly end-effector devices like MIT-Manus (Figure 1b) [2], where users exercised by holding onto a fixed robotic mechanism. More recently, wearable robots such as exoskeletons [1], [3], have gained prominence. In comparison to fixed devices, wearable robots offer greater flexibility, enabling users to train in various locations. This mobility makes them particularly well-suited for home-based rehabilitation, enabling users to practice movements during everyday activities. Additionally, wearable robots open up opportunities for integrating training with interactive features, such as computer games, which have been shown to enhance motivation and adherence to training [6]. This, in turn, can lead to improved training outcomes.

Wearable rehabilitation robots often include features such as mechanisms for providing physical assistance, embedded sensors to monitor training performance and movement kinematics, and wireless connectivity for data transmission. The deployment of such technology in a home environment by vulnerable users raises important safety, ethical, and legal concerns that must be carefully considered and addressed.

Despite these technological advancements, the real-world adoption of such robots in neurorehabilitation remains limited [7]. Research on the feasibility and user-centred development of these robots primarily focuses on technical aspects, often overlooking the ethical and legal issues surrounding their use, despite their potential to impact the acceptance of these devices [8]. A recent study highlighted this gap, emphasising that insufficient understanding of these issues hinders the formulation of appropriate regulations to govern the development and deployment of rehabilitation robots [8]. Current guidance, as noted by the authors, is limited to standards for care robots (ISO 13482:2014), data protection laws, and regulations for medical devices and consumer product

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safety. Despite a growing body of knowledge on robots and social robots, the ethical and legal aspects specific to rehabilitation robots remain underexplored. Existing frameworks are not tailored to address the unique challenges posed by rehabilitation robots, particularly in the context of home-based care for vulnerable users. Furthermore, analysing these issues helps to better understand these concerns and to incorporate these considerations into the design and development of such devices.

A user-centred approach involving clinicians with expertise in physiotherapy and occupational therapy could help to address these concerns. Studies have shown that, drawing on their experience in patient care and rehabilitation, these professionals are uniquely positioned to anticipate potential challenges and barriers, offering insights to enhance the safety and ethical integration of robotic devices into clinical and home-based settings [7]. Given the dearth of research in exploring these issues in this context, this paper aims to discuss the safety, legal and ethical issues that arise with the adoption and use of home-based physical rehabilitation robots from the perspectives of clinicians using a qualitative approach. Section II describes the methodology we applied to collect the clinicians' thoughts, followed by a summary of the results of a thematic analysis and their discussion in Section III before concluding the paper in Section IV.

## II. Methodology

This study was conducted during a workshop on robotics for rehabilitation therapy for health and social care professionals as part of the EPSRC EMERGENCE Network+ project to facilitate the creation of a sustainable ecosystem for researchers, clinicians and industrial partners, supporting the transition of technology for the care of people living with frailty. The workshop was held on 21 July 2023 at the National Robotarium in Edinburgh and facilitated by Heriot-Watt University and was approved by the Ethics Committee of the School of Computer Science, University of Nottingham (ethics protocol number: CS-2021-R40). The participants of this workshop included eleven $(n = 11)$ healthcare professionals from the United Kingdom, all with experience in physical rehabilitation. The participants included four physiotherapists, two occupational therapists, three project managers of innovation, and two researchers. These professionals had a median experience of 10 years in their respective fields, with individual experience ranging from 1 to 21 years.

The workshop began with a brief presentation on rehabilitation robots, focusing on a case study involving the SCRIPT passive orthosis (SPO) [1]. SPO is a passive orthosis that allows stroke survivors to perform hand and wrist exercises. Developed in a European Framework 7 project, it was a part of the SCRIPT system that included interactive games and a back-end system for clinical monitoring. The case study included a feasibility study conducted with 23 participants and its key findings, offering the participants an example of a real-world application of such devices. However, the presentation deliberately did not include any images of the orthosis, nor was the device shown to the participants, to prevent them from forming any device-specific opinions. Following the presentation, participants were asked to complete a questionnaire.

The questionnaire included three open-ended questions, encouraging participants to comment on what potential (1) risks and safety issues, (2) legal issues, and (3) ethical issues they thought could be involved in the real-world adoption and use of robots for physical rehabilitation, drawing from their professional expertise.

## III. Results and Discussion

The participants' handwritten responses were transcribed into a digital format by a member of the research team, and 20 % of the comments were re-transcribed independently by a second team member for cross-verification. There was a strong agreement between the two transcribers ($\kappa = 0.86, p < 0.001$). The transcribed participant's thoughts were thematically analysed using an inductive approach, where the codes and themes were derived from the transcribed data [9]. Firstly, the codes were derived from the participants' comments, and similar codes were then mapped to identify the themes. Through this process, across the three categories: risk and safety aspects, legal aspects and ethical aspects, 8 themes were identified as summarised in Figure 2. In this section, these themes are discussed in detail with reference to the existing body of knowledge to provide context.

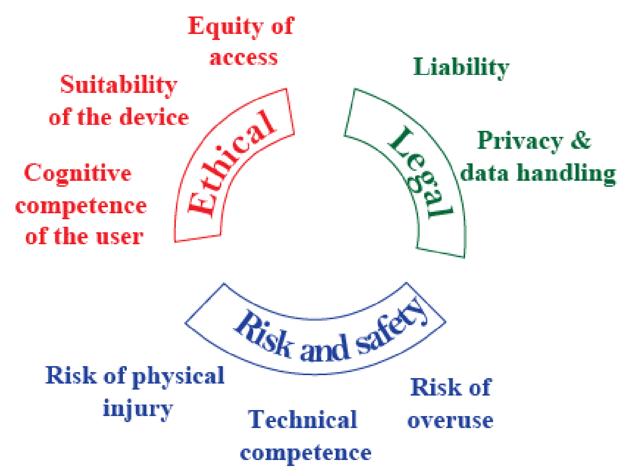


Fig. 2. Identified 8 key themes

### A. Risk and safety aspects

*1) Risk of Physical Injury:* The risk of physical injury emerged as the most frequently reported concern among participants. A significant aspect of this issue is the potential for robots to malfunction during unsupervised use, particularly in actively actuated devices. Such malfunctions could lead to unintended forces being applied to the user's body, potentially causing joint overextension, pain, or even injuries.

"*Risk around glove being worn/applied incorrectly, risk of pain if assisted movement exceeds tolerable level.*"

TABLE I
CODING FRAMEWORK AND FREQUENCY TABLE

| | Themes | Codes | Frequency |
|---|---|---|---|
| **Risk and safety** | Risk of physical injury | Risk of injury | 10 |
| | | Skin abbrassion | 7 |
| | | Family safety | 2 |
| | Technical competence | Ease of Donning/doffing | 8 |
| | | Learnability | 7 |
| | Risk of overuse | Over use | 3 |
| | | Over exertion | 1 |
| **Legal** | Liability | Liability of failure | 6 |
| | | Need for regulation | 3 |
| | | Responsibility of maintenance | 2 |
| | Privacy and data handling | Data storage safety | 6 |
| | | Transparency of data collected | 5 |
| | | Data ownership | 2 |
| **Ethical** | Equity of access | Cost of device | 8 |
| | | Financial support | 6 |
| | | Infrastructure requirement | 4 |
| | Suitability of the device | Suitability for impairment | 4 |
| | | Potential for negative impact | 4 |
| | Cognitive competence of the user | Capacity to learn/use | 3 |
| | | Capacity to consent | 3 |

"*Input systems-how does the system account for the error?*"

While some have attempted to overcome this issue by operating at lower power settings, as pointed out by a review [4], this could compromise the functional capabilities of the device. Several strategies have been suggested to mitigate this concern, including :

- Compliance with user movement: In the case of actively actuated robotic devices, it should be designed to sense resisting forces exerted by the user, especially at joint limits, to prevent overextension [10]. This can be achieved through force or torque sensors and impedance control strategies that modulate the device's response in real time.
- Built-in fail-safes: Ensuring that the control systems can detect erroneous control inputs or signals and react to them in a safe manner [10].
- Passive actuation: An alternate approach is to use passive devices instead of actively actuated ones [1], [11]. They use passive actuators such as spring-based systems that eliminate the risk of electronic malfunction and can be designed to require the user to actively initiate and perform the movements, thereby maintaining greater control and reducing the likelihood of injuries. However, this solution might not apply to users with severe motor function impairments.

Another risk highlighted was skin irritation or abrasion due to prolonged contact with wearable devices. Such discomfort could lead to temporary or long-term discontinuation of use, negatively impacting the recovery process. To mitigate this, it is essential to incorporate extensive user testing throughout the design process, focusing on ergonomic materials and interfaces [12].

Additionally, concerns were raised about the risk to family members, particularly in home-based scenarios. This necessitates careful consideration for the size and form factor of the device so that it reduces the risk of injury to non-users and is suitable for the home environment [11]. Designs should aim for compact, lightweight, and unobtrusive systems that can be safely integrated into shared living spaces without posing tripping hazards or obstructing movement. Such form factors also allow the device to be easily stowed away when not in use, reducing the likelihood of unintended access by children or pets. Additionally, the use of soft materials and rounded edges can further minimise the risk of injury during accidental contact.

*2) Technical competence :* This was identified as a critical theme, especially given that such robots are intended to be used by individuals recovering from neurological conditions or injuries under limited or no supervision. Participants expressed concerns that limited mobility could hinder the ability to don, doff, or adjust training parameters without assistance and that improper usage could increase the risk of injury [11]. Therefore, adequate consideration needs to be given to ensure that users can easily learn to operate the devices independently and safely. For example, donning and doffing mechanisms should minimise the need for fine motor control by incorporating features such as magnetic closures, elastic or Velcro straps, and self-aligning connectors. Similarly, for adjusting parameters such as the level of assistance or resistance, robots should include actuated adjustment mechanisms paired with intuitive control interfaces, such as digital sliders or touch-based inputs, instead of manual manipulation of the device, to facilitate ease of use for individuals with limited dexterity. Furthermore, user-centred installation procedures, including tool-free setup and plug-and-play calibration, can enhance accessibility for users with limited technical experience.

*3) Risk of Overuse:* Participants also raised the risk of overuse as a concern. The convenience of home-based rehabilitation robots might tempt users to overtrain in hopes of accelerating recovery [13]. This can lead to physical fatigue, improper training techniques (e.g., not exercising across the full range of motion), and even emotional fatigue. To mitigate this risk, the users should be given appropriate guidance on training intensity and duration. Remote monitoring systems can enable clinicians to track user progress and intervene if signs of overuse or improper training are detected.

Additionally, studies have demonstrated the potential of surface electromyography (sEMG) signals to detect the onset of fatigue during training [14]. Future designs of home-based rehabilitation robots could incorporate sEMG electrodes to enable real-time fatigue detection. Such systems could automatically adjust training parameters or prompt the user to conclude the session, thereby helping to prevent overuse and excessive exertion.

## B. Legal aspects

*4) Liability:* Liability emerged as a critical concern. Unlike social care robots or surgical robots, rehabilitation robots are often attached to the user's body, creating complex interactions between the robots and their users.

This uniqueness complicates establishing causation in the event of harm. There is a consensus that the law, in this case, is conspicuous and depends on how such robots are interpreted since the development in robotics has outpaced the development in regulations [15]. Participants noted the confusion in establishing liability when safety incidents occur.

"*Any liability issues if injury, function worsens, who is responsible for maintenance?*"

Currently, rehabilitation robots are classified as products, with liability resting on the manufacturer or operator [15]. However, the legal status of these robots remains ambiguous, as they are currently categorised as 'personal care robots', a category between a 'product" and 'medical device' according to [8], [16]. To address this, it is essential for roboticists to collaborate with legal experts and clinicians to develop specific legal frameworks that account for the unique nature of rehabilitation robots.

"*Need to ensure clear framework for regulations around use.*"

*5) Privacy and data handling:* Rehabilitation robots often collect sensitive biometric data, such as EMG readings, kinematic data of the training movements, training schedule and exercise performance metrics, to monitor user recovery and adapt to individual needs. Under regulations like the General Data Protection Regulation (GDPR), this data is classified as sensitive and requires stricter safeguards to protect the user's privacy. Such data could be exploited by malicious actors and commercial entities like insurance providers [8]. The participants' feedback underscored the need for transparency about the type of data collected, its purpose, and how it will be used.

"*What happens to info gathered?*"

"*Does it gather information, where does this go & who is responsible. Does it ID user?*"

These concerns are more pronounced when cloud-based services are used to store and process such data to facilitate remote monitoring by clinicians. Malicious actors could exploit vulnerabilities to gain access to user data or, in extreme cases, remotely control the device. One approach to mitigate these risks is through the implementation of offline functionality and edge computing, where critical data processing and decision-making tasks are performed locally on the device. This allows developers to enhance system responsiveness, ensure functionality in low-connectivity environments, and improve overall data security. These concerns are heightened by the fact that these robots are physically attached to users, making security breaches potentially harmful. The participants' feedback highlights the need for manufacturers to prioritise these considerations from the conceptualisation stage of a robot's development. Privacy and data handling are areas that have been extensively explored in the Human-Robot Interaction (HRI) community, and roboticists are recommended to follow up on this conversation to effectively meet these concerns.

### C. Ethical aspects

*6) Equity of access:* Equity of access emerged as the most significant ethical concern among participants. Rehabilitation robots are often prohibitively expensive, limiting access for economically disadvantaged populations. Costs associated with the technology include the purchase or rental of the device and ongoing expenses such as electricity usage, maintenance, repairs, and training [4]. For instance, a study highlights the case of a Chennai-based hospital in India that operates three rehabilitation robots (a total cost of 1 million dollars), charging patients up to $ 667 for a complete therapy course. This places an immense financial burden on individuals in a country where the estimated per capita gross national income stands at $ 1,120 [17].

Drawing from their experience of working with several patients, the participants were concerned about the difficulty for the economically disadvantaged to afford such technology. Factors like healthcare providers' policies and the availability of financial aid further complicate accessibility [18].

"*Projected cost of use – will this be accessible to everyone, or will there be financial barriers?*"

This highlights a need for designers of such technology to consider affordability in the early development stage [19] and for public policy to ensure equal access.

Additionally, the physical and infrastructural demands of these devices can create indirect barriers to adoption. For instance, limited space at home, incompatibility with the structural design of living environments, requirement of WiFi or internet connectivity or the robot's large form factor may exclude certain users. Developing compact, adaptable devices suitable for various home environments and offering infrastructure support is essential. Use of modular components, such as detachable or interchangeable support frames (like gravity compensation mechanisms), enables the device to be reconfigured to fit varying room layouts and storage constraints. This flexibility supports deployment in diverse home environments without requiring structural modifications. Connectivity limitations can be mitigated through edge computing solutions as discussed in the previous section.

*7) Suitability of the Device:* Ensuring that rehabilitation robots are prescribed appropriately for the intended users is another ethical priority. Participants stressed the need for evidence-based approaches to determine the suitability of a device for specific impairments. Without proper regulation and training for healthcare professionals, there is a risk that commercial interests could exploit patients' desperation for recovery, leading to inappropriate or ineffective prescriptions. Robot designers and clinicians must consider whether the robot accommodates the specific needs of different impairments and avoids unintended consequences. Regulation and professional training are essential to ensure robots are prescribed responsibly and effectively.

*8) Cognitive Competence of the User:* The cognitive competence of users recovering from neurological conditions, such as stroke, was another significant theme. Participants raised concerns about whether users would be cognitively capable of interacting with the technology, given its potential complexity. Older adults, in particular, may face additional challenges, such as unfamiliarity with computer-based interfaces, which are commonly used in gamified training systems.

Moreover, participants emphasised the importance of assessing users' cognitive ability to consent, especially when training data is collected for remote monitoring by clinicians [20]. Collecting user data for remote monitoring introduces additional ethical concerns about privacy and informed consent. Users must fully understand and consent to how their data will be used, but this can be challenging for individuals with cognitive impairments. Cognitive stability is a concern, particularly for older users whose abilities may decline over time. To address these challenges, rehabilitation robots must:

- Be designed with user-friendly, intuitive interfaces that minimise cognitive load.
- Include targeted training programs for both users and clinicians to ensure the technology is understood and used appropriately [21].
- Provide ongoing professional support to monitor users' cognitive capacity and adjust use accordingly.

Moreover, it is essential that there is transparency in what data is collected and how they are handled and that the user is empowered with complete control over these factors [20].

In addition to the common comments discussed across the eight key themes, two other notable comments were raised by specific individuals:

- One participant expressed concerns about the device's ability to adapt to changes in hand size due to swelling, which could potentially impact blood circulation. Attention is needed to ensure that such devices are designed with flexibility to accommodate minor changes in the body's dimensions.
- Gamification of exercises is gaining impetus to improve user engagement and adherence to training. Robots are well-placed to take advantage of this feature since they contain sensors, through which data collected from the user can be used as a control input for computer games in real-time. The effectiveness of this approach depends on the type of games and affects different people to different extents based on their age, gender, culture, exposure to games, etc. It is imperative to ensure that the games are age-appropriate and take the cognitive load of the participant into account.

## IV. Conclusion

Home-based rehabilitation robots hold significant potential to improve the quality of life for individuals recovering from neurological diseases or injuries while supporting clinicians in delivering effective therapy. However, realising this potential demands immediate attention to the critical safety, legal, and ethical considerations associated with their use. This study explored these concerns through the perspectives of experienced neurorehabilitation clinicians, identifying eight key themes that encapsulate their insights.

To translate these insights into actionable design guidance, this paper highlights several design considerations and strategic recommendations. As injury risk and overuse emerged as central concerns among clinicians, design solutions such as compliant actuation, passive assistance mechanisms, and integrated fatigue detection systems can be considered to address these challenges. It also addresses the significance of privacy concerns in such devices, requiring the adoption of privacy-conscious design approaches such as edge computing for local data processing and engagement with ongoing conversations in the HRI community on responsible data handling and storage. Additionally, it emphasises the importance of developing clear regulatory frameworks, collaboratively shaped by legal experts, clinicians, and roboticists, to establish accountability and safeguard users' rights. Finally, ethical issues such as equitable access and the responsible prescription of technology—prioritising users' needs over commercial interests are crucial considerations for rehabilitation robot designers to help prevent the widening of existing healthcare disparities.

The feedback provided by clinicians emphasises that moving forward, collaboration between roboticists, clinicians and policymakers is essential to address these challenges holistically. By taking proactive steps to mitigate these risks, the development of rehabilitation robots can pave the way for transformative advancements in neurorehabilitation, ultimately improving the quality of life for both users and caregivers.

## V. Acknowledgement

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