Regulatory Considerations for Physically Assistive Robotics Researchers

Afifah Kashif
University of Washington
Seattle, USA
afifahk@cs.washington.edu

Amal Nanavati
University of Washington
Seattle, USA
amaln@cs.washington.edu

Maya Cakmak
University of Washington
Seattle, USA
mcakmak@cs.washington.edu

***Abstract*—Physically assistive robots (PARs) have the potential to enhance independence and quality of life for individuals with disabilities. While work in this field has progressed significantly, the translation from research to product remains challenging due to complex regulatory processes involving approval and funding. This work seeks to initiate a discussion about aligning research efforts to better support long-term adoption of PARs.**

***Index Terms*—physically assistive robots, policy, insurance**

I. Introduction

Physically assistive robots (PARs) have the potential to improve the lives of people with disabilities by increasing independence, reducing caregiver burden, and improving quality of life [14, 20, 29]. PAR research has grown significantly in the last decade [14], including an increasing number of in-context robot deployments [8, 10, 15, 18, 24]. We are nearing the stage of thinking about translating PARs from research prototypes into deployable and usable products.

A key challenge in translating PARs from research to product is navigating the complex processes that govern the approval, funding, and distribution of such assistive technologies (ATs) [3]. There are several stakeholders involved—insurance organizations, regulatory agencies, healthcare providers, robotics companies, and more – each of whom has their own incentives and processes. For example, insurance organizations tend to require evidence of cost effectiveness, while regulatory agencies prioritize safe and positive outcomes. Research plays an important role in helping agencies assess whether to approve and fund assistive technologies, reducing delays in access to ATs for users.

The goal of this work is to start a conversation amongst PAR researchers about how our work can contribute to positive long-term outcomes when it comes to insurance and regulatory approvals. We highlight insights from the existing policy landscape (Sec II), focused on insurance and regulatory agencies in the United States (U.S.). We then discuss ideas for how PAR research can be informed by these insights (Sec III).

II. Existing Landscape

Despite 2.5 billion people needing ATs, access remains limited to as low as 3% in certain regions [20]. Regulatory and insurance processes play a key role in determining the availability and affordability of ATs [19]. This section briefly outlines that policy landscape and examines key patterns in how assistive technologies are classified and approved, focusing on the U.S. We draw on case studies of both PARs and general ATs, illustrating nuances in the regulatory process. Although this work is country-specific, we encourage future work similar to [11, 22] that transcends national boundaries.

A. Differing Criteria

Evaluation criteria for ATs can vary significantly depending on the primary goals of the agency conducting the assessment. A crucial distinction is between agencies governing approval vs. funding. Approval agencies typically focus on regulating medical devices to ensure they are safe and effective, while funding agencies assess whether to cover any of the costs associated with those devices. For example, the Food and Drug Administration (FDA) in the US, an approval agency, "is responsible for assuring medical devices available in the U.S. are **safe** and **effective**" [2]. On the other hand, the Centers for Medicare & Medicaid Services (CMS) in the U.S., a funding agency, covers medical devices that are "'**reasonable** and **necessary**' for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" [1]. These terms—"safe," "effective," "reasonable," "necessary"—are part of the core mandates of the agencies, and define the differing criteria they use to assess whether to approve and fund ATs. As a result, medical devices may be approved but not funded. Understanding these differing criteria is crucial to ensuring our research lays the foundation for downstream approval and funding.

B. Function-Based Approval

Agencies use a function-based approach for approval, where different components of a device are assessed separately based on their individual functions. Regulatory agencies like CMS typically focus on the user-centered function, assessing whether a component meets medical necessity and is essential for improving the user's health and quality of life. A notable example is the iBOT 4000 Mobility System, a powered wheelchair with groundbreaking capabilities of balancing on two wheels, climbing stairs, and seat elevation. The iBOT's mobility base was approved by CMS in 2003 as a **medically necessary** mobility aid, but the seat elevation feature, which enables users to raise their seat to a standing position was evaluated separately. In 2005, CMS deemed this feature **not presumptively medical** and did not approve it for funding. Lack of approval for one part of an AT can prevent users from accessing the entire device. Luckily, in 2009, with accumulated

evidence that seat elevation prevented pressure ulcers and improved health outcomes, CMS reversed its position and approved the feature for coverage, provided that a physician prescribed it [7].

C. Incremental Approval

Agencies often have different regulatory processes for completely novel medical devices, versus those that are considered an incremental improvement upon prior technology [6]. Thus, developers may argue that their AT is an incremental improvement upon already-approved ones. The DEKA arm system, a prosthetic arm, gained approval for their Gen3 version by using company and VA (Veterans Affairs) studies to ensure that the new version of the device does not "negatively impact safety or effectiveness" compared to the Gen2 model [17, 30]. Sometimes, the incremental approval pathway relies on expanding what is approved within existing categories. For instance, the ReWalk powered exoskeleton, which helps individuals with spinal cord injuries walk, navigate stairs, and perform other activities of daily life, was approved in 2024 due to a change in how "brace" is defined by CMS. After urging from ReWalk and stakeholders, "brace" now includes exoskeletons [5, 26]. This incremental strategy is effective for gaining approval faster, but can be at odds with norms in fields like robotics research, where the novelty of a technology is often a key point of emphasis. The incremental approval pathway may require us to reform how we present our work, putting more emphasis on ways in which our technology *builds upon* existing ATs, even non-robotic ones.

III. Paving A Path Forward

This section presents ideas on reforming our research practices to lay a foundation for upstream regulatory approvals.

- **Aligning Research Metrics with Agency Criteria:** Studying case files from prior approvals in your legislative region can shed light on the metrics used by regulatory or funding agencies and can therefore guide your study design. For example, CMS evaluated the iBOT mobility system by assessing its eligibility as durable medical equipment (DME) [7], focusing on functions which aligned with traditional power-operated wheelchairs, essential for medical purposes. As a researcher, aligning study metrics with these criteria—such as functional mobility assessments and validated quality-of-life measures—can provide stronger justification for reimbursement.
- **Concisely Articulating Functions:** While the trend in robotics often leans toward creating multi-functional devices [12, 16, 28], articulating specific functions in research can help ensure these devices align more easily with regulatory frameworks. The International Classification of Functioning (ICF) provides a starting framework which is recognized by agencies globally. For example, work on a robotic prosthetic can use code *e1151: assistive products and technology for personal use in daily living*.
- **Utilizing Incremental Approval:** Although robotics research papers tend to emphasize how the system is novel, we recommend emphasizing how the system builds off of existing, perhaps non-robotic, ATs. This can help build a case that the technology should fall under the incremental approval pathway, which may allow for faster approval.

In addition to framing research differently, stronger interdisciplinary collaborations may also facilitate policy changes and broader adoption of ATs.

- **Involving Occupational Therapists and Physicians in the Research Process:** Many approval processes build off of medical recommendations. In the case of iBOT, CMS required physician opinion and clinical backing [7]. Additionally, collaborations with non-technical stakeholders throughout the technology development process, like [15, 18, 23] did, helps ensure the technology will be usable and integrate smoothly into stakeholders' routines. In practice, the DEKA arm system received approval following the inclusion of a VA study which included clinical and lab trials [30].
- **Engaging with Intersectionality:** An individual's experience with disability is shaped by a multitude of identity factors, including race, gender, and socioeconomic status. To address disparities in access across multi-faceted identities, researchers should adopt a multidisciplinary approach by integrating insights from health policy, disability rights, and socioeconomic papers such as [25, 27, 31].
- **Developing Economic Analyses:** Funding agencies often prioritize evidence of cost-savings when making decisions. To support long-term adoption of ATs, it is crucial to increase economic cost-benefit analysis and research. These analyses can demonstrate the long-term cost-effectiveness of ATs, highlighting their potential to reduce overall healthcare costs by improving outcomes and decreasing reliance on more expensive interventions [9].

As PARs evolve, we can anticipate the long-term regulatory, social, and global contexts that will shape their development and adoption.

- **Anticipating the Role of Autonomy in HRI:** As technology becomes more autonomous, researchers should anticipate change in approval criteria, as future technologies will increasingly blur traditional categories. Some papers on healthcare and AI present trends that may be seen in approval of autonomous PARs [4, 13].
- **Advocating for Systemic Change:** Researchers should engage with organizations focused on disability rights, healthcare policy, and technology regulation to ensure that advocacy efforts are aligned with both the needs of individuals with disabilities and the evolving technological landscape. For example, The Center for Disability Rights, The Center for Health Policy at Brookings and National Council on Independent Living advocate for civil rights and equity.
- **Pushing for Global Policy:** Advocacy efforts should also extend beyond national borders to promote inclusive global-level policies for ATs as emphasized in [11, 20, 21]. This will also contribute towards the *2030 Agenda for Sustainable Development*, which emphasizes universal health coverage to ensure access and improved quality of life for all [21].

Acknowledgment

We thank Vinitha Ranganeni and the occupational therapists, policy experts, and end-users we talked to, who provided key insights for this article. This work was funded by the National Institute of Biomedical Imaging and Bioengineering (#1R01EB034580-01).

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