A Stakeholder Analysis of Patient Reported Outcomes Measures(PROM) in Healthcare

(STS Paper)

Evaluation of a Novel Class of Ankle-Foot Orthotics for Improvement of Patient Outcomes

(Technical Paper)

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
School of Engineering and Applied Science
University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

By
Pratham Sriskandarajah

November 8, 2024

Technical Team Members: Miranda Sedehi and Cooper Wyatt

On my honor as a University student, I have neither given nor received unauthorized aid
on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

ADVISORS

Dr. Richard D. Jacques, STS Advisor, Department of Engineering and Society

Cole Yantiss, Technical Advisor, Icarus Medical Innovations, Inc.

Introduction

Ernest Amory Codman was the first documented 20th-century physician to advocate for an "end result system" to establish standards for comparing hospitals and tracking patient outcomes (Brand, 2012). Codman faced strong opposition from his colleagues, who viewed his ideas as a threat to income (Leung et al., 2020). In the current U.S. healthcare system, patient follow-up is still lacking, and there is a corresponding dissatisfaction with treatment outcomes (Amat et al., 2022; Roehr, 2007). Codman's vision for an ideal "end result system" has not yet been fully realized or implemented.

Progress is being made, however. Today, patient-reported outcome measures (PROMs) are defined as standardized, validated survey tools that assess health outcomes reported by patients across areas such as general health, quality of life, specific symptoms, and physical, mental, and social health (Patient-Reported Outcome Measures (PROMs) | CIHI, n.d.). These metrics are widely used in clinical research and are being studied for use in longitudinal settings (Cai & Houts, 2021). Given their ability to quantify patient outcomes at a low cost when electronically administered, PROMs serve as a promising candidate for the "end result" metric that Codman envisioned. However, despite their use in research, several barriers continue to prevent PROMs from becoming part of routine clinical practice.

The Science, Technology, and Society (STS) aspect of this capstone will explore these barriers to PROM implementation in healthcare through a Social Construction of Technology (SCOT) framework. While PROMs are designed to bring patient feedback into the healthcare process, obstacles like time constraints, IT issues, and survey fatigue hinder their widespread adoption. This research aims to analyze the perspectives of stakeholders, including patients,

providers, and administrators—to better understand and address these challenges, and to find ways for healthcare systems to better support patient-centered metrics in clinical practice.

This aligns closely with the technical component of the capstone, which involves designing and conducting clinical study in which PROMs are the primary measurement, with clinical gait metrics as a secondary measure. Specifically, the study will assess the effectiveness of the Hermes Ankle-Foot Orthosis (AFO), a new device developed by Icarus Medical, in improving quality of life, mobility, and gait in patients with foot drop.

The connection between the technical and socio-technical aspects of this project emphasizes that engineering innovation alone cannot solve the challenges faced by individuals with foot drop. The AFO's success depends on its ability to integrate smoothly into users' lives. By prioritizing a patient-focused, iterative design approach, we aim to create a solution that is both technically effective and well-suited to real-world use.

A Stakeholder Analysis of Patient Reported Outcomes Measures(PROM) in Healthcare

Here, a social construction of technology (SCOT) framework analysis, established by Bijker et al. (1987), is employed to examine what barriers are faced by the technology of PROMs in healthcare. Specifically, the first stage of SCOT theory, interpretive flexibility, sets the framework to 1) determine the various meanings and interpretations of PROMs for relevant stakeholders, and 2) elucidate how to resolve the technological problems created by these interpretations that prevent the integration of PROMs in healthcare. Bijker and Pinch's SCOT holds that acceptance or rejection of a technology is based on the groups and stakeholders that participate in defining it. Thus, to determine the best framework to implement PROMs, stakeholder analysis is critical.

In the general healthcare setting, the main stakeholders are patients, providers (professionals and institutions), payers, and policymakers, often referred to as the "4 P's" in healthcare (Leveraging interoperability standards to link patient & Network, 2014). In the hospital and outpatient setting, providers, patients, and policymakers are the most directly relevant stakeholders to PROM implementation. Patients provide the data for the survey (although they can also utilize outcomes to determine their healthcare decisions), clinicians interpret the data, and healthcare administrators establish the framework for PROM implementation.

To determine the stakeholder consensus on perceived barriers and benefits of patient-reported outcome measures, Philpot et al. (2018) conducted a semi-structured focus group. For patients, the length and the complexity of the survey discouraged them from completing it. Equally important was the concern that with structured questionnaires, there would be no opportunity to voice concerns, and that the physician would interact less effectively with the patient. A focus group was repeated with healthcare administrators, finding the top concerns to be the lack of patient health literacy and survey fatigue. Together, both patients and administrative staff found patient completion and reliability of the survey data to be the most contentious barriers.

On the other hand, as the primary stakeholder involved in the use of PROMs, clinicians and providers express more pragmatic concerns with framework implementation, according to questionnaires administered to healthcare providers by Amini et al. (2021). For responses regarding the "commencement of PROM implementation," the most frequent response included time constraints and the labor-intensive nature of incorporating PROMs in care. This is in line with the current state of healthcare, as many physicians have reported that they are often

overloaded with information (Nijor et al., 2022). The questionnaires administered further revealed secondary concerns with IT issues and non-uniformity in the implementation of PROMs, both factors which can lead to further time consumption and additional costs.

Various solutions to the barriers expressed by different stakeholders have been proposed, but they can sometimes conflict with each other. For all stakeholders, it seems most important that surveys are short and simple, allowing fast completion times for the patient, succinct results for use by clinicians, and validity of reported outcomes for healthcare providers. Although question banks of PROMs are long, short forms are being developed for many, such as the Short-Form 12 (SF-12) and Short-Form 36 (SF-36), which both provide measures of general health-related quality of life in patients (Lins & Carvalho, 2016; Ware et al., 1996). If the patient is in a medical setting that facilitates the completion of longer question banks, it would provide clinicians with accurate data. However, for follow-up outside of the clinic, it would be most beneficial to use short forms to avoid patient fatigue.

Barriers such as uniform implementation and IT platform issues for clinicians can be resolved by developing software that is user-friendly and compatible with the current EHR and metrics that an organization uses (Foster et al., 2018). More important than the software itself, however, is the addition of a team that can work seamlessly with clinicians in PROM implementation. In 2013, a value-based healthcare (VBHC) initiative from Erasmus University Medical Center established a PROM data collection linked to the EHR or accessible through the Web. Multidisciplinary teams were then deployed within the university to implement routine capture of PROMs by providing feedback to healthcare providers (Van Norman, 2016). Similarly, to ensure successful PROM implementation, healthcare institutions must be willing to invest in the form of VBHC teams. This can conflict with the desires of stakeholders such as

payers and policymakers. However, by shifting toward value-based care—from the costs of acute hospitalization to providing PROM implementation—long-term costs for healthcare institutions and insurance companies can be lowered.

Evaluation of a Novel Class of Ankle-Foot Orthotics for Patient Outcomes Improvements

Foot drop is a disorder characterized by the inability to lift the forefoot due to weakness or paralysis of the dorsiflexors, the muscle group anterior to the shin (Nori & Stretanski, 2024). This condition leads to foot-dragging, causing patients to lift their knees higher to compensate for the dropped foot. Ankle-foot orthoses (AFOs) are commonly used to brace individuals with foot drop, preventing excessive plantarflexion, facilitating foot clearance, and restoring a more natural gait pattern (Choo & Chang, 2021). Traditionally, AFOs are made from rigid materials such as thermoplastics, but more recent innovations have incorporated materials like carbon fiber or employ 3D printing to enhance comfort, mobility, and customization for patients (Nori & Stretanski, 2024). Despite these advancements, many existing designs remain rigid and lead to slow walking speeds due to the excessive cost associated with current state-of-the-art carbon fiber braces (Lewallen et al., 2010).

Local to Charlottesville, Icarus Medical has designed the Hermes AFO. This innovative technology uses springs and 3D printing technology to design custom-fit braces that push on the user's foot as they walk. The brace has numerous benefits for their gait: more efficient ankle movement, increased walking speed, and reduced ankle and knee joint pain. Given the lack of follow-up and patient-reported outcomes in healthcare, Icarus is seeking to conduct a clinical study that further characterizes the benefits of the Hermes Ankle Brace for both PROMs and established gait metrics.

Thus, the technical dimension of this project is centered on designing and performing a 3-month longitudinal clinical study to determine the effect of the Hermes AFO on patient-reported outcomes (PROs) in individuals with foot drop. At various time points, 3 surveys will be electronically administered: the EuroQol 5-Dimension (EQ-5D) as a measure of overall quality of life, Orthotic Patient-Reported Outcome - Mobility (OPRO-M) 20-Item Short Form as a measure of functionality, and Orthotic Prosthetic User Satisfaction (OPUS) surveys as a measure of comfort and satisfaction. As a secondary measure, kinematic and kinetic data will be obtained to quantify and evaluate a patient's gait cycle utilizing 3D motion capture, force plates, and electromyography. Additionally, at the end of the study, patients will be asked for open-ended feedback about the brace. With the patient-centered information obtained from the study, Icarus can iteratively design a version of the ankle brace that is more compatible with various portions of its users' daily lives and improves their quality of life.

Conclusion

The integration of patient-reported outcome measures (PROMs) in healthcare is still in the interpretive flexibility stage of SCOT. While PROMs hold promise as tools that bring patient perspectives into care, significant barriers—such as time constraints, IT challenges, and survey fatigue—continue to hinder their adoption. Addressing these issues requires a stakeholder-focused approach, as identified through a Social Construction of Technology (SCOT) framework, to better understand the needs and limitations faced by patients, clinicians, and healthcare administrators.

The technical component of this project, the clinical study of the Hermes Ankle-Foot Orthosis (AFO), exemplifies how PROMs can capture meaningful insights on the effectiveness of medical devices like the Hermes AFO, which aims to enhance mobility and quality of life for

patients with foot drop. The study's findings will contribute valuable feedback to iteratively refine the device, underscoring the importance of patient-centered, evidence-based innovation. Through both the technical and socio-technical facets, this project aims to advance a healthcare system that not only innovates but integrates technology in a way that respects and responds to the lived experiences of patients.

References

Amat, M., Duralde, E., Masutani, R., Glassman, R., Shen, C., & Graham, K. L. (2022). "Patient Lost to Follow-up": Opportunities and Challenges in Delivering Primary Care in Academic Medical Centers. *Journal of General Internal Medicine*, *37*(11), 2678–2683. https://doi.org/10.1007/s11606-021-07216-3

Amini, M., Oemrawsingh, A., Verweij, L. M., Lingsma, H. F., Hazelzet, J. A., Eijkenaar, F., & van Leeuwen, N. (2021). Facilitators and barriers for implementing patient-reported outcome measures in clinical care: An academic center's initial experience. *Health Policy*, *125*(9), 1247–1255. https://doi.org/10.1016/j.healthpol.2021.07.001

Bijker, W. E., Hughes, T. P., & Pinch, T. (Eds.). (1987). *The Social construction of technological systems: New directions in the sociology and history of technology*. MIT Press.

Brand, R. A. (2012). Biographical Sketch: Ernest Amory Codman, MD (1869–1940). *Clinical Orthopaedics and Related Research*, *471*(6), 1775. https://doi.org/10.1007/s11999-012-2750-4

Cai, L., & Houts, C. R. (2021). Longitudinal Analysis of Patient-Reported Outcomes in Clinical Trials: Applications of Multilevel and Multidimensional Item Response Theory. *Psychometrika*, *86*(3), 754. https://doi.org/10.1007/s11336-021-09777-y

Choo, Y. J., & Chang, M. C. (2021). Commonly Used Types and Recent Development of Ankle-Foot Orthosis: A Narrative Review. *Healthcare*, *9*(8), 1046. https://doi.org/10.3390/healthcare9081046

Foster, A., Croot, L., Brazier, J., Harris, J., & O'Cathain, A. (2018). The facilitators and barriers to implementing patient reported outcome measures in organisations delivering health related services: A systematic review of reviews. *Journal of Patient-Reported Outcomes*, *2*, 46. https://doi.org/10.1186/s41687-018-0072-3

Leung, B., Ricketts, D., Ge, X., & Li, C. (2020). Reporting orthopaedic surgeons' outcomes: 100 years after Codman. *The Bulletin of the Royal College of Surgeons of England*, *102*(8), 378–381. https://doi.org/10.1308/rcsbull.2020.209

Leveraging interoperability standards to link patient, P., & Network, J. L. (2014). *Connecting Health Information Systems for Better Health*. Joint Learning Network for Universal Health Coverage. https://pressbooks.pub/jln1/

Lewallen, J., Miedaner, J., Amyx, S., & Sherman, J. (2010). Effect of Three Styles of Custom Ankle Foot Orthoses on the Gait of Stroke Patients While Walking on Level and Inclined Surfaces. *JPO: Journal of Prosthetics and Orthotics*, *22*(2), 78. https://doi.org/10.1097/JPO.0b013e3181d84767

Lins, L., & Carvalho, F. M. (2016). SF-36 total score as a single measure of health-related quality of life: Scoping review. *SAGE Open Medicine*, *4*, 2050312116671725. https://doi.org/10.1177/2050312116671725

Nijor, S., Rallis, G., Lad, N., & Gokcen, E. (2022). Patient Safety Issues From Information Overload in Electronic Medical Records. *Journal of Patient Safety*, *18*(6), e999. https://doi.org/10.1097/PTS.0000000000001002

Nori, S. L., & Stretanski, M. F. (2024). Foot Drop. In *StatPearls*. StatPearls Publishing. http://www.ncbi.nlm.nih.gov/books/NBK554393/

Patient-reported outcome measures (PROMs) | CIHI. (n.d.). Retrieved November 8, 2024, from https://www.cihi.ca/en/patient-reported-outcome-measures-proms

Philpot, L. M., Barnes, S. A., Brown, R. M., Austin, J. A., James, C. S., Stanford, R. H., & Ebbert, J. O. (2018). Barriers and Benefits to the Use of Patient-Reported Outcome Measures in Routine Clinical Care: A Qualitative Study. *American Journal of Medical*

Quality, *33*(4), 359–364. https://doi.org/10.1177/1062860617745986

Roehr, B. (2007). US has highest dissatisfaction with health care. *BMJ : British Medical Journal*, *335*(7627), 956. https://doi.org/10.1136/bmj.39388.639028.DB

Van Norman, G. A. (2016). Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices. *JACC: Basic to Translational Science*, *1*(4), 277–287. https://doi.org/10.1016/j.jacbts.2016.03.009

Ware, J., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: Construction of scales and preliminary tests of reliability and validity. *Medical Care*, *34*(3), 220–233. https://doi.org/10.1097/00005650-199603000-00003