The Role of Clinical Input in Health Technology Assessments of Neurological Rehabilitation Medical Devices

PP-029

Richards, B., Hobbs Rehabilitation, UK Email: BarryRichards@hobbsrehabilitation.co.uk

Introduction

- **Advancements in neurorehabilitation technologies** including robotic exoskeletons, end effectors and neurostimulation devices have demonstrated potential for improving function and quality of life in individuals with neurological impairments (Dobkin, 2017; Mehrholz et al., 2020).
- Despite these innovations, **translation to widespread clinical adoption and utilisation remains inconsistent**.
- A key factor in this gap is the **Health Technology Assessment (HTA) process**, which evaluates safety, design, utility, and cost-effectiveness to inform clinical adoption (Husereau et al., 2022).
- However, **clinical expertise is often underutilized** in HTAs, which is usually introduced in later stages or focused narrowly on clinical outcomes (Facey et al., 2015).
- This misalignment can lead to technologies that are technically sound but **poorly suited for real-world use**, limiting adoption and reducing patient benefit (Facey et al., 2015).

Study Aims

This study investigates:

- The extent and nature of clinical input in HTAs of neurological rehabilitation technologies.
- Barriers preventing clinicians from engaging in HTA processes.
- The correlation between clinical involvement in HTAs and subsequent technology adoption and patient outcomes.

Methods

A **systematic literature review** was conducted using the PubMed database, identifying HTAs of neurological rehabilitation medical devices from 2018–2024. Studies were included if they referenced clinical consultation, outcomes, or usability testing.

Semi-structured interviews were carried out with:

- **12** Clinicians working with neurological rehabilitation technologies
- **5** Regulatory professionals
- **6** Representatives from neurological medical device companies

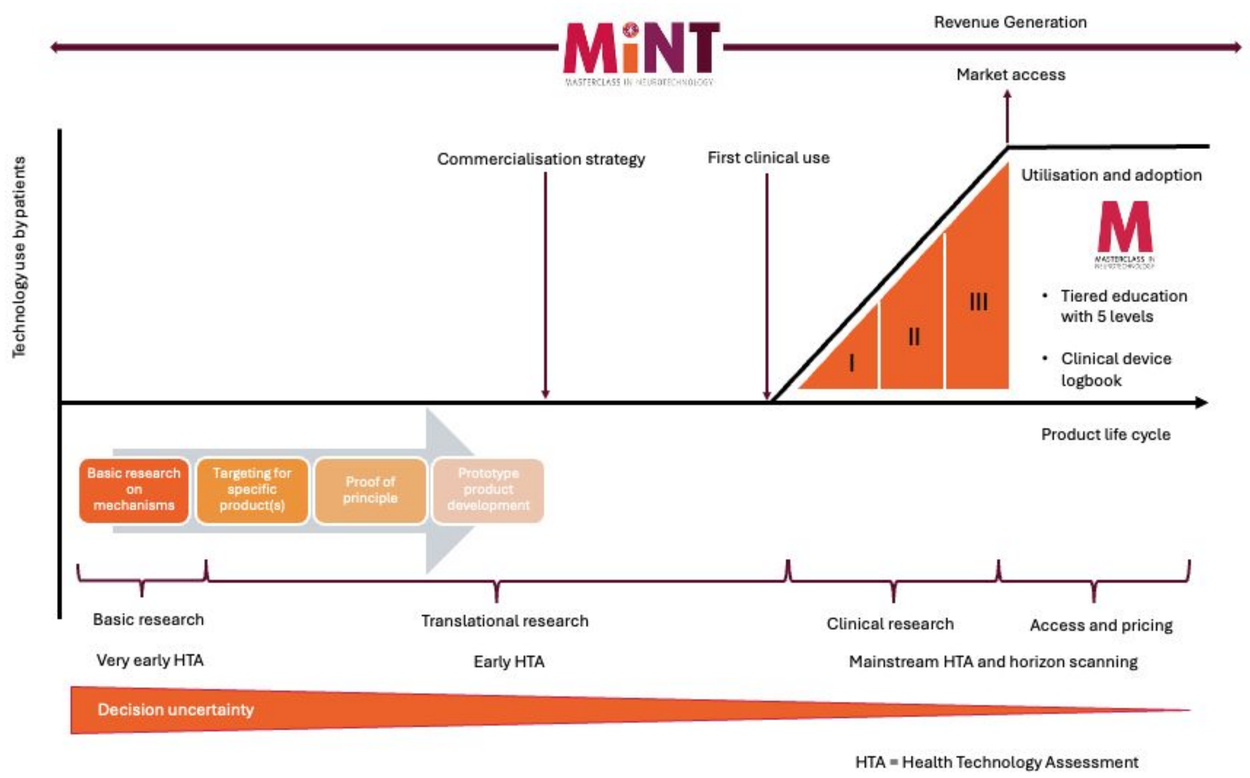
Interview topics included perceived value, timing, and feasibility of clinical input during HTA stages.

Case studies were drawn from documented instances within the MiNT consultancy and education ecosystem, which integrates early-stage clinical co-design into HTA frameworks.

1. Dobkin, B. H. (2017). Neurorehabilitation and neural repair: clinical and translational insights. *Neurorehabilitation and Neural Repair*, 31(5), 389–398.
2. Facey, K., Boivin, A., Gracia, J., et al. (2015). Patients' perspectives in health technology assessment: a route to robust evidence and fair deliberation. *International Journal of Technology Assessment in Health Care*, 31(2), 87–95.
3. Greenhalgh, J., Gooding, K., Gibbons, E., et al. (2019). How do patient reported outcome measures (PROMs) support clinician-patient communication and patient care? *Journal of Patient-Reported Outcomes*, 3(1), 42.
4. Husereau, D., Drummond, M., Augustovski, F., et al. (2022). Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. *Value in Health*, 25(1), 10–31.
5. Mehrholz, J., Thomas, S., Werner, C., Kugler, J., Pohl, M., & Elsner, B. (2020). Electromechanical-assisted training for walking after stroke. *Cochrane Database of Systematic Reviews*, (10).

Results

- Only **32%** of reviewed HTAs involved clinicians beyond outcome data provision.
- Clinical input was predominantly present in post-marketing surveillance or effectiveness evaluation stages.
- A total of **83%** of clinicians reported insufficient time, training and unclear pathways for engaging in HTA processes.
- Case studies showed earlier clinical collaboration led to more favourable HTA outcomes.



NeuroVirt

Collaborating with clinical experts and patients *at Hobbs Rehabilitation has provided* ***unique insight*** *that helped* ***guide product development*** *to meet* ***patient and clinical needs*** *from the initial development steps.*

– Eve Gregoriou NeuroVirt Founder and CEO

able human motion

MiNT *has an* ***established process*** *of assessing new neuro-technologies and* ***running feasibility / clinical trials***

– Kaitlin Kreamer Product Manager ABLE Human Motion

VALKYRIE INDUSTRIES

Testing with therapists and especially patients *is very useful for* ***iterative product development. Discussions*** *on the best* ***patient cohorts, ease of use*** *for therapists and* ***commercial aspects*** *were very important. Generating ideas for how a device / feature can* ***meet specific needs in therapy*** *is a result of* ***collaborative working.***

– Ivan Isakov Director and Co Founder Valkyrie Industries Limited

Conclusion

Despite acknowledgment of its value, clinical input remains marginal in most HTAs. Structured frameworks that facilitate clinician involvement throughout HTA phases, from early design to evaluation, can significantly enhance real-world applicability and patient benefit.

There is a systemic shortfall in current early HTA methodologies regarding the integration of clinical perspectives into the product lifecycle of neurological rehabilitation medical devices.

Implications for Practice and Policy

- Policymakers should mandate clinician representation in HTA panels for rehabilitation technologies.
- Policymakers should provide structured avenues and incentives (e.g., protected time, training) for clinician involvement.
- Technology developers should embed co-design principles in their early assessment frameworks to anticipate clinical workflow integration.