The Acceptability of Wearables in Remote Monitoring According to Health Technology Assessment (HTA) Bodies

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Introduction

- Wearable technologies such as smart watches, which monitor physiological data, are widely used by the public for tracking fitness and activity.[1,2]
- The physiological data that wearables capture can also be used for monitoring overall health and disease.
- Wearables may support health economic and outcomes research (HEOR) by capturing health deterioration and disease progression.[1-4]
  - Patient outcomes identified by wearables in clinical trials may inform health technology assessment (HTA).
- However, wearables may not be accessible to individuals of all sociodemographic groups due to high costs and required technological literacy to use wearables properly.[5-7]
- We aimed to explore the acceptability of wearables, including medical devices, for remote monitoring in HEOR and by HTA bodies, and the further potential of wearables from an HEOR perspective. We also aimed to identify challenges for obtaining reimbursement for wearables from HTA and implications for patient access.

Methods

- We conducted a focused evidence search of published literature, clinical trial databases and HTA websites: National Institute for Health and Care Excellence (NICE; UK), Haute Autorité de Santé (HAS; France), Gemeinsame Bundesausschuss (G-BA; Germany), Agenzia Italiana del Farmaco (AIFA; Italy) and Agencia Española de Medicamentos y Productos Sanitarios (AEMPS; Spain).
- Evidence relating to the current and potential use and acceptability of wearables in clinical trials, HTA submissions, reimbursement pathways and healthcare decision-making was summarised.
- Targeted evidence searches were limited to the last 15 years to identify established wearables (such as continuous glucose monitors; CGMs), which have been available for a long time, as well as novel wearables (including smart technologies) which are still under investigation.

Results

- Precedents of wearable technologies reimbursed across Europe and implemented into healthcare systems and/ or informing healthcare decision making were identified. Wearables technologies currently used within clinical trials were also captured. Potential future uses of wearables were identified from investigational studies.

Current wearable technologies informing clinical decision-making

- Within our search, wearables that are currently reimbursed by healthcare systems and are used within healthcare systems included CGMs and hybrid closed loop (HCL) systems for patients with diabetes.

- **First evidence of reimbursement 2016:[8] CGMs** are widely utilised by patients with type 1 and type 2 diabetes and transmit data on glucose levels to connected devices (e.g., smartphones).[9] CGMs allow for insulin to be delivered when necessary.[9]
  - Findings from real-world studies demonstrate that following the implementation of CGMs, hospitalisation rates, acute diabetes-related adverse events, and the number of days missed from work decrease among patients with type 1 and type 2 diabetes.[10]

- **First evidence of reimbursement 2019:[11] Hybrid closed loop (HCL) systems** are used by paediatric and young patients with type 1 diabetes to deliver insulin automatically in response to CGM results.[12] The CGM data are transmitted to an insulin pump which calculates the insulin requirements to maintain blood glucose levels within a healthy range.[12]
  - Continuously managing blood glucose levels results in a substantial mental burden for patients with type 1 diabetes and their families or caregivers; HCL systems have the potential to reduce this burden.[13]

Current wearable technologies used in clinical trials

- Findings from our searches highlighted that the use of wearables within clinical trials is relatively rare, although use is expected to accelerate.[14,15]
- Regulatory and HTA experience with evidence generated via technologies worn by patients is minimal.[14] Our search did not derive any HTA assessment records on consumer-focused wearables such as smartwatches.
- This finding highlighted that some endpoints that have been derived from wearables technologies are supported by regulatory authorities:

Stride velocity 95th centile (SV95C)

- SV95C is the first wearable device-derived clinical outcome assessment (COA) to receive European Medicines Agency (EMA) qualification as a suitable clinical trial endpoint for ambulant patients with Duchenne muscular dystrophy.[16]
- SV95C is a digitally measured endpoint that represents the minimum velocity of the top 5% of most rapid strides while walking.[16] This endpoint highly correlates with traditional motor function clinical outcome assessments, and can be measured by any wearable device or sensor worn at the ankle that meets EMA requirements.[16]
- Wearable devices measuring SV95C provide the means to continuously and accurately collect data throughout daily living as opposed to limiting data collection to clinical settings only.[16]

Mobilise-D

- Mobilise-D produce validated digital mobility outcomes which monitor the daily life gait of patients with conditions causing mobility problems, including Parkinson's disease, multiple sclerosis, chronic obstructive pulmonary disease (COPD), proximal femoral/ hip fracture recovery and congestive heart failure.[17,18]
- The digital mobility outcomes measured using sensors collect continuous, real word mobility data with the aim to improve follow-up and personalized care.[17]
- The term "digital mobility outcomes" summarises the combination of the digital mobility assessment of real-world walking speed as a primary outcome and other relevant mobility outcomes as secondary outcomes.[17]
- The EMA have provided a letter of support and regulatory approval for Mobilise-D.[19]

- Several studies have demonstrated feasibility of physiological data measured by wearables and a correlation with patient-reported outcomes (PROs), highlighting potential within clinical trials.[20,21]
  - In a prospective, longitudinal non-interventional study, patients with amyotrophic lateral sclerosis (ALS) used a wrist-worn activity monitor (ActiGraph Insight Watch) or an ankle-worn activity monitor (Modus StepWatch) to continuously assess disease progression.[21] Several daily physical activity measures demonstrate significant change over time and associations with validated patient reported outcomes (PROs).[21]

Results (continued)

Opportunities and potential of wearables

- The literature search identified evidence on how endpoints derived from wearables technologies are performing against current endpoints and additional opportunities and potential uses of wearables to monitor disease status.
- Some wearable and smartphone-based technologies (e.g., SV95C) have been shown to outperform conventional assessments (such as the 6-minute walk test and Movement Disorder Society Unified Parkinson's Disease Rating Scale [MDS-UPDRS]), by capturing subtle motor and cognitive changes in conditions such as Duchenne muscular dystrophy and Parkinson's disease.[14]
  - This demonstrates the potential of wearables technologies for more convenient and accurate data collection for monitoring physiological data and disease progression.[14,22]
- There is ongoing research into the opportunities and potential for wearable technologies in evidence generation and healthcare decision-making.
  - Feasibility studies demonstrate that wearable smartwatches can monitor changes in biometric physiological data, such as heart rate and oxygen saturation, for patients with sickle cell disease and predict pain crisis events using machine learning algorithms.[23,24] Severe pain crises events can result in hospitalisations and leads to a high number of days missed from work.[23]
    - Use of wearables to predict pain events enables proactive and timely pain relief, preventing the need for hospitalisation and missed days from work.[24]
  - A pilot study assessed fatigue and sleep using VitalPatch, a wireless wearable patch sensor, for patients with chronic diseases.[20] The research found sufficient data quality for physiological measures such as heart rate, respiratory rate, skin temperature, number of steps, and posture, which also correlated with fatigue and sleep PROs.[20]
    - This demonstrates the potential of wearables to provide clinicians with realistic insights of fatigue and sleep, which are areas of unmet need.

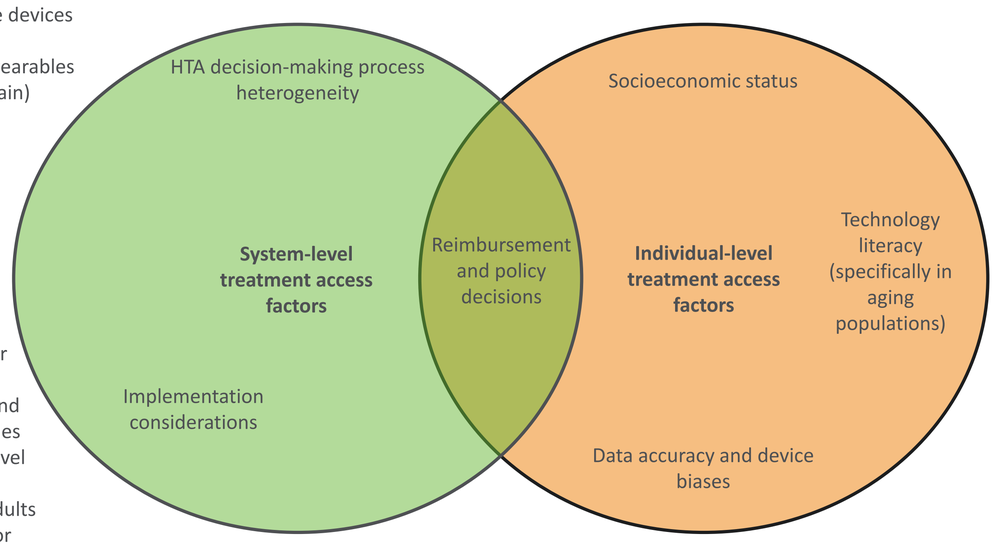
Access and adoption barriers

- Despite advancements in wearables technologies, including regulatory support and use of digital endpoints within clinical trials, we found individual and systemic barriers that can impact patient access and adoption (**Figure 1**).

Reimbursement pathways

- HTA reimbursement pathways for wearable technologies across EU4 and UK are presented in **Table 1**. Patient access to wearable devices for monitoring health can be impacted by reimbursement status across countries.[25] The HTA evaluation process for wearables differs across Europe with some countries (i.e., Italy and Spain) lacking appropriate reimbursement pathways.
- Heterogeneity in HTA evaluation processes and reimbursement drivers (e.g., cost-effectiveness) present as challenges for reimbursement of wearables, which may restrict access for some patients and introduce health disparity and inequalities, particularly for those of low socioeconomic status.[26]

Figure 1. Interplay between systemic and individual treatment access barriers



Reimbursement considerations

- In addition to reimbursement pathways themselves, individual-level implementation considerations, such as user sociodemographic characteristics (e.g., age, ethnicity, sociodemographic status, or prevalence of comorbidities) and acceptability, availability, accuracy, and adoption of wearables may impact HTA decisions (**Figure 1**). However, individual-level implementation considerations are difficult to address in populations with low technological literacy, such as older adults (e.g., >70 years), who are among the primary target users for health monitoring with wearables.[27,28]
- Data finds that user device features alone do not lead to continued use, and adequate support structures are required to foster user-motivation, peer engagement and adaption of devices to user preferences.[27,28]
- Additional data suggests that wrist-worn devices have higher error margin rates in tracking heartrate among individuals with darker skin tone and higher body mass index (BMI), who are groups that may have a higher prevalence of comorbidities.[29] Higher rates of error can lead to mistrust and underutilisation in these populations and may in turn, create algorithmic biases favouring those who have access to, and willingly utilise wearables.[30]
- Some markets across Europe require demonstration of how these factors have been addressed by manufacturers to prevent widening health inequity (**Table 1**), however, negative HTA decisions arising from inadequately addressing these considerations may exacerbate the issue and limit access to advantaged populations only.

Table 1. Reimbursement pathways for wearables in EU4 and UK

	France[31]	Germany[32]	Italy[33]	Spain[34]	United Kingdom[35,36]
Reimbursement pathway?	✓	✓	✗	✗	✓
Detail	LALAT allows CE marked DMD that are listed telemonitoring solutions and medical devices to be eligible for permanent reimbursement PECAN fast-track allows rapid temporary reimbursement of innovative DMD for therapeutic purposes or medical telemonitoring in the absence of clinical data	DiGA allow CE marked listed DMD to be prescribed and rapidly reimbursed to support the detection and treatment of diseases	No specific pathways or frameworks in place to evaluate wearables, however, they may be assessed and reimbursed by standard reimbursement frameworks if recognised as medical devices	No specific pathways or frameworks in place to evaluate wearables, however, they may be assessed and reimbursed by standard reimbursement frameworks if recognised as medical devices and assigned a national product code	HTEP and MTEP are reimbursement pathways applicable to wearables and MTFM enables widespread reimbursement and timely adoption following a positive HTA decision
Primary drivers of positive reimbursement	Clinical data and demonstration of organisational impact on quality of care (i.e., reduction in disease complications and treatment-related AEs, duration/number of hospital stays, improvements in patient quality of life, decreases in treatment use or number of procedures)	Product quality and design (i.e., evidence on robust data protection processes, interoperability and user-friendliness) and impact on quality of care	Clinical performance (i.e., ability of a device to achieve its intended purpose) and clinical benefit (i.e., positive impact of a device on the health of an individual, measured by clinical outcomes demonstrating positive impact on patient management and public health)	Unclear	Product quality and design (i.e., useability, accessibility, handling health inequalities), demonstration of value (i.e., clinical utility and economic data), deployment and implementation considerations

Abbreviations: AE: Adverse events; CE: Conformité Européene (European conformity); DiGA: digitale Gesundheitsanwendungen (digital health applications); DMD: Digital medical devices; EU: European Union; HTA: health technology assessment; HTEP: health technology evaluation programme; LALAT: list of remote medical monitoring activities; MTEP: medical technology evaluation programme; MTFM: MedTech Funding Mandate; PECAN: Prise en Charge Anticipée (early coverage of digital medical devices); UK: United Kingdom.

Conclusions

- Overall, wearables such as CGMs have successfully been implemented into healthcare systems to inform clinical decision making.
- Although the use of wearables within clinical trials is currently rare, some endpoints derived from wearables technologies are supported by regulatory authorities and outperform conventional assessments. This suggests wearables technologies may provide more convenient and accurate data collection for monitoring physiological data and disease progression.
- Therefore, wearables technologies could support clinical decision-making through personalisation of treatment plans and prediction of disease events to encourage preventative healthcare.
- However, heterogeneity in HTA decision-making frameworks and processes may limit patient access to those who are able to afford it.
- Individual-level factors may further limit wearable use to users with technological literacy and higher socioeconomic status, which may contribute to algorithmic biases and exacerbate underuse in minority groups.
- Overall, there is a need to address both systemic and individual-level barriers to wearable access simultaneously, given that patients of higher socioeconomic status are disproportionately more likely to use health monitoring technologies. This disparity has the potential to widen existing health inequities.

References

1. Carrier B, Barrios B, Jolley BD, Navalta JW. Validity and reliability of physiological data in applied settings measured by wearable technology: A rapid systematic review. Technologies. 2020;8(4):70; **2.** Wu M. Wearable technology applications in healthcare: a literature review. On-Line Journal of Nursing Informatics. 2019;23(3); **3.** Gao W, Brooks GA, Klonoff DC. Wearable physiological systems and technologies for metabolic monitoring. Journal of applied physiology. 2018;124(3):548-556; **4.** Liao Y, Thompson C, Peterson S, Mandrola J, Beg MS. The Future of Wearable Technologies and Remote Monitoring in Health Care. Am Soc Clin Oncol Educ Book. Jan 2019;39:115-121. doi:10.1200/edbk_238919; **5.** Canali S, Schiaffonati V, Aliverti A. Challenges and recommendations for wearable devices in digital health: Data quality, interoperability, health equity, fairness. PLOS digital health. 2022;1(10):e0000104; **6.** Stowell E, Lyson MC, Saksono H, et al. Designing and evaluating mHealth interventions for vulnerable populations: A systematic review. 2018:1-17; **7.** Weiss D, Rydland HT, Øversveen E, Jensen MR, Solhaug S, Krokstad S. Innovative technologies and social inequalities in health: a scoping review of the literature. PloS one. 2018;13(4):e0195447; **8.** Dexcom. Reimbursement of Dexcom CGM Technology for Patients with Type 1 and Type 2 Insulin-Dependent Diabetes is Now Available in Germany. https://investors.dexcom.com/news/news-details/2016/Reimbursement-of-Dexcom-CGM-Technology-for-Patients-with-Type-1-and-Type-2-Insulin-Dependent-Diabetes-is-Now-Available-in-Germany/default.aspx?utm_source=chatgpt.com; **9.** Klonoff DC, Ahn D, Drincic A. Continuous glucose monitoring: a review of the technology and clinical use. Diabetes Research and Clinical Practice. 2017;133:178-192; **10.** Gavin JR, Bailey CJ. Real-World Studies Support Use of Continuous Glucose Monitoring in Type 1 and Type 2 Diabetes Independently of Treatment Regimen. Diabetes Technol Ther. Sep 2021;23(S3):S19-s27. doi:10.1089/dia.2021.0211; **11.** Zacks. Medtronic's (MDT) MiniMed 670G Gains German Reimbursement. https://www.nasdaq.com/articles/medtronics-mdt-minimed-670g-gains-german-reimbursement-2019-09-10; **12.** National Institute for Health and Care Excellence. Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes. https://www.nice.org.uk/guidance/ta943; **13.** Franceschi R, Mozzillo E, Di Candia F, et al. A systematic review on the impact of commercially available hybrid closed loop systems on psychological outcomes in youths with type 1 diabetes and their parents. Diabet Med. Sep 2023;40(9):e15099. doi:10.1111/dme.15099; **14.** Jadoenathmisier KD, Gardarsdottir H, Mol PG, Pasmooij AM. Insights from the European Medicines Agency on digital health technology derived endpoints. Drug Discovery Today. 2025:104388; **15.** National Institute for Health and Care Excellence. HTA Lab projects. https://www.nice.org.uk/what-nice-does/our-research-work/hta-lab/hta-lab-projects; **16.** Rabbia M, Guridi Ormazabal M, Staunton H, et al. Stride Velocity 95th Centile Detects Decline in Ambulatory Function Over Shorter Intervals than the 6-Minute Walk Test or North Star Ambulatory Assessment in Duchenne Muscular Dystrophy. J Neuromuscul Dis. 2024;11(3):701-714. doi:10.3233/jnd-230188; **17.** Mikolaizak AS, Rochester L, Maetzler W, et al. Connecting real-world digital mobility assessment to clinical outcomes for regulatory and clinical endorsement–the Mobilise-D study protocol. PLOS ONE. 2022;17(10):e0269615. doi:10.1371/journal.pone.0269615; **18.** Micó-Amigo ME, Bonci T, Paraschiv-Ionescu A, et al. Assessing real-world gait with digital technology? Validation, insights and recommendations from the Mobilise-D consortium. Journal of NeuroEngineering and Rehabilitation. 2023/06/14 2023:20 (1):78. doi:10.1186/s12984-023-01198-5; **19.** European Medicines Agency. Letter of support for Mobilise-D digital mobility outcomes as monitoring biomarkers. https://www.ema.europa.eu/en/documents/other/letter-support-mobilise-d-digital-mobility-outcomes-monitoring-biomarkers-follow_en.pdf; **20.** Antikainen E, Njoum H, Kudelka J, et al. Assessing fatigue and sleep in chronic diseases using physiological signals from wearables: a pilot study. Frontiers in Physiology. 2022;13:968185; **21.** Johnson SA, Karas M, Burke KM, et al. Wearable device and smartphone data quantify ALS progression and may provide novel outcome measures. npj Digital Medicine. 2023/03/06 2023;6(1):34. doi:10.1038/s41746-023-00778-y; **22.** European Medicines Agency. ICH E9 statistical principles for clinical trials - Scientific guideline. https://www.ema.europa.eu/en/ich-e9-statistical-principles-clinical-trials-scientific-guideline; **23.** Johnson A, Yang F, Gollarahalli S, et al. Use of Mobile Health Apps and Wearable Technology to Assess Changes and Predict Pain During Treatment of Acute Pain in Sickle Cell Disease: Feasibility Study. JMIR Mhealth Uhealth. Dec 2 2019;7(12):e13671. doi:10.2196/13671; **24.** Vuong C, Urkarsh K, Stojancic R, et al. Use of consumer wearables to monitor and predict pain in patients with sickle cell disease. Frontiers in Digital Health. 2023;5:1285207; **25.** Downes E, Horigan A, Teixeria P. The transformation of health care for patients: Information and communication technology, digiceuticals, and digitally enabled care. Journal of the American Association of Nurse Practitioners. 2019;31(3):156-161. doi:10.1097/jxx.0000000000000109; **26.** Chandrasekaran R, Katthula V, Moustakas E. Patterns of Use and Key Predictors for the Use of Wearable Health Care Devices by US Adults: Insights from a National Survey. J Med Internet Res. Oct 16 2020;22(10):e22443. doi:10.2196/22443; **27.** Moore K, O'Shea E, Kenny L, et al. Older Adults' Experiences With Using Wearable Devices: Qualitative Systematic Review and Meta-synthesis. JMIR Mhealth Uhealth. Jun 3 2021;9(6):e23832. doi:10.2196/23832; **28.** Canali S, Schiaffonati V, Aliverti A. Challenges and recommendations for wearable devices in digital health: Data quality, interoperability, health equity, fairness. PLOS Digit Health. Oct 2022;1(10):e0000104. doi:10.1371/journal.pdig.0000104; **29.** Shcherbina A, Mattsson CM, Waggott D, et al. Accuracy in wrist-worn, sensor-based measurements of heart rate and energy expenditure in a diverse cohort. Journal of personalized medicine. 2017;7(2):3; **30.** Hines A, Jones L, Pizzetta C, et al. The Use of Wearable Devices as a Self-Help Approach to Wellness Promotion, Overcoming Health Disparities and Reducing Medical Distrust Among African Americans. J Public Health Issues Pract. 2023;7:220; **31.** Haute Autorité de Santé. Dispositifs médicaux numériques : la HAS explicite ses principes d'évaluation. https://www.has-sante.fr/jcms/p_3644653/fr/dispositifs-medicaux-numeriques-la-has-explicite-ses-principes-d-evaluation; **32.** Bundesinstitut für Arzneimittel und Medizinprodukte. DiGA: digital health applications. 2023; **33.** Martini N, Calabria S, Recchia G, Gussoni G, Ciani O. Digital therapeutics, HTA and reimbursement in Italy. Tendenze Nuove. 2021;4:117-26; **34.** Agencia Española de Medicamentos y Productos Sanitarios. Medical devices. https://www.aemps.gob.es/medical-devices/?lang=en#; **35.** National Institute for Health and Care Excellence. NICE health technology evaluations: the manual. 2025; **36.** National Health Service. MedTech funding mandate. https://www.supplychain.nhs.uk/suppliers/product-innovation/medtech-funding-mandate/#;