Informing the Product Development of an mHealth Solution for People with Multiple Sclerosis Through Early Health Technology Assessment

Giunti, Guido; Haverinen, Jari; Reponen, Jarmo

DOI
10.3233/SHTI220258

Publication date
2022

Published in
MEDINFO 2021

MEDINFO 2021: One World, One Health – Global Partnership for Digital Innovation
P. Otero et al. (Eds.)

doi:10.3233/SHTI220258

Informing the Product Development of an mHealth Solution for People with Multiple Sclerosis Through Early Health Technology Assessment

Guido Giunti[ab], Jari Haverinen[ac], Jarmo Reponen[ad]

[a] *University of Oulu, Oulu, Finland*
[b] *Delft University of Technology, Delft, The Netherlands*
[c] *Finnish Coordinating Centre for Health Technology Assessment (FinCCHTA), Oulu University Hospital, Oulu, Finland*
[d] *Medical Research Center Oulu (MRC Oulu), Oulu University Hospital and University of Oulu, Oulu, Finland*

Abstract

The potential of mHealth is enormous for chronic conditions, yet the integration of these technologies into the clinical infrastructures and healthcare pathways remains an ongoing challenge. Digi-HTA has been developed to support health technology assessment activities for novel digital healthcare technologies. The use of Early Health Technology Assessment (EHTA) can help product development. The present study describes the way in which EHTA can guide the development of a product to anticipate future needs and market access.

Keywords:

Telemedicine; Health Technology Assessment; Chronic Disease

Introduction

The potential of mHealth for chronic conditions is great, yet the integration of these technologies into healthcare pathways remains an ongoing challenge. There is a need for objective, transparent, and standards-based evaluation of digital health products[1].

Health technology assessment (HTA) typically becomes part of the decision-making processes at the stage when the products are already in production [2]. The application of HTA methods to earlier stages of technology development is known as Early Health Technology Assessment (EHTA) [3]. EHTA can reduce the uncertainty associated with decisions regarding a follow-up funding of a research project or a procurement decision related to the product [3]. Digi-HTA is an HTA framework focused on novel digital healthcare technologies such as mHealth, AI and robotics [4].

More Stamina is an mHealth app for multiple sclerosis (MS), created through a user-centered design approach in iterative development phases that is now part of an ongoing multicenter pilot study [6]. However, More Stamina is still in early prototype phase. The present study describes the way in which EHTA can guide the development of a product to anticipate future needs and market access.

Methods

More Stamina was used as an instrumental case study using Digi-HTA to provide insights as to how EHTA methods can be used to guide mHealth developers. In the Digi-HTA framework, experts score the product's key domains from -4 (weak or unknown) to 2 (sufficient) based on: effectiveness, cost, safety, usability and accessibility, and data security and protection. An overall score of 10 indicates that the product is recommended; 5-9 shows some considerations; <4 are critical issues.

Results

Product information

EHTA analysis: The solution targets people with MS for assisting in their fatigue self-management. The Technology Readiness Level (TRL) is between 4 and 5.

Actions suggested: Once TRL 6 is reached, medical device certification should commence. Intended purpose needs to be properly defined for product classification.

Costs

EHTA analysis: No cost-benefit analysis yet.

Actions suggested: Business models and value chain analysis need be done. Estimates about initial and maintenance costs for end-users, healthcare professionals and other stakeholders should be explored at this phase.

Effectiveness

EHTA analysis: More Stamina is currently being piloted for usability and feasibility.

Actions suggested: More evidence is needed on clinical benefits to end-users and other stakeholders.

Safety

EHTA analysis: No potential risks, possible side effects, or other undesirable effects have been detected.

Actions suggested: Pre and post market surveillance strategies should be in place to detect risks, side effects, or other undesirable effects. Risk analysis and mitigation actions need to take place and be periodically revised.

Data security and protection

EHTA analysis: Steps have been taken to de-identify and anonymize gathered data. Users have the option to request and delete the stored data.

Actions suggested: Data management plans need to be continuously revised. It is recommended to establish and document processes that ensure adequate data security and data protection like periodic systems monitoring, regular software updates and security testing.

Usability and accessibility

EHTA analysis: People with MS are subject to visual impairment, UI/UX were designed with usability in mind.

Actions suggested: Improving overall usability should be iterative. An accessibility statement should be available.

Interoperability

EHTA analysis: The platform connects with Google Fit services as well with the OpenWeatherMap API.

Actions suggested: Implement standardized interfaces and test in a sandbox environment if available.

Technical stability

EHTA analysis: More Stamina has an automated deployment and versioning process. A developer console allows access to extensive logs and error tracking.

Actions suggested: Dedicated testers and automated unit testing is advised to improve debugging processes.

Artificial intelligence

EHTA analysis: More Stamina uses machine learning algorithms to provide personalized recommendations.

Actions suggested: Metrics regarding the accuracy, precision and limits of the algorithms should be provided.

More Stamina Revised Roadmap

Figure 1 – More Stamina's Digi-HTA scoring.

Figure 1 shows an overview of the current and projected scoring. A case-control methodology will be used to assess health outcomes. Resources will be directed for designing a post market surveillance strategy. Iterative UX/UI evaluations will be conducted. HL7 interfaces will connect with the Oulu University Hospital's Test Lab and ESKO system. AI transparency will be improved.

Conclusions

The use of Digi-HTA for EHTA helped adapt More Stamina's roadmap to meet requirements. Further exploration of EHTA impact on overall compliance and healthcare integration is needed.

Acknowledgements

The present work was funded by Business Finland. The development of Digi-HTA was part of Oulu DigiHealth Knowledge Hub funded by the Regional Council of Northern Ostrobothnia.

References

[1] S.C. Mathews, M.J. McShea, C.L. Hanley, A. Ravitz, A.B. Labrique, and A.B. Cohen, Digital health: a path to validation, *Npj Digit. Med.* **2** (2019) 38. doi:10.1038/s41746-019-0111-3.

[2] V. Smith, R. Warty, A. Nair, S. Krishnan, J.A. Sursas, F. Da Silva Costa, B. Vollenhoven, and E.M. Wallace, Defining the clinician's role in early health technology assessment during medical device innovation - A systematic review, *BMC Health Serv. Res.* **19** (2019) 1–14. doi:10.1186/s12913-019-4305-9.

[3] M.J. IJzerman, and L.M.G. Steuten, Early Assessment of Medical Technologies to Inform Product Development and Market Access, *Appl. Health Econ. Health Policy*. **9** (2011) 331–347. doi:10.2165/11593380-000000000-00000.

[4] J. Haverinen, N. Keränen, P. Falkenbach, A. Maijala, T. Kolehmainen, and J. Reponen, Digi-HTA: Health technology assessment framework for digital healthcare services, *Finnish J. EHealth EWelfare*. **11** (2019) 326–341. doi:10.23996/fjhw.82538.

[5] M. Marziniak, G. Brichetto, P. Feys, U. Meyding-Lamadé, K. Vernon, and S.G. Meuth, The Use of Digital and Remote Communication Technologies as a Tool for Multiple Sclerosis Management: Narrative Review, *JMIR Rehabil. Assist. Technol.* **5** (2018) e5. doi:10.2196/rehab.7805.

[6] G. Giunti, O. Rivera-Romero, J. Kool, J. Bansi, J.L. Sevillano, A. Granja-Dominguez, G. Izquierdo-Ayuso, and D. Giunta, Evaluation of More Stamina, a Mobile App for Fatigue Management in Persons with Multiple Sclerosis: Protocol for a Feasibility, Acceptability, and Usability Study, *JMIR Res. Protoc.* **9** (2020) 1–11. doi:10.2196/18196.

Address for correspondence

Guido Giunti MD PhD, guido.giunti@oulu.fi