A metadata-driven tool to determine the robustness of digital health technologies assessments for Parkinson's disease leveraging the voice of the patient

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Objective:

To develop a decision tool for assessing the robustness of digital health technology (DHT)-based measures in Parkinson's disease (PD) using a patient-centric approach.

Background:

The Development of effective therapeutics in PD is hampered by the lack of drug development tools that adequately capture this phenotypically heterogeneous disease over time. DHT-based assessments are being explored for drug development, but despite the numerous ongoing efforts, tools to assess the robustness of DHTs that measure clinically meaningful aspects of PD are lacking. The robustness of a DHT-based assessment is defined as the extent to which supporting research exists for an assessment of a symptom using a given technology, and its implementation in proof-of-concept studies and clinical trials.

Methods:

Information was collected for the voice of the patient (VoP), clinical outcome assessments (COAs), and studies using DHTs to assess PD features. For the VoP, 38 abstracts were identified and reviewed for information on aspects of the disease that are important to patients and their caregivers. In addition, to link COAs being utilized in PD to the VoP, 172 COAs were identified from 22 publications from the Movement Disorder Society (MDS) taskforce assessing rating scales. Lastly, 51 studies utilizing DHTs in PD were identified and reviewed to create a digital data inventory (DDI). Metadata from each source domain was extracted for analysis to inform decision criteria in the framework.

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Results:

A decision framework was developed by incorporating information from the three source domains—VoP, COA, and DDI—into a metadata evidence-based decision tree to assess the robustness of DHT-based measures for a specific PD drug development context. Broadly, the decision tree uses the VoP, COA, and DDI meta-analysis to 1) rank the importance of stage-specific symptoms and select the relevant ones for the assessments (Figure 1) 2) identify gaps in existing COAs that assess those symptoms; and 3) analyze the robustness of DHT to fill such gaps. Figure 2 shows the level of evidentiary support present to make the DHT assessment robust.

Figure 1. Criteria and stages used in the information flow for identifying signs and symptoms important to patients.

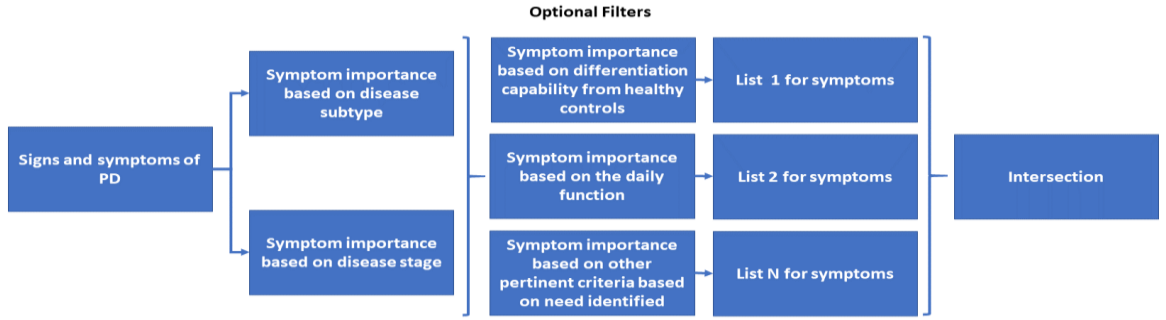
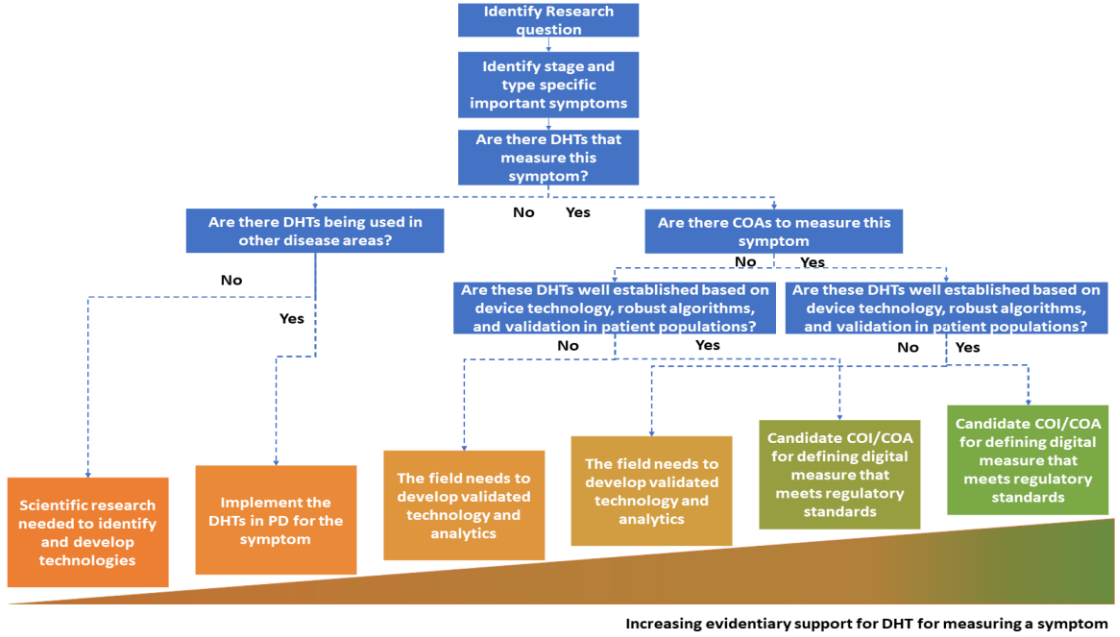


Figure 2. Overview of the information flow and filter criteria that constitute the decision tool for assessing the robustness of DHT by assessing available evidentiary support



Conclusions:

A patient-centric approach is critical to inform the application of DHT use in PD drug development. The decision tool presented here provides a basis to link clinically meaningful aspects of PD to existing DHTs, thereby identifying DHTs for PD drug development that would be robust, require more research to improve their robustness or, need to be developed and implemented in PD.

Next Steps:

The next steps will be to generate a report for

1. The meta-analysis carried out to identifying inputs and decision criteria at various stages
2. Use of inputs and decision criteria to develop a detailed workflow for the decision tool

Reference:

[1] The abstract was orally presented at the 15th International Conference on Alzheimer's and Parkinson's Diseases on March 14, 2021 and will not be published..

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