Identifying concepts of physical activity which are clinically meaningful to patients and care providers: A systematic review of qualitative studies

Jake Centra[1], Jie Ren[2], Candice Taguibao[1], Jennifer C. Goldsack[1], on behalf of the DATAcc by DiMe Physical Activity Project Team[1]

1. The Digital Medicine Society - Boston (United States); 2. Merck & Co., Inc. - New Jersey (United States)

DATAcc
Digital Health Measurement Collaborative Community
by DiMe
CORE MEASURES *of* PHYSICAL ACTIVITY
Digital Measures Development

Background

- Physical activity (PA) is an essential component of health, with impairments of PA linked to higher risk of falls, reduced quality of life, and increased likelihood of chronic disease and premature death.[1,2,3,4]
- The Food and Drug Administration (FDA) developed patient-focused drug development (PFDD) guidances to ensure clinical outcomes are underpinned by aspects of health that are meaningful to patients.[5]
- Digital health technology (DHT) derived measures provide opportunities to capture physical activity in meaningful real life contexts, with more granularity to support informed clinical decision making.[6,7]
- Providing clarity on common core concepts of physical activity will provide a valuable pathway forward for innovative, patient-centered measurement of PA.

Objective

Project aim

Identify aspects of PA that are meaningful to patients to inform a core set of digital measures of PA

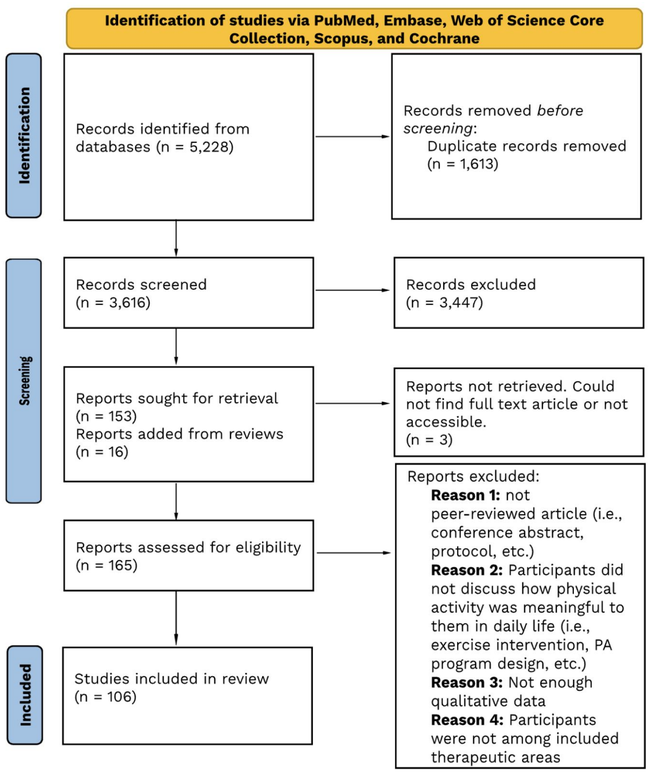
Research questions

1. What concepts of PA are globally meaningful to patients and their health care providers?
2. How is each concept meaningful to patients and their health care providers, and under what contexts?

Methods

Systematic literature review (SLR)

1. Therapeutic area selection:
   - Parkinson's Disease (PD), Multiple Sclerosis (MS), Chronic Obstructive Pulmonary Disease (COPD), cancer, Duchenne's Muscular Dystrophy (DMD), Chronic Heart Failure (CHF), Sickle Cell Disease, osteoarthritis (OA), and sarcopenia.
2. Search strategy and study selection:

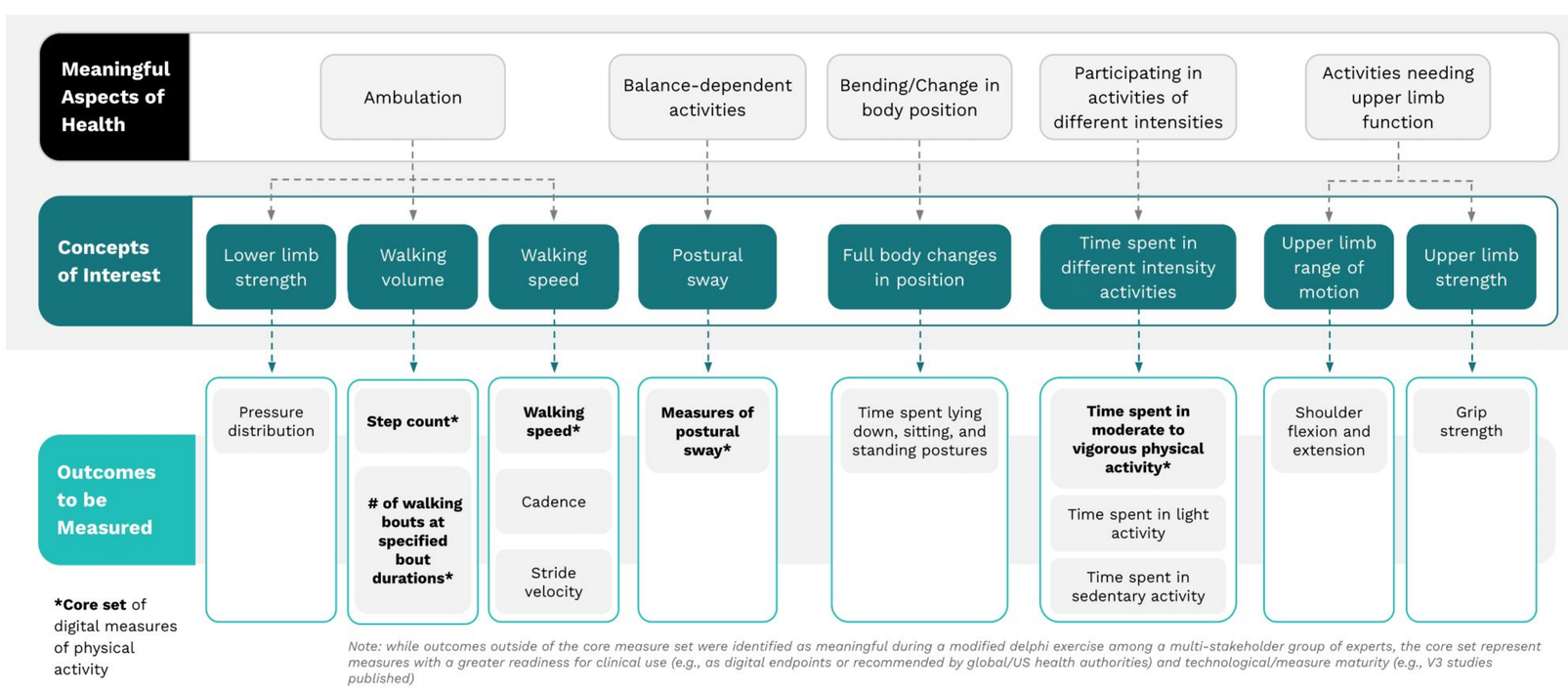


3. Data extraction and synthesis:
   - Data was extracted by the two reviewers using a standard framework based on the UK National Institute for Health and Clinical Excellence (NICE) universal template.[8]
   - Findings included quotes, PA concepts of interest (COIs), themes related to context of concepts, authors' opinions, and other phenomena of interest relevant to the review questions.
   - "Line by line" coding of the results/findings section of included articles was undertaken using a thematic synthesis approach outlined by Thomas and Harden[9]. Descriptive themes were then generated, followed by identification of analytical themes organized into meaningful aspects of health (MAH) and contextual factors influencing the health COIs.

Results

Conceptual model for digital measurement of physical activity

The aspects of PA that patients described as most meaningful were related to the way impairments restricted their participation in self-care, domestic, and community & leisure activities. Representative quotes for each meaningful aspects of health (MAH) are provided from the patient perspective for a variety of therapeutic areas, though the provider perspective was also considered.



Ambulation	Balance dependent activities	Bending / Change in body position	Participating in activities of different intensities	Activities needing upper limb function
▹ "I used to go walking three times a week. My friend across the street asked me to go walking. So I told her that morning, "I can't walk as fast as you. Just go on. Don't wait on me." Then I got to a place where I couldn't walk anymore." (CHF patient)[10] ▹ "Quality of life, for me, is being able to walk on the beach and climbing stairs effortlessly and being able to walk" (OA patient)[11]	▹ "No, but now you know that your balance is affected. But it's not like I'm reluctant to do things because my balance is so bad. I do not avoid going into town and such, I mean I have a target when I do things. I am goal oriented." (PD patient)[12]	▹ "It would be important to be able to get up on your own and be able to move around in your home / car, or at least to be able to turn around on your own in bed." (DMD patient)[13]	▹ "There are a lot of things I've had to give up, you know. Well playing football. ...Can't walk along the corridor, never mind run. And as I said, when you go out with your wife and she's carrying two big bags and your walking along there with nothing, people must say to themselves "oh look at that man his wife carrying the bags and he's got nothing", but at the end of the day they dinnae ken [don't know] what's happening inside you!" (COPD patient)[14]	▹ "I also notice that my arms get really, really tired and—well, all of me gets tired, like I can't wash my hair without taking breaks because my arms get tired." (MS patient)[15] ▹ "I don't volunteer in the library anymore because I can't pick up heavy books and put them up on the shelf." (Sarcopenia patient)[16]

Discussion

- **Identifying MAHs from patient and provider perspectives in this SLR was the essential first step in developing our conceptual model for the measurement of PA.**
- COIs and outcomes were later added as part of a broader evidence generation process, including a **modified delphi approach** with subject matter experts for selecting our **core digital measures of PA:**
  - Step count, number of walking bouts at specified bout durations, walking speed, measures of postural sway, and time spent in MVPA.
- Core measures of PA were selected based on maturity of DHTs on the market, the evidence available for the PA measures captured by those DHTs, and potential clinical research and practice applications.
- DATAcc by DiMe's **Library of Digital Measurement Products** was also developed to catalog verification, analytical validation, and clinical validation (V3) studies[17] for technologies measuring PA outcomes.
- Ontologies and stakeholder-specific resources were generated to align the field with key definitions and use cases that are necessary to promote standardization and drive the adoption of digital PA measures.
- **The research and resources enable the development and selection of meaningful digital measures of PA in clinical trials and clinical care, moving the industry forward by reducing duplicative efforts and speeding the path to discoveries that will benefit the patients we aim to serve.**

References

1. Fritz & Lusardi. J Geriatr Phys Ther. 2009;32: 2.
2. Brodie et al. IEEE Trans Biomed Eng. 2015;62.
3. HHS. Physical Activity Guidelines for Americans, 2nd edition. 2018.
4. WHO. WHO guidelines on physical activity and sedentary behaviour. 25 Nov 2020.
5. FDA. Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments. Draft Guidance. June 2022.
6. Shimoni et al. Eurohealth. 2019.
7. WHO. Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment. 2016.
8. NICE. Appendix H Quality appraisal checklist – qualitative studies | Methods for the development of NICE public health guidance (third edition). 2012.
9. Thomas & Harden. BMC Med Res Methodol. 2008;8: 1–10.
10. Hopp et al. Soc Work Health Care. 2012;51.
11. Holmenlund et al. Health Qual Life Outcomes. 2021;19.
12. Johansson et al. Phys Ther. 2019;99.
13. Schuster et al. Therapeutic Innovation & Regulatory Science. 2022;56: 572–586.
14. Dobbels et al. Eur Respir J. 2014;44: 1223–1233.
15. Matza et al. Mult Scler Relat Disord. 2019;27: 139–146.
16. Evans et al. J Am Med Dir Assoc. 2011;12.
17. Goldsack et al. NPJ digital medicine. 2020;3.

Join us for industry day!

We appreciate the support of our collaborators and experts (Salma Ajraoui, Christina Daskalopoulou, Astrid Horstman, Alberto Conde, Aikaterini Themis, Kieran Reid, Alan Hamilton, John Wagner, Elena Izmailova, Jessilyn Dunn).