



# Striding Past the 6MWT: Complementing Physical Activity Assessment with a Consensus Set of Digital Clinical Measures

Tuesday, June 27 at 11am-12pm ET



**Dr. Alan Hamilton**

Senior Director of Research  
**COPD Foundation**

*Panel Moderator*



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Program Lead, PA Project  
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# Agenda

- **Welcome and Background of Project**
- Opening Remarks from Bray Patrick-Lake (FDA, CDRH)
- Presentation of Early Findings
- Multi-Stakeholder Panel
- Q&A

# But first, housekeeping

- Please note: **today's session is being recorded**
  - Slides and recording will be available on DiMe's webinar page after the session
- To ask a question for discussion during live Q&A, please
  - **Type your question** into the chat box

*\*\*\* Participants are not permitted to transcribe this webinar, violators will be removed from the session.*

## Our purpose

DiMe is a global non-profit dedicated to advancing the **ethical, effective, equitable, and safe** use of digital medicine to redefine healthcare and improve lives.

... and sit at the intersection of two communities





## CORE MEASURES *of* PHYSICAL ACTIVITY

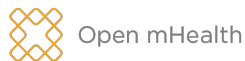


*Digital Measures Development*

### Project Partners



Duke | BIG IDEAS LAB



### Digital Solutions Collaborators

Activinsights



HumanFirst



koneksa



parexel.



# Digital Measures Conceptual Model

## CRITICAL PATIENT INPUT:

### Meaningful Aspect of Health

Aspect of a disease that a patient (a) does not want to become worse, (b) wants to improve, or (c) wants to prevent

- *May be shared across some conditions and diseases*

### Concept of Interest

Simplified or narrowed element that can be practically measured

- *Patients may have different symptoms*
- *Symptoms may vary over time*
- *Symptom relevance may vary over time*

### Outcome to be measured

Specific measurable characteristics

- *Measures may be relevant to multiple symptoms*
- *Assess technical specifications of sensor and whether it is suitable for measuring this outcome in this population*



What do you wish that you could do, but your condition prevents you from doing it?

What part of your life is most frustratingly impacted by your condition?

What are the symptoms that most impact your ability to do these activities?

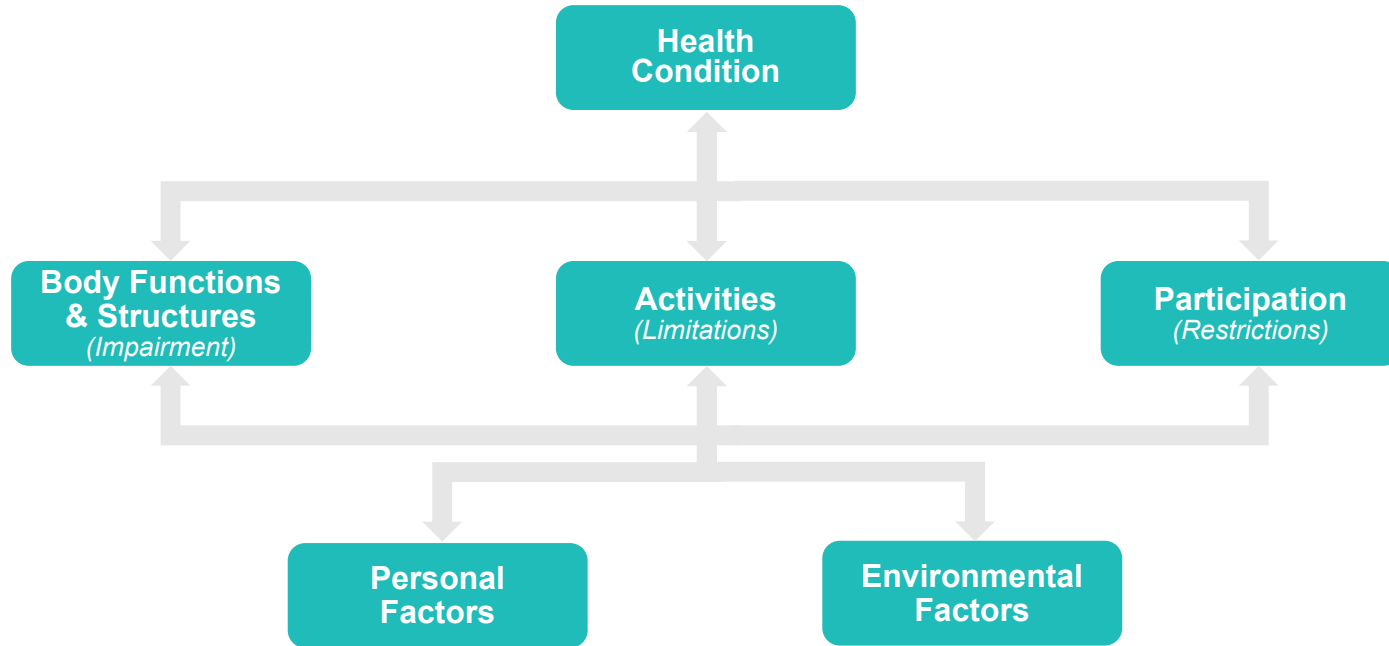
Do these measures make sense to you?

\*Manta, C., Patrick-Lake, B., & Goldsack, J. C. (2020). Digital measures that matter to patients: a framework to guide the selection and development of digital measures of health. *Digital Biomarkers*, 4(3), 69-77.

\*Walton, M. K. et al. (2015). Clinical outcome assessments: conceptual foundation—report of the ISPOR clinical outcomes assessment—emerging good practices for outcomes research task force. *Value in Health*, 18(6), 741-752.

\*FDA Patient Focused Drug Development Guidances

# International Classification of Functional, Disability and Contextual Factors (ICF) Framework



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**Physical Activity (PA).** "Any bodily movements produced by skeletal muscles that result in energy expenditure." (Caspersen et al., 1985)

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# Putting Patient Perspectives in the Centre: Systematic Review of Qualitative Studies

**Protocol Available**



## Review Questions

### Primary Question

What concepts of physical activity are globally meaningful to patients and their health care providers?

### Secondary Question

How is each concept meaningful to patients and their health care providers, and under what contexts?

## Approach



**Multi-stakeholder workshop** to explore gaps, enablers, and pathways forward for physical activity



Develop and register **protocol** for systematic review, defining search strategy and eligibility criteria



Conduct **screening and full-text review** of eligible articles



**Qualitative coding and thematic analysis** to identify meaningful aspects of health and concepts of interest

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This search includes perspectives from people living with Parkinson's disease, multiple sclerosis, COPD, cancer, Duchenne's muscular dystrophy, chronic heart failure, osteoarthritis, and sarcopenia

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# Topline Findings



## Meaningful Aspects of Health

The aspects of physical activity that patients describe as most meaningful were related to how impairments restricted participation in activities of daily living (ICF: community & leisure, self-care and domestic activities). These were summarized into meaningful aspects of health as activities dependent on **ambulation, upper extremity function, and bending or changing body positions.**



## Concepts of Interest for Physical Activity

For each meaningful aspect of health, we identified measurable health concepts based on the qualitative evidence.



## Contextual Factors

Participants also described health concepts of PA as being influenced by disease symptoms, functional impairments (based on ICF framework), personal and environmental factors.



## Independence

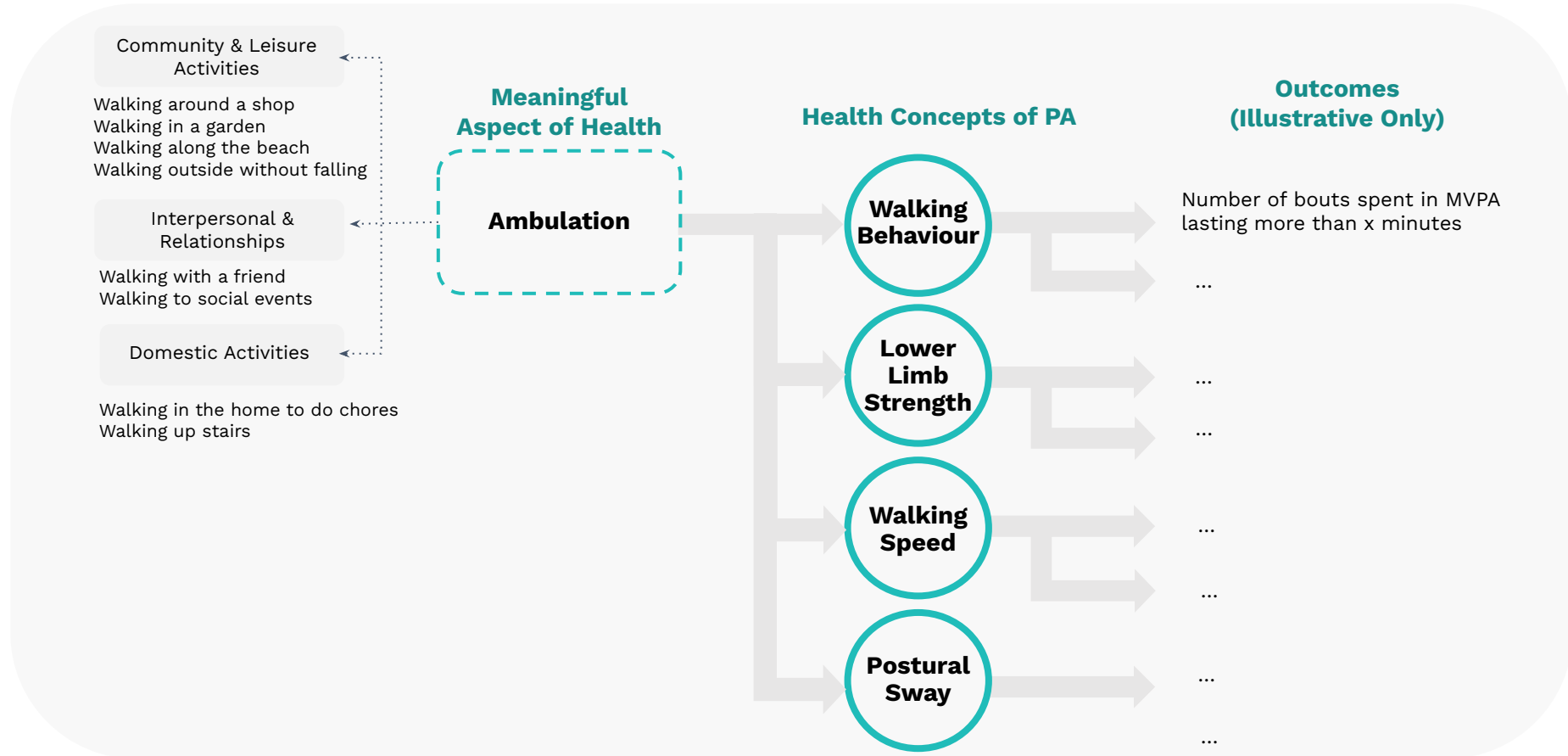
**Independence** emerged as a theme across therapeutic areas and health concepts: patients wanted to improve or maintain function to freely take care of themselves, do chores, and move around in the community (instrumental ADLs).



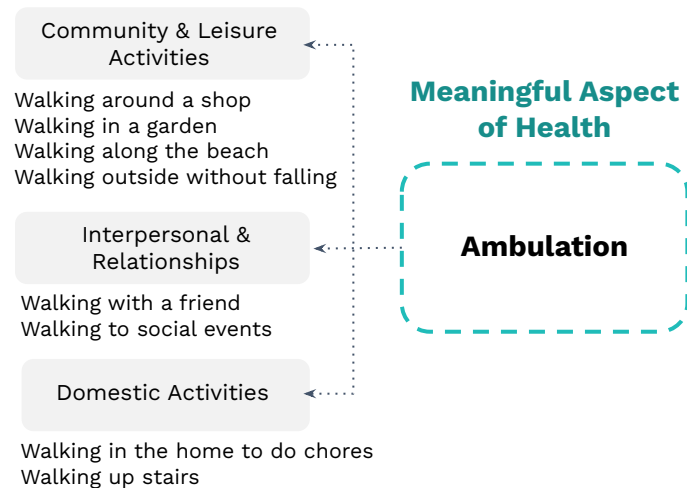
## Quality of Life

Quality of life was also linked to patients' physical ability to engage in **pleasurable or enjoyable activities**, such as socializing, playing sports, and volunteering in the community (ADL).

# Illustrative Conceptual Model



# Conceptual Model



Patients described ambulation as an important aspect of physical activity, specifically to walk outside leisurely, walk to the store, and participate in social and relationship-building activities. Patients also expressed how impaired balance while walking and fear of falling prevented them from participating in social activities.

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)

**"I can't go shopping.** Now that everything is online, I just shop online. [...] **Because, I can't walk** for most periods of time." (Patient 14, 64 years) "I try to grocery shop. [...] there are so many times when I actually have to go sit down, because I can't make it all the way through the shop." (Patient 26, 49 years) (CHF patients)

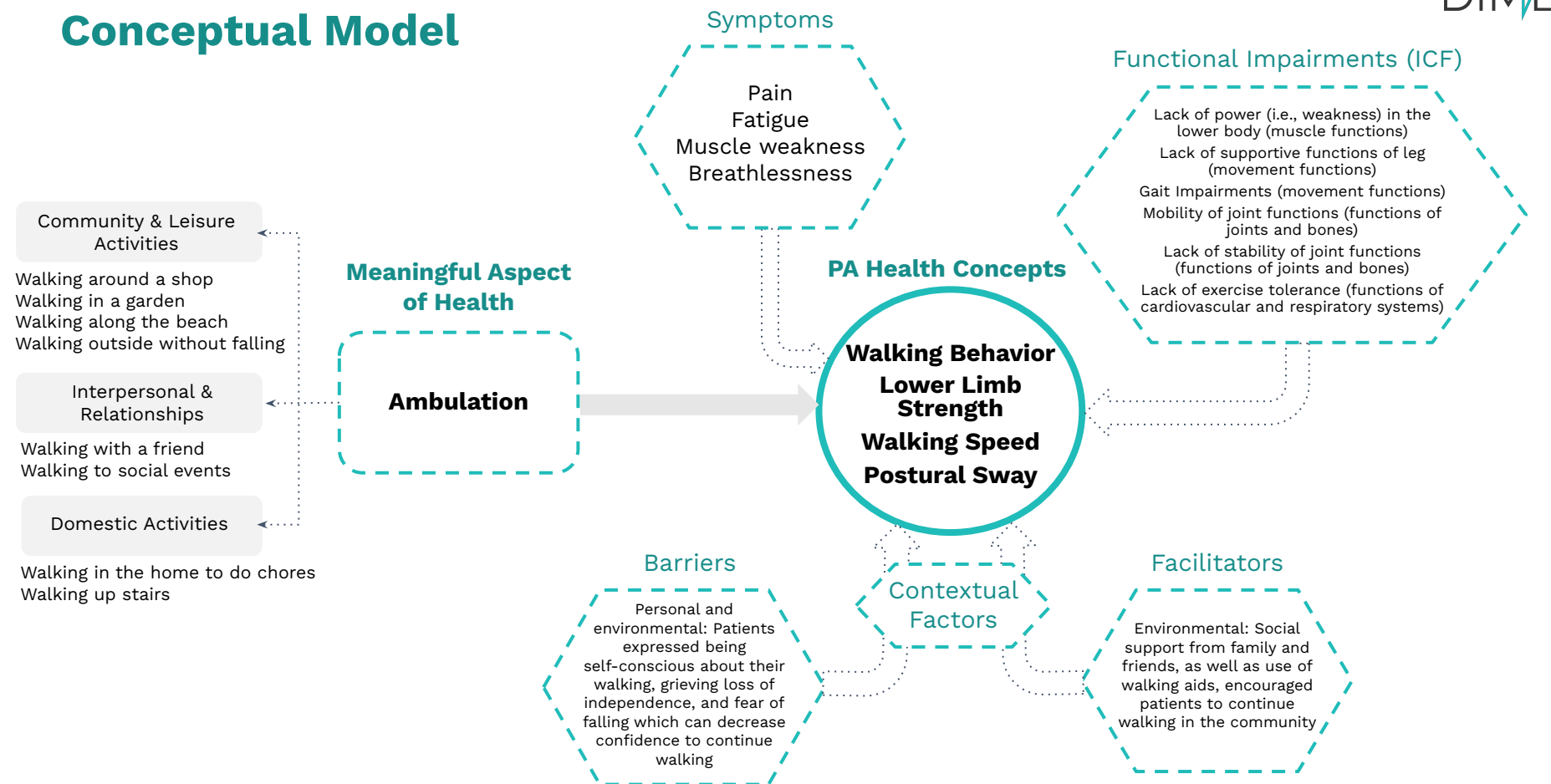
"I, you know, **could not leave, go places because I couldn't walk well** and I had to **cancel some things** that I was going to do and I **felt very self-conscious about my barely walking** and just ended up staying home. I was **concerned about tripping, falling.**" (MS patient)

Being **deprived of social activities**, such as entertainment, hobbies, traveling, sports and participating in parties had a negative impact on the QOL of some of the participants; **"That I cannot walk and exercise much, has made me feel that I lack something"** ... "It makes me upset that I am always at home"...A 69- year-old man said: **"I wish I could travel** and do sightseeing more frequently, but I cannot" (CHF patients)

**"Quality of life, for me, is being able to walk on the beach** and climbing stairs effortlessly and being able to walk" (OA patient)

**Having an impaired balance capacity** often meant having to refrain from, or adapt, one's activities. No longer being able to perform things one previously could, led to a reduced sense of freedom and independence. .... **"You lose the freedom to move in the way that you would like to.** That must be the biggest freedom that you have, to be able to go where you like." (PD patient)

# Conceptual Model





# Conceptual Model

Impairments in arm mobility and strength were related to limitations in instrumental activities of daily living, including ability to care for oneself and do household chores. Patients also had to give up participation in sports and activities of leisure requiring arm function.

## Meaningful Aspect of Health

### Upper Extremity Function

#### Community & Leisure Activities

Playing upper body dependent sports  
Volunteering  
Lifting a paintbrush

#### Self-Care Activities

Lifting a hairbrush  
Washing one's hair  
Lifting eating utensils

#### Domestic Activities

Putting dishes in the cupboard  
Carrying a laundry basket  
Pushing around a vacuum

"I just **wanted to be able to get more of a range with this arm** because it meant the **end of my golf**—if I couldn't swing it all the way up." ... "Obviously, I **gave up playing tennis**. I gave up playing volleyball. I can't do any of my upper extremity sports. I still ski; I just don't pole-plant anymore." (Breast cancer patient)

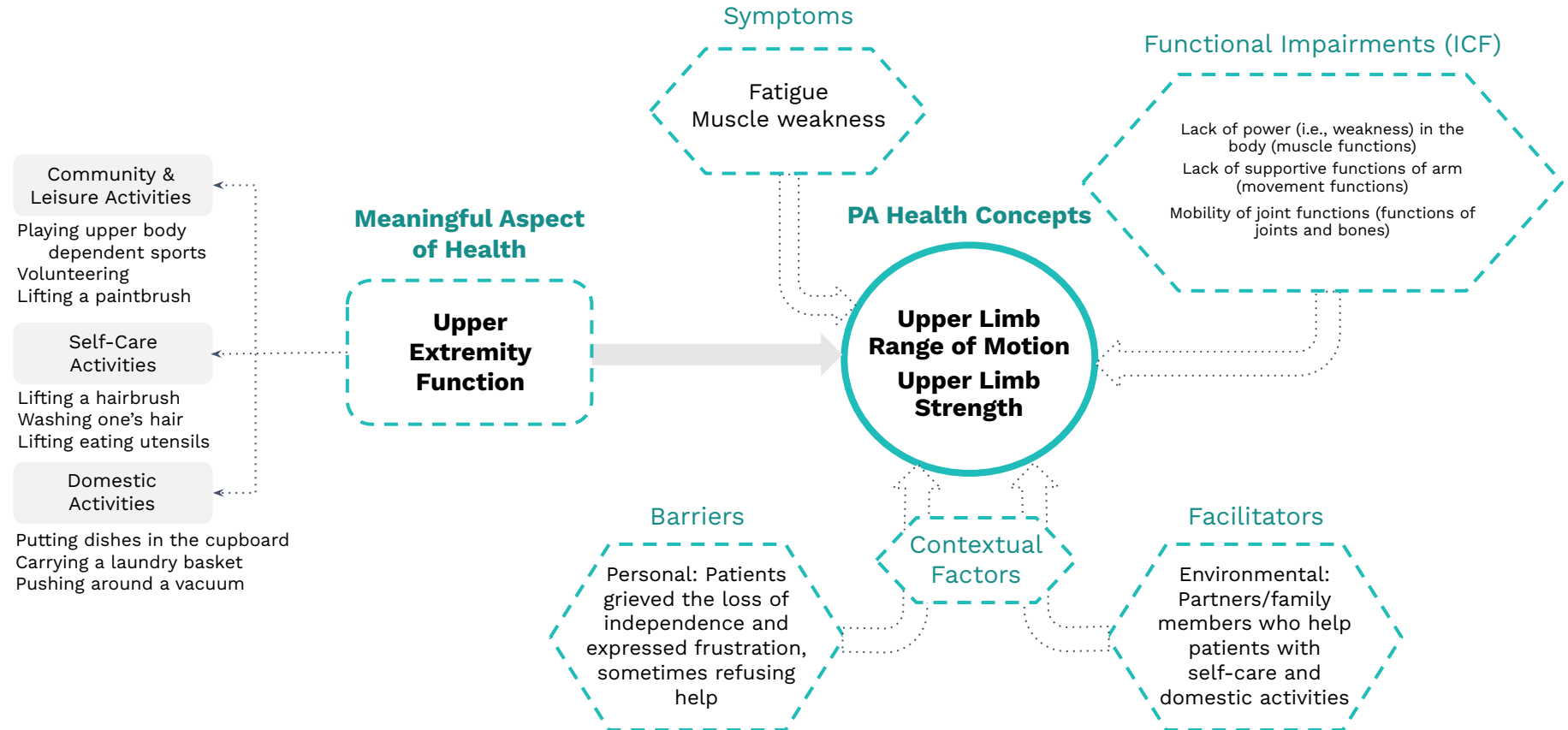
Upper limb impairments were described as loss of mobility and/or strength in arms, hands, and/or fingers. Some responses provided explicit examples of how loss of arm, hand, or finger function impacted day-to-day life. "**The arm weakness is a real problem for me because I cannot reach for a lot of things that I would like to reach**. It can get **frustrating** to have somebody help me every time I need to get something." (DMD patient)

"I **don't volunteer in the library anymore because I can't pick up heavy books and put them up on the shelf**. Well, I dabbled in needlework and things like that. If I work too long, then my hands cramp up." (Sarcopenia patient)

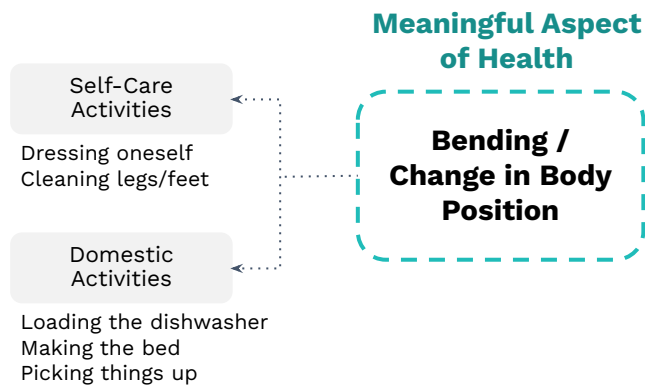
"I also notice that **my arms get really, really tired** and—well, all of me gets tired, like I **can't wash my hair** without taking breaks because **my arms get tired**." (MS patient)

Most participants reported reduced strength, particularly in the arms "My physical strength is gone. I used to be able to lift pretty heavy stuff, and now, it's like, **lifting a hairbrush... I'm so tired that it's... difficult**." (breast cancer patient)

# Conceptual Model



# Conceptual Model



Impairments related to bending and changing body positions limited patients' ability to independently complete instrumental activities of daily living, including self-care and domestic activities

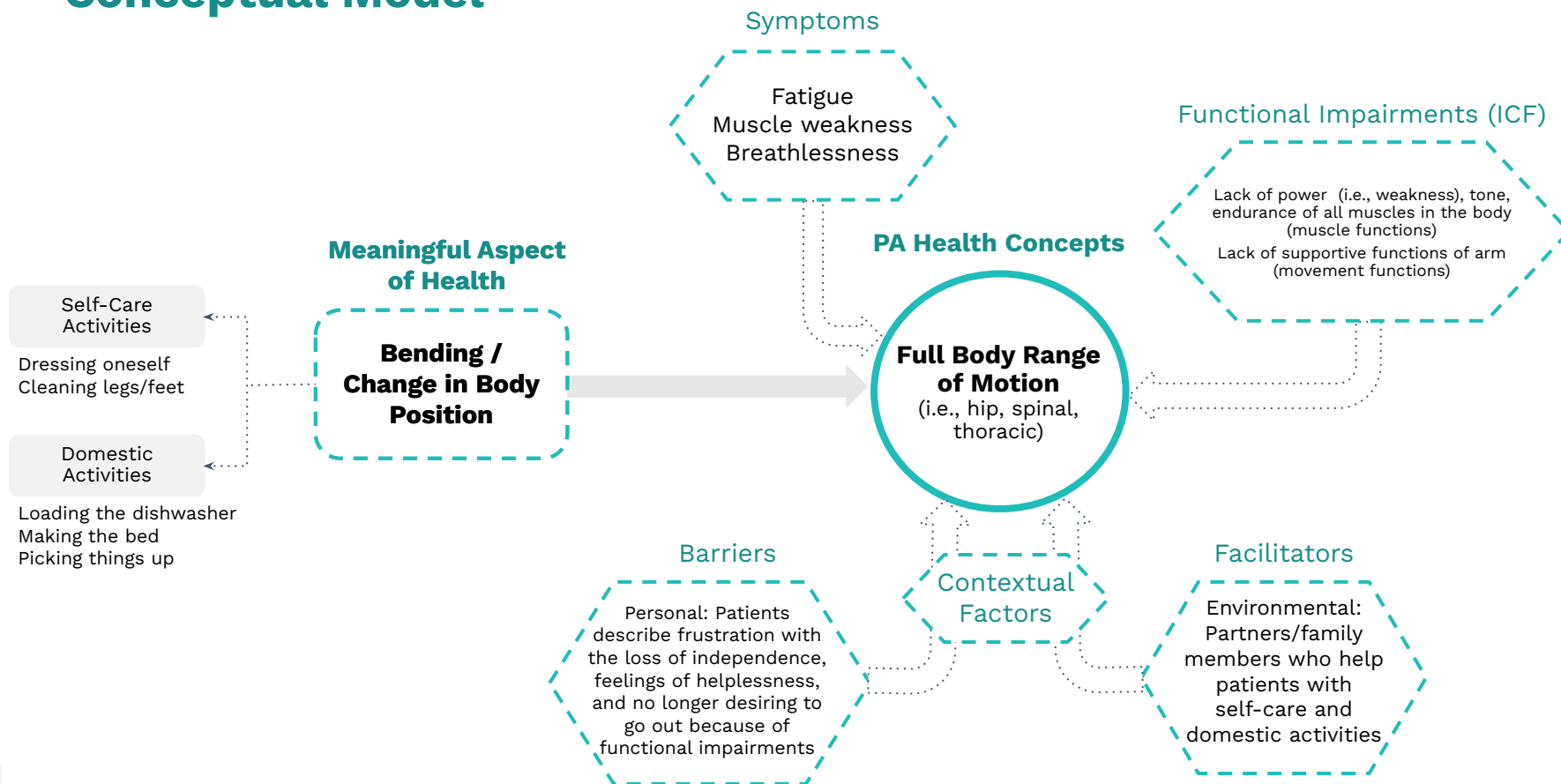
**“[I fear] getting down [to] where I can’t live by myself.”**... “The vacuum cleaner de-winded me; sweeping is just as bad. **I can’t bend over** ... I can’t raise my arms up or I lose my air, so I’m just really a helpless person.” (COPD patient)

**“To grab dishes out of the dishwasher, if I keep on doing the bending and standing motion (that’s hard).”**  
Participants further explained that reduced ability to squat limits picking up items such as groceries, and the combination of squatting and picking up items may result in balance issues. (Lung cancer patient)

Seemingly easy activities, like washing one’s hair (with arms lifted) or bending down to the floor, caused breathlessness and fatigue. **“It’s hard to bend over** like this [down toward the floor]; my entire body quite simply gives out ... and I get short of breath, and have **difficulties, when I bend over like this.**” (CHF patient)

“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)

# Conceptual Model



# CONSIDERATIONS

- We've identified evidence-based concepts of physical activity that are common across therapeutic areas, which will inform development of a core set of digital clinical measures later in the project. By defining those measures, we aim to provide the field with a starting point, but these measures will still need to be validated among specific patient populations based on context of use.
- We are mindful that these concepts can be influenced by the full patient experience, including a patient's disease progression or the effects of treatment.

# NEXT STEPS



Further data analysis and manuscript writing



Define a core set of digital clinical measures for physical activity



Conduct a subsequent systematic review to define ontologies of the measures



Continue to engage with the community to refine measures and resources

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# THANK YOU

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