Utilizing a modified Delphi approach to select digital measures of physical activity



CORE MEASURES of PHYSICAL ACTIVITY



Digital Measures Development

Core Set of Digital Measures of Physical Activity



Project Team Approach

888	Meaningful Aspects of Health	Systematic Review of Qualitative Studies Review questions: What concepts of physical activity (PA) are globally			
	Concepts of Interest (COIs)	meaningful to patients and their health care providers? How is each concept meaningful to patients and their health care providers, and under what contexts? (PROSPERO <u>CRD42023416708</u>)			
	Outcomes to be Measured	 Modified delphi approach to identify appropriate outcomes for PA Selected a core set of digital measures of PA, based on readiness for adoption, by reviewing: Maturity of technologies and measures related to PA concepts 			
	Core Set of Digital Measures of Physical Activity	 of interest. Digital measures of PA being used in <u>clinical trials as</u> <u>endpoints</u>. Global and US recommended physical activity measures for clinical care (<u>1,2</u>). 			

Modified Delphi Approach to Identify a Consensus List of Digital Measures





A review of the literature was conducted to propose initial digital measures of physical activity per concept of interest.



An electronic survey was sent to **subject matter experts (SMEs) in physical activity and digital measurement to vote on measures for inclusion** and provide evidence and reasoning behind their selection.



Anonymized survey results were **summarized and shared with the SMEs**. The **survey was revised** accordingly and **sent back to the SMEs for re-vote.**



The **survey rounds** and anonymized results dissemination continued **until a reasonable consensus was achieved** (i.e., similar voting patterns between rounds).



After no more rounds were necessary, there was a **live debrief workshop** to review measures selected and resolve remaining decisions related to inclusion/exclusion of measures.

Modified-Delphi Approach: Methods

Modified-Delphi Approach Timeline







Round 2 Survey Changes Based on Round 1 Suggestions

- 1. After suggestions to apply a tier to the measures, we changed option selection for each measure to:
 - a. "Yes, I would recommend as a primary measure"
 - b. "Yes, but recommended as a secondary/supplemental measure"
 - c. "No, I would not recommend"
 - d. "I need more information"
- For the COI "Walking Volume," based on survey 1 comments, we combined "Number of Walking Bouts" and "Bout Duration" from survey 1, to "Number of Walking Bouts at Defined Durations" in survey 2

Measures for Activity Intensity and Walking Volume

by Dit E

		Nb of Min in Moderate to Vigorous Physical Activity (MVPA)*	Step Count*	Nb Walking Bouts at Specified Duration*
Round 2	Recommended as Primary Measure	40%	53%	60%
	Recommended as Secondary/ Supplemental Measure	27%	40%	40%
	Not Recommended	33%	7%	0%
	More Info Needed	0%	0%	0%

Round 1		Nb of Min in MVPA	Step Count	Nb Walking Bouts	Walking Bout Duration
	Recommended	62%	69%	62%	54%
	Not Recommended	31%	31%	8%	8%
	Don't Know	8%	0%	31%	38%

Measures for Activity Intensity: Nb of Min Spent in MVPA



Reported Reasoning for Inclusion:

- Evidence-based, in line with the Physical Activity Guidelines recommendations, accommodates all populations in their PA and movement, will be in line with US federal regulation on interoperability and measure standardization.
- MVPA is a clinically relevant measure with known association with health outcomes across various therapeutic areas.
- This measure is consistent with both US and WHO PA Guidelines.
- In clinical trials, the disease and patient context would determine endpoint position (exploratory, primary or secondary endpoint).
- It is a validated measure with minimal clinically important differences (MCID) established for certain diseases.

Reported Considerations:

- Not all patients can participate in MVPA, so time spent in sedentary and light activity should also be captured.
- It's important to be mindful of relevance across disease conditions and sensitivity to change.

by Dime

Measures for Walking Volume: Step Count



Reported Reasoning for Inclusion:

- Easily applicable and indicative of general health.
- Applicable in many diseases, part of true activities of daily living (ADL) and important to functioning. Note: need to be mindful of people who use assistive devices.
- Step count is frequently used to quantify one's mobility and walking volume and has known association with clinical and health outcomes across various therapeutic areas.
- It is easy to collect and it's a versatile measure; it's been validated for its predictive value in a number of conditions, including as a predictor for hospitalizations.
- Not perfect (i.e., does not capture level of effort) but seems to be a good approximation

by Ditte

Measures for Walking Volume: Nb of **Walking Bouts at Specified Durations**





7.7%

Recommended 53.8%

Measures for Walking Speed

Don't Know



		Walking Speed*	Stride Velocity*	Cadence*
Recommen Primary Me	ided as easure	40%	29%	14%
Recommen 2 Secondary/ Supplemen Measure	nded as / ntal	40%	50%	71%
Not Recom	mended	0%	0%	14%
More Info N	Needed	20%	21%	0%
		Walking Speed*	Stride Velocity*	Cadence*
Recomme	nded	69%	54%	85%
d 1 Not Recon	nmended	8%	23%	8%

23%

* Indicates where 50% or more respondents selected the measure as either a primary or secondary/supplemental measure

23%

8%

Measures for Walking Speed: Walking Speed





Reported Reasoning for Inclusion:

- Clinically relevant; predicts morbidity, mortality, falls, cognitive impairment, and disability.
- Straightforward to measure.
- Easy to interpret.
- Captures intensity.

- Important measure, but variability in accuracy based on context (i.e., indoors vs outdoors) - need to ensure digital health technologies (DHTs) are verified/validated before use of measure (which is true for every measure).
- Need to be mindful of usability of DHTs in real world conditions.
- Very widely established metric, but may want to consider distinguishing between "usual" walking speed versus maximal walking speed.

Measures for Walking Speed: Stride Velocity





Reported Reasoning for Inclusion:

- Clinically relevant and can measure difference in mobility patient populations vs. healthy populations.
- Seems to be more specific than walking speed.
- SV95C is only digital measure qualified by a regulatory agency (i.e., Duchenne's Muscular Dystrophy by European Medicines Agency (EMA)).

- Not as "consumer friendly" or interpretable as walking speed.
- Seems specific to particular patient populations (children, patients with mobility impairments, rare disease patients, etc.).
- Although stride velocity can be highly relevant, capturing it in real-life settings across different contexts (e.g., outdoors) is technically less feasible (i.e., not so accurate) for longer term deployment with good user experience. Therefore, its applicability and utility can be limited.

Modified-Delphi Approach: Findings

Measures for Walking Speed: Cadence





Reported Reasoning for Inclusion:

- Useful measure to capture walking speed.
- Similar to walking speed but offers another perspective on ambulation, which could be more applicable in some populations; good insight into quality of ambulation.
- Can provide insight into shuffling patterns.
- Cadence can be technically feasible alternative for walking speed with better accuracy.
- Not as susceptible to measurement bias.

- Can be coupled with walking volume metrics (i.e., walking bout duration, number of walking bouts).
- Between stride velocity and walking speed, cadence may not not add anything more. Most people can easily understand walking speed, but may have a harder time understanding cadence as something different than speed.

Measures for Lower Limb (LL) Strength



		LL Muscle Activation	Ground Reaction Forces*	LL Muscle Force	Pressure Distribution*
Round 2	Recommended as Primary Measure	14%	14%	14%	23%
	Recommended as Secondary/ Supp'l Measure	21%	36%	29%	31%
	Not Recommended	29%	29%	29%	15%
	More Info Needed	36%	21%	29%	31%

		LL Muscle Activation	Ground Reaction Forces	LL Muscle Force	Pressure Distribution
Round 1	Recommended	23%	15%	15%	46%
	Not Recommended	15%	15%	15%	0%
	Don't Know	62%	69%	69%	54%

* Indicates where 50% or more respondents selected the measure as either a primary or secondary/supplemental measure

Measures for Lower Limb Strength: LL Muscle Activation



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Reported Reasoning for Inclusion:

- Implications for physical functioning and physical therapy.
- In certain populations or with certain diseases, this measure could prove to be the most direct measurement of a person's capacity such as with motor neuron diseases or other diseases that make walking difficult but can contract the muscle to some extent.

- Not necessarily a measure of muscle strength.
- May be more of a lab measure.
- Not very sensitive to conditions like Parkinson's Disease (PD), aging, or sarcopenia.
- Lower limb strength is essential to ambulation, but it is not yet clear on how sensitive any of these measures are when capturing change over time.
- Still difficult to measure repeatedly; interpretably also remains a challenge.
- More information needed.

Measures for Lower Limb Strength: Ground Reaction Forces



Reported Reasoning for Inclusion:

• Clinically relevant for specific populations it's studied in (eg., PD and other gait-limited patients).

Reported Considerations:

- Not consumer friendly.
- May be more of a lab measure.
- Data collection is highly dependent on instrumentation used to collect the data and may be limited to in-clinic tests.

Measures for Lower Limb Strength: LL Muscle Force



Reported Reasoning for Inclusion:

- Has implications for physical functioning and physical therapy.
- Well-established, relatively easy to measure and interpret.

Reported Considerations:

- Would need to be measured independently for each of the large muscles, which is impractical (other than in research settings).
- Estimating muscle force with inertial measurement units (IMU) has been recently explored in feasibility studies, but its broad applicability in different patient populations with abnormal gait or in elderly patients still needs warrant.
- Not enough is currently known.

by DHE

Measures for Lower Limb Strength: Ground Reaction Forces



Reported Reasoning for Inclusion:

• Clinically relevant for specific populations it's studied in (eg., PD and other gait-limited patients).

Reported Considerations:

- Not consumer friendly.
- May be more of a lab measure.
- Data collection is highly dependent on instrumentation used to collect the data and may be limited to in-clinic tests.

Measures for Lower Limb Strength: Pressure Distribution



Reported Reasoning for Inclusion:

- Helpful to understand weakness/frailty.
- Slightly less useful than ground reaction forces but more established as a biomarker/parameter.
- Easy to measure.
- Might have some biofeedback utility to individuals, may help to guide patients in balance training and stance.
- May have the widest applicability across populations.
- Can be a more direct measure than gait and indicates imbalances or postural issues that can be present for some indications.

Reported Considerations:

- Also related to other concepts of interests (eg., pressure ulcers related to diabetic neuropathies).
- Currently, mostly a lab measure.

Measures for **Postural Sway**



by DHE

		Postural Sway Amplitude*	Postural Sway Distance*	Postural Sway Velocity	Postural Sway Area	Postural Jerk
	Recommended as Primary Measure	50%	21%	21%	8%	14%
Round 2	Recommended as Secondary/ Supp'l Measure	21%	29%	7%	23%	21%
	Not Recommended	7%	14%	21%	23%	14%
	More Info Needed	21%	36%	50%	46%	50%

		Postural Sway Amplitude	Postural Sway Distance	Postural Sway Velocity	Postural Sway Area	Postural Jerk
	Recommended	58%	31%	23%	8%	46%
Round 1	Not Recommended	0%	0%	0%	0%	0%
	Don't Know	42%	69%	77%	92%	54%

Measures for Postural Sway: Postural Sway Amplitude



Reported Reasoning for Inclusion:

- Very important for assessment in neurological conditions, fall risk, etc., but not as important for population-level PA measure.
- Good measure to capture postural stability (depending on the modality of sensor data collection (e.g., wrist), additional information may be needed (e.g., hands are not holding an object)).
- One of the most commonly interpretable metrics for postural sway.
- Clinical relevant across various diseases.
- Versatile measure.

Reported Considerations:

• Need to ensure method for collection is not burdensome.

by DHE

Measures for Postural Sway: Postural Sway Distance



Reported Reasoning for Inclusion:

- Clinically relevant across various diseases.
- One of the most commonly interpretable metrics for postural sway.
- Versatile measure.

Reported Considerations:

- Need to ensure method for collection is not burdensome.
- Need to ensure accuracy of measure.
- Good measure to capture postural stability (depending on the modality of sensor data collection (e.g., wrist), additional information may be needed (e.g., hands are not holding an object)); either this measure or postural amplitude may be chosen.

Measures for Postural Sway: Postural Sway Velocity



Reported Reasoning for Inclusion:

• Can be useful to detect fall, which is a major clinical event for some therapeutic areas (e.g., movement disorders) and overall aging.

Reported Considerations:

- Need to consider whether this measure provides more/less sensitivity compared to others mentioned.
- Measure needs more clinical validation.

Measures for Postural Sway: Postural Sway Area





Reported Reasoning for Inclusion:

• Can be useful to detect fall, which is a major clinical event for some therapeutic areas (e.g., movement disorders) and overall aging.

Reported Considerations:

- Need to consider whether this measure provides more/less sensitivity compared to others mentioned.
- Measure needs more clinical validation.

Measures for Postural Sway: **Postural Jerk**





Reported Reasoning for Inclusion:

- Clinically relevant and useful for assessing efficacy across a number of diseases or conditions and for post-rehabilitation.
- Can be useful to understand one's stability during motion (e.g., walking stability).

Measures for Upper Limb Range of Motion (ROM)

		Elbow Flexion and Extension	Shoulder Abduction and Adduction	Shoulder Flexion and Extension*
Round 2	Recommended as Primary Measure	29%	29%	36%
	Recommended as Secondary/ Supp'l Measure	14%	14%	21%
	Not Recommended	29%	21%	14%
	More Info Needed	29%	36%	29%

		Elbow Flexion and Extension	Shoulder Abduction and Adduction	Shoulder Flexion and Extension
Round 1	Recommended	42%	50%	50%
	Not Recommended	17%	8%	8%
	Don't Know	42%	42%	42%

Measures for Upper Limb ROM: Elbow Flexion & Extension





Reported Reasoning for Inclusion:

- A good objective measure of a common injury area, easily adapted to real-world use.
- Included for comprehensive understanding of upper body motion.

- May not be as relevant for healthy populations.
- The shoulder area (rather than elbow) is primary to upper mobility, but this also depends on the indication.
- Currently, while technologies exist for measurement outside of clinical settings, mostly an in-clinic measure in practice.

Measures for Upper Limb ROM: Shoulder Abduction & Adduction



Reported Reasoning for Inclusion:

- A good objective measure of a common injury area, • easily adapted to real-world use.
- Applicable to various aging and disease populations. •
- Included for comprehensive understanding of upper • body motion.
- Shoulder limitations are much more common and can • have a greater impact on ADLs and balance.

Reported Considerations:

- Can be considered in addition to other shoulder • measures.
- Currently, while technologies exist for measurement • outside of clinical settings, mostly an in-clinic measure in practice.

Measures for Upper Limb ROM: Shoulder Flexion & Extension





Reported Reasoning for Inclusion:

- A good objective measure of a common injury area, easily adapted to real-world use.
- Applicable to various aging and disease populations.
- Included for comprehensive understanding of upper body motion.
- Shoulder limitations are much more common and can have a greater impact on ADLs and balance.

- Can be considered in addition to other shoulder measures.
- Currently, while technologies exist for measurement outside of clinical settings, mostly an in-clinic measure in practice.

Measures for Upper Limb Strength



		Grip Strength*	Muscle Force during Contraction*	Muscle Activation
Round 2	Recommended as Primary Measure	36%	29%	0%
	Recommended as Secondary/ Supp'l Measure	43%	29%	29%
	Not Recommended	7%	7%	29%
	More Info Needed	14%	36%	43%

		Grip Strength	Muscle Force during Contraction	Muscle Activation
Round 1	Recommended	69%	46%	8%
	Not Recommended	0%	15%	8%
	Don't Know	31%	38%	85%

Measures for Upper Limb Strength: Grip Strength



Reported Reasoning for Inclusion:

- Easily measured and includes functional assessment.
- Very evidence-based measure for muscular strength.
- Grip strength is a proven prognostic indicator and should be used as a screening tool for muscular strength.
- Simple to understand, easy to perform, predictive of mortality, and related to frailty and other health outcomes.

Reported Considerations:

- Provides useful but somewhat limited information.
- Currently, while technologies exist for measurement outside of clinical settings, mostly an in-clinic measure in practice.

Modified-Delphi Approach: Findings

Measures for Upper Limb Strength: Muscle Force during Contraction





Reported Reasoning for Inclusion:

Has relevance across diseases and treatments.

- Need to understand more about the utility of this measure.
- Currently, while technologies exist for measurement outside of clinical settings, mostly an in-clinic measure in practice.

Measures for Upper Limb Strength: Muscle Activation



Reported Reasoning for Inclusion:

- Potentially able to measure muscle development.
- Potentially helpful measure for physical therapy.

- Not clear how this measure could offer more information than muscle strength.
- Difficult to accurately measure, which limits interpretation.
- If used, should be coupled with a muscle force measurement.
- Currently, while technologies exist for measurement outside of clinical settings, mostly an in-clinic measure in practice.



Measures for **Hip ROM**



Round 2		Hip Flexion & Extension*	Hip Abduction & Adduction	Hip Internal & External Rotation
	Recommended as Primary Measure	43%	31%	15%
	Recommended as Secondary/ Supp'l Measure	7%	15%	31%
	Not Recommended	29%	31%	23%
	More Info Needed	21%	23%	31%

Round 1		Hip Flexion & Extension	Hip Abduction & Adduction	Hip Internal & External Rotation
	Recommended	36%	27%	27%
	Not Recommended	0%	9%	9%
	Don't Know	64%	64%	64%

* Indicates where 50% or more respondents selected the measure as either a primary or secondary/supplemental measure

Measures for Hip ROM: Hip Flexion & Extension





Reported Reasoning for Inclusion:

• Clinical relevance to various populations (e.g., arthritis, aging, etc.).

Reported Considerations:

• Can potentially combine the three hip measures for hip-related conditions.

Measures for Hip ROM: Hip Abduction & Adduction



Reported Reasoning for Inclusion:

• Clinical relevance to various populations (e.g., arthritis, aging, etc.).

Reported Considerations:

• Can potentially combine the three hip measures for hip-related conditions.

by DHE

Measures for Hip ROM: Hip Internal/External Rotation



Reported Reasoning for Inclusion:

• Clinical relevance to various populations (e.g., arthritis, aging, etc.).

Reported Considerations:

• Can potentially combine the three hip measures for hip-related conditions.

Measures for **Spinal ROM**



Round 2		Spinal Flexion & Extension	Spinal Lateral Bending	Spinal Rotation	Time Spent in Lying Down, Sitting, & Standing Postures*
	Recommended as Primary Measure	31%	15%	15%	54%
	Recommended as Secondary/ Supp'l Measure	8%	23%	23%	23%
	Not Recommended	31%	23%	23%	8%
	More Info Needed	31%	38%	38%	15%

Round 1		Spinal Flexion & Extension	Spinal Lateral Bending	Spinal Rotation
	Recommended	27%	27%	27%
	Not Recommended	0%	0%	0%
	Don't Know	73%	73%	73%

* Indicates where 50% or more respondents selected the measure as either a primary or secondary/supplemental measure

Measures for Spinal ROM: Spinal Flexion & Extension



Reported Reasoning for Inclusion:

• Clinical relevance to various populations (e.g., arthritis, aging, spinal cord injury, etc.).

Reported Considerations:

• The sensitivity to change and ability to measure could render this measure not usable.



Measures for Spinal ROM: Spinal Lateral Bending





Reported Reasoning for Inclusion:

• Clinical relevance to various populations (e.g., arthritis, aging, spinal cord injury, etc.).

- May need more context/data for decision-making.
- Can potentially combine spinal measures for spine-related conditions.

Measures for Spinal ROM: Spinal Rotation





Reported Reasoning for Inclusion:

• Clinical relevance to various populations (e.g., arthritis, aging, spinal cord injury, etc.).

- May need more context/data for decision-making.
- Can potentially combine spinal measures for spine-related conditions.

Measures for Spinal ROM: Time Spent in Lying Down, Sitting, and Standing Postures



Reported Reasoning for Inclusion:

- May be more reflective of the meaningful aspect of health, "change in body positions."
- Helpful to understand "energy" and muscular fatigue; may be confounded by cognitive fatigue, mental health, other conditions that lead to fatigue.
- Seems a reasonable measure of body motion, with limitations for people in wheelchairs, for example; also seems to be most easily measurable.

Reported Considerations:

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May need more context/data for decision-making.

by DHE

Recommendations for Measures of Physical Activity



Recommendations for Measures of Physical Activity

Concepts of Interest	Measures which proceeded to next round (informed by delphi results & debrief workshop selection decisions)
Walking Volume	Step Count Nb Walking Bouts at Specified Duration
Activities	Time Spent in MVPA Time Spent in Light and Sedentary PA
Walking Speed	Walking Speed Stride Velocity Cadence
Lower Limb Strength	Ground Reaction Forces Pressure Distribution
Postural Sway	Postural Sway Amplitude Postural Sway Distance Postural Sway Area
Upper Limb ROM	Shoulder Flexion/Extension
Upper Limb Strength	Grip Strength Muscle Force during Contraction
Hip ROM	Hip Flexion and Extension
Spinal ROM	Time Spent in Lying Down, Sitting, and Standing Postures



Next steps to identifying the core digital measures of physical activity:

- Determine the level of evidence (verification, analytical validation, and clinical validation) associated with each digital measure, measured in real world settings.
- Determine digital measures which are about to be captured by emerging digital health technologies on the market.
- Identify a narrowed-down core measure set based on the "readiness" for their use in clinical research and care.

Recommendations for Measures of **Physical Activity**

Concepts of Interest	Measures where there is not enough evidence to make a recommendation	
Walking Volume		
Activities		
Walking Speed		
Lower Limb Strength	LL Muscle Activation LL Muscle Force	
Postural Sway	Postural Sway Velocity Postural Sway Area Postural Jerk	
Upper Limb ROM	Elbow Flexion and Extension Shoulder Abduction and Adduction	
Upper Limb Strength	Upper Limb Muscle Activation	
Hip ROM	Hip Abduction and Adduction Hip Rotation	
Spinal ROM	Spinal Flexion and Extension Spinal Lateral Bending Spinal Rotation	



by DHE

- There is not enough evidence to support these measures as sensor-derived, real-world measures.
- Recommendation for more innovation and research to support measures related to these concepts of interest.

Identifying the Core Set of Digital Measures of Physical Activity: Method

Selecting the Core Set of Digital Measures of Physical Activity





The core set of digital measures of physical activity (PA) were narrowed down based on their readiness for widespread adoption in clinical research and care. To inform selection, we reviewed:

<u>Maturity of technologies and PA measures</u>, including the level of recent verification, analytical validation, and clinical validation studies conducted for measurement in real-world settings.

Digital measures of PA being used in <u>clinical trials as endpoints</u>.

Globally- and US-recommended physical activity measures for clinical care (1,2).

Based on this evidence, the core set of digital measures of physical activity selected were: (1) Number of Walking Bouts at Specified Durations, (2) Step Count, (3) Walking Speed, (4) Time Spent in Moderate to Vigorous Physical Activity, and (5) Postural Sway.

Conceptual Model: Digital Measurement of Physical Activity

CORE MEASURES of PHYSICAL ACTIVITY





