Mobile App for Physical Function Measurement

Requirements Document

**Background**

Physical function and physical activity are important measures in cancer care. *Performance status* is a term for a clinical measure in which providers assign scores based on patients’ ability to be active and participate fully in usual activities. Performance status has been used as a very important measure for many years in oncology because it is so predictive and prognostic for health outcomes, and this measure is used to make clinical decisions and to design and conduct clinical trials. Patients can also rate their own “performance status” with a single item measure. However, a better patient-reported outcome for this concept, instead of a single-item performance status measure, may be a report of physical function using a standardized set of questions. Physical function appears to be the health concept that best represents performance status. Patient-reported physical function is an important part of quality of life, and patient-reported physical function predicts clinical events that are important to clinicians and patients. However, patient report is only one way to obtain information from patients that is related to physical function. Standardized tasks (for example, a walk test) or passively acquired wearable sensor data (for example, continuous heart rate, heart rate variability, and activity counts) contribute information about physical function that is complementary to responses to survey questions.

Physical activity is related to physical function, but it is distinct. Individuals with better physical function are usually more physically active, but physical activity can be used as a measure that also reflects voluntary exercise. There are now many studies that show the benefit of physical activity and exercise in improving cancer outcomes.

Accurate, home-based measures of physical function and physical activity in cancer patients would be very useful to patients, clinicians, researchers, payers, and others. Potential uses of such measures include: screening patients for clinical trials, especially those that have decentralized, pragmatic and/or hybrid models; clinical decision making (e.g. selection of cancer treatments or intensities); determining who is at high risk of adverse health outcomes from disease or treatment; monitoring adverse effects of disease or treatment over time; provision of health coaching interventions for patients; and supportive care delivery.

Many consumer-grade wearable activity trackers (e.g. Fitbit, Garmin, others) have associated mobile apps that visually display daily activity for device owners. However, these consumer grade wearable activity trackers are not optimally designed to measure physical activity or physical function in patients with cancer. Limitations of available consumer devices and apps for the purpose of physical activity and function measurement in cancer patients include:

* **a)** not many devices that include additional physiologic metrics (e.g. heart rate, heart rate variability) *and* are “fit for purpose” for health care settings (e.g. meeting standards for data quality and device usability);
* **b)** limited incorporation of other these other metrics (e.g. heart rate, heart rate variability) into algorithms and visualizations;
* **c)** uneven visualization of activity-related data with particular relevance to cancer care (e.g sedentary time, moderate/vigorous physical activity may be important in cancer care applications, but these displays are lower priority in consumer applications);
* **d)** absence of data that comes from *patient report* relevant to activity and function (e.g. responses to standardized questionnaires of physical activity or physical function, and responses to standardized questionnaires of contextual factors such as disease- or treatment-related symptoms),
* **e)** absence of data that comes from *patient task performance* relevant to activity and function (e.g. results of home-based standardized physical function tasks, such as a walk test or stair climb test);
* **f)** absence of reports based on these data for clinicians or researchers, to help with decision making;
* **g)** lack of integration with health care delivery (e.g. electronic health records).

Because of the limitations of available consumer grade devices and mobile apps, we believe that there is a need for a new mobile app that measures physical activity and physical function for use in cancer care, with potential application to other health care settings.

**Goals**

Our *short-term* goal is to **develop a mobile app that measures and displays multi-source data** (passively collected sensor data, self-reported data, standardized physical task performance) **relevant to physical function in patients with cance**r. In the short term, we also wish to identify one or more wearable sensors that are fit for purpose and can transmit data to the newly designed app.

Our *long-term* goal is to integrate multi-source data collected by the app into a **composite, multi-source measure of physical function**. In the long term, we also wish to integrate the composite physical function measure that we will build, and components of the composite measure, into health care applications relevant to different stakeholders, such as electronic health records, clinical trials websites, administrative dashboards, and others.

**Desired Components**

1. iOS and Android smartphone compatibility
2. Integration with a wearable that collects comprehensive physiologic data appropriate for health care settings - such as one that includes a PPG sensor to accurately capture heart rate variability and other metrics besides activity counts
3. Customizable displays and reports of sensor data relevant to patients, clinicians, and others;
4. Ability to obtain standardized surveys (e.g. physical function, symptoms) on a scheduled, as needed, or triggered basis, with customized displays and reports of the self-reported data;
5. Ability to obtain standardized, self-administered or remotely-administered physical performance tests (e.g. walk test, stair climb test) on a scheduled or as needed basis, with customized displays and reports of the performance test data;
6. Ability to display customizable reports to other users (e.g. clinicians, coaches, administrators, others) on individual patient or population (i.e. dashboard) basis
7. Ability to connect and embed within other websites or applications by API
8. Ability to aggregate and send data for analysis

**Desired Content Modules**

Consents

Opportunity to provide informed consent for:

* Data collection and storage under an approved research protocol.
* Re-contact for future studies
* Permission for automated access of medical records via participating EHRs

Dashboard

Buttons and visualizations for subsets of data contained within the modules below

Patient Profile

A series of questions that give information about the participant to help provide context for physical activity and physical function data. Responses to these questions can also be visualized or reported for other purposes (patient engagement, clinical care, trial planning, etc).

* Demographics
* Disease
* Treatment characteristics
* Income
* Employment
* Zip code
* Health behaviors
* Health related quality of life
  + Physical
  + Emotional
  + Social
  + Other

Sensor-acquired Data

Data acquisition and visualization from a chosen wearable with a PPG sensor. Visualization features:

* Overall activity
* Sedentary time
* Moderate/Vigorous activity
* Integration of other metrics, including heart rate and heart rate variability, into “health” scores

Patient-reported Data

Data acquisition and visualization from patient-reported physical function data. Ability to complete these assessments in a scheduled or as-needed way.

Task-based Data

Data acquisition and visualization from guided or remotely administered physical performance tasks. Ability to complete these assessments in a scheduled or as-needed way. Tasks could include a standardized walk test, timed up and go test, stair climb test, or others

Contextual Data

Data acquisition and visualization of other contextual data related to physical function and activity. Ability to complete this assessments in a scheduled, as-needed, or triggered way

* Symptoms
* Other major events (injury, hospitalization, emergency room visit, treatment change, disease change)

**To Be Determined**

* Identification of best wearable sensor for integration
* Physical function questionnaire - identification of instrument
* Physical performance tasks - what is already available through other apps or projects for remote administration and can be incorporated
* Activity data - what displays are already available through other sensors and can be used as guides
* Contextual data - symptom questionnaire - identification of instrument - and other contextual data items
* Baseline profile - identification of questions
* Displays of data and report formatting