Cover page

Title: Standing Balance as the Fifth Vital Sign in Clinical Setting

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Does use of a quantitative balance measurement device influence clinical decision making?

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I. Objective

This 18-month prospective, observational study involving real world data will determine if the use of a standing scale that delivers a quantitative measure of standing balance along with weight (balance + weight) in place of a scale that only delivers weight (weight only) influences clinical decision making by health care practitioners in the ambulatory outpatient setting. Providers will be randomized to receive the balance+weight scale or weight-only scale for 9 months, then to crossover and receive the other for 9 months. The primary outcome measures are (1) providers' self-reported perceptions of whether the balance measurement influences their clinical decision making and (2) the rate of performing falls risk assessments or referring to a specialist for evaluation and treatment based on aggregate billing data. The secondary outcome measure is qualitative interviews with practitioners regarding their perceptions on the utility and barriers to using the device.

II. Background and Rationale

Falls prevention efforts are poised to reduce the significant impact of this high-risk injury, but a critical component for success of a falls prevention program is measurement of risk for falls. While effective measurement is available, barriers prevent implementation due to the need for primary care providers to undertake assessment within the limited time available in the short patient visit.

Falls have significant health and financial costs to society, hence identifying fall risk is a National Institute of Aging priority. Falls are a significant source of early morbidity and mortality in the aging population [1], accounting for more than 50% of Canadian injury-related hospitalizations in seniors over the age of 65 [2]. A fall can result in a long hospital stay, perhaps for the rest of an aged and frail person's life, as well as increased dependence, loss of autonomy, cognitive impairment, and depression. Beyond these effects, the financial burden of falls also places a major strain on the health care system in the USA and other countries, as an injurious fall has been predicted to cost about $35,000 in 2018 dollars and the overall cost of falls to the US health care system is predicted to be about $50 billion. Many factors may indirectly lead to increased fall risk, from medications to fatigue to orthostatic hypotension, but the proximal cause of a fall is a loss of balance, meaning an inability to detect (sensory) or respond to (motor) a change in body posture that occurs due to an external or self- imposed perturbation such that gravity pulls the body downward to the floor or a lower level. As such, the National Institute of Aging has placed a strategic priority on:

> "Measuring ambulation and assessing factors contributing to problems in and/or related to ambulation and mobility through development of improved instrumentation for biomechanical assessment of ambulation and falls; development of assessments for balance, sway, gait, or postural control [emphasis added] to identify stable and unstable patterns of movement during activities of daily living; or development of improved quantitative methods of assessing postural perturbations relevant to activities of daily living. [emphasis added]" (Omnibus Solicitation of NIH, CDC and FDA for SBIR and STTR Applications, PHS 2018-2, p. 21) [3].

While assessments of postural control exist, degraded postural control often escapes early identification and intervention. The American and British Geriatrics Societies (AGS/BGS) have released a clinical practice guideline and algorithm to identify individuals with poor postural control and elevated risk of falls [4], as has the CDC with its STEADI program [5], but primary care providers (PCP's) have been slow to put these guidelines into practice. Many PCP's report that they do not know how to conduct a fall risk assessment or do not have enough knowledge about fall prevention [6,7]. Moreover, many PCP's feel overloaded when the average visitor has several health problems to address in a very short encounter (10 minutes or less). As a result, PCP's may only be asking vulnerable patients the important questions that begin the AGS/BGS or STEADI algorithms 25% of the time, leaving falls risk unscreened as much as 75% of the time [8]. Moreover, both of these algorithms depend on either patient's subjective recall, which could be unreliable especially in the case of a very gradual decline, or

a direct observation of unsteadiness by the PCP or their staff, which may not be reasonable in a very busy clinic setting. These problems further underscore the priority of developing methods of assessing postural perturbations that do not depend on recall and that minimally impact clinical efficiency.

Quantitative postural control assessment has been around in research settings and has been commercially available for decades, but has not entered widespread clinical practice. Over 50 years ago, Murray et al. presented an approach for quantitatively measuring center of pressure [9], and since then many research studies have demonstrated the use of this and successively more sophisticated equipment in identifying the sensory contributions to postural control [10], predicting falls [11], and quantifying changes in postural control over time [12]. This quantitative approach is more sensitive than self-report [12] or clinical balance testing [13] and can be done in under a minute [14]. However, the approach has not entered the clinic due in large part to perceived barriers that the equipment is too expensive [13], technically too challenging to use in the clinic [13], or difficult to interpret.

The contribution of the proposed project is expected to be an evaluation of whether a quantitative postural control assessment that aligns with workflow in the clinical environment influences clinical decision making. This contribution will be significant because every patient could receive objective, quantitative postural control assessment at every office visit. Repeated measurements of postural control would create a better chance for early identification and intervention to manage balance deficits and reduce falls. It would also provide information for both providers and patients that a significant change (for better or worse) in balance status has occurred, whether due to a change in medication, neurological degeneration, an exercise intervention, or a lifestyle change.

III. Procedures

1. Research Design

   This prospective, observational study uses real world data to understand whether the addition of commercially-available quantitative balance measurement informs clinical decision making by physician and advanced practice providers. A randomized crossover design will be used: Providers who enroll in the study will be randomized to receive either a scale that measures weight only, or a scale that measures balance and weight for nine months. After nine months, the scales will be switched so that every provider has the other type of scale for nine months. The first primary outcome is self-report from providers to determine if they believe the additional balance information influences their clinical decision-making within their normal clinical practice. The second primary outcome is aggregate coding and billing information for the provider over each 9-month period, to determine if diagnosis, procedure, and referral patterns by each provider differ between the two types of scale. The third, secondary outcome will be the analysis of focus-group discussions with participants to better understand their experiences in using the Balance+Weight device within their normal clinical practice.

2. Sample

   The desired population includes practitioners who regularly diagnose and treat patients in ambulatory outpatient settings. We anticipate recruiting 20 clinical practices in which there are physicians, nurse practitioners or physician assistants. In the case where multiple practitioners at a single clinical site choose to participate, the clinic site is treated as a single participant with the primary outcome measures lumped together for all participating practitioners.

3. Measurement / Instrumentation

   Immediate feedback from provider on clinical decision-making process. After each patient encounter in which the provider chooses to use the balance measurement feature of the Balance+Weight device based on their own clinical decision-making process, the provider who made a clinical decision regarding balance or falls risk is asked to press a button on a small kiosk that we will provide which logs their agreement with the statement, “The balance measurement influenced my clinical decision making with this patient.”

Data pull of clinic-level diagnosis and referral data. At or just after the crossover between sites has occurred, study personnel in conjunction with the IT departments at participating clinics will pull de-identified aggregated clinic diagnosis and referral data for all participating providers. We will pull this data from both the 9 months of participation in the study, as well as the same 9 month-period in the previous year before the study began as a historical control. The data will be pulled again upon completion of the study for the second 9-month period. The data will include all patients that the provider saw.

Focus group discussions after completion of RCT. Following conclusion of the trial, we will engage all participants in focus groups regarding their experience using the Balance+Weight device.

4. Detailed study procedures

Recruitment of clinics to participate in study. Study personnel will recruit clinics to participate in an 18-month trial of the quantitative postural control assessment (Balance+Weight) device. Eligible clinics include any that self-report a substantial component of their patient population that may be at risk of falls, but that are not a referral site for patients previously identified as being at elevated falls risk. In clinics where multiple providers see patients, at least one provider must be willing to participate and commit to placing the novel device in their clinic, as well as to the other components of participation detailed below. Due to the number of ambulatory care clinics within a radius to allow same-day servicing of the devices and resource limitations to manufacture units, we will cap recruitment when we reach 20 clinics or 60 devices in service, whichever is reached first. Every participating clinic will have the opportunity to receive the device that delivers Balance+Weight either immediately or after a 9-month waiting period depending on randomization.

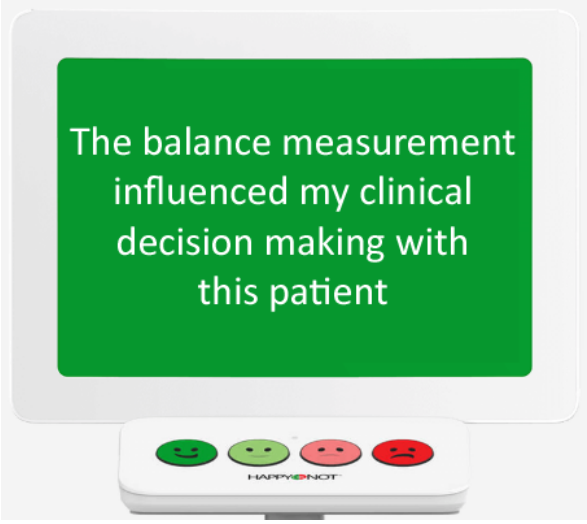
Randomization of clinics. A block randomization scheme by clinic type will be used to assign which clinics receive the Balance+Weight device in the first 9 months and which clinics receive the Balance+Weight device in the second 9 months. The block randomization scheme is proposed instead of simple randomization because of the expected variation between clinics in the types of patients they see. Blocks will be determined based on the estimated percent of patients seen who are over 65, diabetic, undergoing chemotherapy (all oncology clinics), or are using assistive devices during some of their care (e.g. orthopaedic trauma clinics). Clinics for whom 50% or more of their patients are in any of these categories will be included in one block, whereas clinics for whom less than 50% of their patients are in any of these categories will be included in the other block. While this scheme does not fully account for the confounder of multiple risk factors for falls or multiple co-morbities in some clinics, equipoise between treatment arms is also achieved through the crossover design whereby every clinic serves as its own control as well.

Training of clinics. At delivery of the Balance+Weight device to the clinic, a one-hour in-service will be performed by study personnel to train all providers and medical assistants on its proper use and the entry of data into the electronic medical record. This training will include how to operate the device and how to use the accompanying documentation with the reported data to inform clinical decision-making. This documentation will include threshold values for likelihood of the patient's balance being Within Normal Limits as well as the change in value that would indicate a change in the patient's balance status along with appendices that contain the published peer-reviewed journal articles upon which these recommendations are based. Upon request by the clinic, study personnel will repeat the training if refreshers are needed by clinic staff. An unlimited number of refresher trainings are permitted for each clinic, and the number of trainings requested per clinic will be recorded.

Incorporation of quantitative postural control assessment device into clinic flow including immediate feedback on clinical utility. Each participating clinic will place the study device in a location to allow its use instead of their weight scale. In the Balance+Weight arm, the device is capable of either just giving weight, or of providing balance data if the patient stands quietly with eyes closed for 30s. In the Weight Only arm, the device only gives a weight measurement, just as a standard weight scale would. In both

cases, the provider and their staff make their own clinical decisions as to which patients to make measurements of and how to use the provided information. The medical assistant may choose to enter the appropriate values into the medical record and continue with any other standard procedures in that clinic setting as part of the rooming or initial evaluation process. The provider can then examine the recorded balance measurement along with their standard examination and determine whether any further evaluations in that clinic or referral to a specialist, physical therapy, or other falls prevention is appropriate and record that diagnosis or referral into the medical record.

Immediate feedback from provider on clinical decision-making process. After each patient encounter in which the provider assessed balance using the Balance+Weight device, the provider who made a clinical decision regarding balance or falls risk is asked to press a button on a small kiosk that we will provide which logs their agreement with the statement, "The balance measurement influenced my clinical decision making with this patient." These kiosks from Happy-Or-Not.com are completely wireless and use their own 3G network to communicate the results of a single 4-point Likert scale question back to a central server that the study staff can monitor to collect data and get a real-time indication of whether the providers are using the Balance+Weight device.



Crossover of sites after 9 months. At the 9-month point, study personnel will go to every site to reprogram each device from Balance+Weight mode to Weight Only mode or vice versa, and to move the immediate feedback kiosks to the new Balance+Weight sites.

Data pull of clinic-level diagnosis and referral data. At or just after the crossover between sites has occurred, study personnel in conjunction with the IT departments at participating sites will pull the clinic diagnosis and referral data for all participating providers. After Casey et al.[15], our initial plan is to count instances of the following Common Procedural Terminology Category II codes:

- (Primary) CPT II 3288: Assessment of falls risk
- CPT II 0518: Development of a falls care plan
- CPT II 1101: Documentation of falls in past year (no falls/ single fall without injury)
- CPT II 1100: Documentation of an injurious fall/ multiple falls
- Other referral codes as appropriate

Because CPT codes are updated each calendar year, we will review the new codes each year and revise this code list as new codes related to falls assessment are added or subtracted. We will pull this data from both the 9 months of participation in the study, as well as the same 9 month period in the calendar year before the study began as a historical control. The data will be pulled again upon completion of the study for the second 9-month period.

Focus group discussions after completion of RCT. Following conclusion of the trial, we will engage all participants in focus groups regarding their experience using the Balance+Weight device. These discussions are intended to complement and enrich our understanding of how the users of the device (providers and medical assistants) either benefitted or did not benefit from having it in the clinic. Feedback will be used to assess the implementation toolkit and inform the development of the final version of the toolkit. Seed questions for these focus groups include:

- In what ways, if any, did you find having a quantitative postural control assessment on every patient useful in your clinical decision making?
- If you applied the device's data differently for different patients, how did you use it across these different patients?
- Did the time it took to make the measurement or interpret the measurement impact the efficiency of your clinic (positively or negatively) and how?
- In what ways could we better implement and train you to use the device, and use it with the electronic medical record?

5. Internal Validity

   As described above in section D, we use randomization and a crossover design to assure equipoise between the two arms of the study. All statistical analyses described below in section F will be performed by blinded analysts to mitigate the chance of bias. Given that the study uses real world data with commercially available devices in true clinical settings, the external validity of the study results is expected to be excellent.

6. Data Analysis

   Statistical analysis of kiosk data. The kiosk data will be analyzed by tabulating the frequencies of scores by kiosk (0-3) and performing a weighted kappa analysis to determine if providers agree upon whether the balance measurement influenced their clinical decision making. The proportion of decisions across all providers where the balance measurement positively influenced the decision-making process (top two options) and its 95% confidence interval will be calculated.

   Statistical analysis of clinical billing data. Counts of each code listed above will be tabulated for each provider during the 9 month period in the year before beginning the trial, during the 9 months with the Balance+Weight device, and during the 9 months with the Weight Only device; normalized by the total patient encounters by that provider over the same time periods to get incidence rates of each code for each condition (historical, Balance+Weight, Weight Only). The incidence rate ratios of Balance+Weight to the other two conditions will then be calculated, and the 95% confidence intervals of those incidence rate ratios will be calculated to see which are significantly different from 1.0, as we have previously done with other epidemiological data [16]. Each code is considered separately, because it is possible that multiple codes may be used in a single encounter, but as the primary goal of a quantitative postural control assessment is to trigger further action by the provider to confirm that the individual has a balance impairment, the primary variable of interest is CPT II 3288: Assessment of falls risk. This approach would statistically test the hypothesis that the provider is more likely to proceed in any falls risk algorithm such as STEADI on to a further assessment of falls risk with quantitative postural control information in addition to patient self-report or clinical observation. Using the data reported by Casey et al. in their implementation of STEADI [15], where they reported an initial rate of an assessment of falls risk of 19% across 16 providers over 3 months leading to 360 screens, we estimate that with 10 providers in each group over 9 months there could be approximately 3552 patient encounters in each group, or 7105 patient encounters over 18 months. With this number of patient encounters, we would have sufficient power to detect an incidence rate ratio of 1.1, or a 10% increase in Assessments of falls risk. Given the reported rate from Casey et al. that 35% of assessed patients score as high risk, that 10% increase could lead to approximately 47 additional high-risk individuals being identified, which we deem a clinically significant improvement.

IV. List of References

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