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Please cite this article as: Aaron Thrush DPT, MPH , Emma Steenbergen MPT , Clinical properties of the 6-clicks and Functional Status Score for the ICU in a hospital in the United Arab Emirates, *Archives of Physical Medicine and Rehabilitation* (2022), doi: https://doi.org/10.1016/j.apmr.2022.04.008

Global Outcome Measure Psychometrics

Clinical properties of the 6-clicks and Functional Status Score for the ICU in a hospital in the United Arab Emirates

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Clinical trial registration number: n/a.

Highlight

- Both instruments are responsive to measure mobility among hospitalized adults
- The 6-clicks has more disadvantageous floor and ceiling effects
- Minimal detectable change for the 6-clicks is 4.3 and FSS-ICU is 3.9

Asbtract

Objective: To determine measurement properties of the Activity Measure for Post-Acute Care Inpatient Mobility Short Form (6-clicks) and Functional Status Score for the Intensive Care Unit (FSS-ICU).

Design: Retrospective analysis of scores from a cohort of patients over twenty-four months. Outcome measures were administered to patients referred to physical therapy on admission and discharge.

Setting: Tertiary care hospital in the United Arab Emirates.

Participants: 2,793 adults referred to physical therapy, 62% male, with a median age of 58 (interquartile range 44-70) and median length of stay 14 days (interquartile range 8-28).

Interventions: Not applicable.

Main Outcome Measure: Instruments' clinical measurement properties: 1) responsiveness as per mean change and effect size (ES), 2) floor and ceiling effects, and 3) minimal important difference (MID). Results were analyzed for the whole group as well as three subgroups: patients with stroke as primary diagnosis (n = 644), discharged from heart and vascular floors (n = 642), and discharged from medical floors (n = 554).

Results: The mean change and ES (Cohen's d) for the 6-clicks were +8.3 (±8.6) and 0.97; and for the FSS-ICU were +6.8 (±7.8) and 0.87, respectively. 6-clicks had a floor effect on admission among patients with stroke (16.9%) and patients discharged from medical floors (19.3%), as well as a ceiling effect on discharge (25.5% in whole group). The FSS-ICU had a ceiling effect on discharge (23.2% in whole group). The estimated MID for the 6-clicks was 4.3, and for the FSS-ICU was 3.9.

Conclusion: Both instruments demonstrate good responsiveness in adults hospitalized in the United Arab Emirates. The FSS-ICU exhibited several advantages in performance which suggests

greater clinical utility than the 6-clicks. Minimal important differences were generated, which has not before been reported for the 6-clicks.

Keywords: outcome assessment (health care), critical care, mobility limitation, physical therapy department (hospital), patient outcome assessment

Abbreviations: Activity Measure for Post-Acute Care Inpatient Mobility Short Form (6-clicks), Consensus-based standards for the selection of health measurement instruments (COSMIN) Functional Status Score for the Intensive Care Unit (FSS-ICU), minimal important difference (MID)

Hospitalized adults face the harmful effects of illness and immobilization, leading to impaired physical function and impacting quality of life and a return to social roles.[1-4] Physical therapists minimize functional limitations that patients incur and facilitate safe transitions back to the home and community.[5] Objective measurements of physical function are essential in order for physical therapists to monitor progress and evaluate the impact of interventions, improve

communication and continuity of care, justify current and future rehabilitation needs, predict rehabilitation prognosis, and advise discharge decisions.[6,7] The call to implement objective measurements of physical function in rehabilitation began many years ago with numerous publications spanning several decades[8-11] and more recently has included clinical practice guidelines and policy statements.[12] Furthermore, transparency regarding the effectiveness of healthcare services has been identified as a key determinant in lowering health care costs and improving patient outcomes.[13,14] Despite this, the use of outcome measures by physical therapists is remarkably variable,[6,15] and evidence suggests that physical therapists in the acute care setting use outcome measures with the least frequency.[7]

Physical performance outcome measures should be chosen based on proven properties such as reliability, validity, and the ability to detect meaningful change.[16-19] Investigations are essential in order to elucidate these properties and enable physical therapists to standardize the use of outcome measures in practice. While most physical performance outcome measures are designed for and applied to specific patient conditions or populations, there is a need for the clinical use of instruments which can be applied across the general hospitalized population.[20]

Physical therapists at our hospital began implementing the use of two such measures in 2017. The Activity Measure for Post-Acute Care Inpatient Mobility Short Form (6-clicks) was implementing beginning in August 2016, and the Functional Status Score for the Intensive Care Unit (FSS-ICU) was implemented beginning in July 2017. Both instruments measure basic functional mobility by assigning scores for performance on tasks that are common among hospitalized adults. Extensive training of department staff was undertaken using resources published by instrument developers and by reviewing implementation practices described in

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published literature. Communications with instrument developers clarified aspects of scoring that were previously unanswered in existing resources and literature, topics which subsequently were incorporated into updated version of instrument instructions. Chart audits, ongoing review of scoring instructions, and standardization of practice were completed prior to the time from which data was included in this study. While the use of two instruments which measure the same construct may appear redundant, published literature was not sufficient to inform us which instrument was more suitable to apply - in particular with respect to possible differences in our geographic and cultural context as neither have been studied in the Middle East.

The purpose of this study was to investigate clinical properties of the 6-clicks and FSS-ICU in hospitalized adults who received physical therapy at our academic medical center in the Middle East. The primary outcomes of interest were responsiveness, floor and ceiling effects, and minimal important difference (MID).

METHODS

This analysis was conducted in accordance with the Consensus-based standards for the selection of health measurement instruments (COSMIN) guidelines.[21] Ethics approval was obtained from the Research Ethics Committee of Cleveland Clinic Abu Dhabi (A-2020-066).

Study Design

We performed a retrospective review of the electronic medical records of all hospitalized patients receiving physical therapy and discharged in a 24-month period (March, 2018 to February, 2020). All available data from this time period was used with the inclusion criteria discussed below. The hospital is a 364-bed tertiary care facility with 72 critical care beds in Abu Dhabi, and uses Epic (Verona, WI, USA) for the electronic medical record. Both outcome measures were administered according to instructions provided in prior publications.[22,23]

Both outcome measures were administered by the physical therapist at the time of evaluation, which were identified as the "admission" scores. If unable to administer the instruments at time of evaluation, they were administered as early as possible in a subsequent follow-up session. Outcome measures were administered at minimum once per week in follow-up physical therapy treatment sessions, and as close to hospital discharge as possible. Administering either instrument did not require changes to the procedures of a typical evaluation or treatment session, nor were physical therapy interventions or patient management altered in any way during the course of the study. The English version of each instrument was used as all hospital operations are conducted exclusively via the English language.

The last record of each measure prior to hospital discharge or discontinuation of physical therapy was identified as the "discharge" score. Scores were recorded in the electronic medical record and were extracted with demographic data into data visualization software (Tableau; Seattle, WA, USA). All analyses were conducted using Microsoft R Open 3.5.3 (Redmond, WA, USA).

Patients were excluded if they were referred to physical therapy but not evaluated (deemed not suitable for or not requiring assessment by physical therapist) and if they did not have both an admission and discharge score on both instruments. This exclusion was put in place in order to capture a cohort of patients who complete a course of physical therapy management rather than those who are evaluated and had no need for follow-up, and also in order to ensure that one cohort of patients is used for analysis of both instruments. No restrictions to medical diagnosis or clinical conditions were applied because the intent was to determine the usefulness of the instruments as outcome measures for all hospitalized adults undergoing physical therapy. Analysis was completed at the admission level, so that if a patient was re-admitted during the 24-month period, each admission was considered a separate entry. Data was analyzed for the whole group, as well as in three hospital sub-populations: 1) patients with a primary diagnosis of stroke, 2) patients discharged from the heart and vascular floor, and 3) patients discharged from the medical floors.

Responsiveness (defined as the mean within-person change) was modeled using mixed-effects regression. The pre- and post-scores served as the dependent variable. A random patient-level intercept was included to account for the repeated-measures nature of the data and a dichotomous time indicator was used to distinguish time points within patients. Specifically:

$$Y_{ij} = \beta_0 + \beta_1 * time_{ij} + \mu_{0j} + r_{ij}$$

, where the j subscript indicates patient j, subscript i indicates pre/post time points, μ_{0j} is the random patient-specific intercept, r_{ij} is the time-specific residual, Y_{ij} is the time-specific value on the outcome variable (6-clicks or FSS-ICU), and $time_{ij}$ is the pre/post time dummy indicator. This mixed-effects formulation produced estimates of the average within-patient change

(quantified by β_1), associated p-values, and the person-level pooled SD in the outcome variable. To provide context for estimated change, Cohen's D ES (calculated as the average within-person change divided by the person-level SD) was also calculated using these mixed-effects based estimates.

Effect sizes were categorized as small, medium, or large, according to definitions provided by Husted et al[24] (0.2 to <0.5, 0.5 to 0.8, and >0.8, respectively).

Floor and ceiling effects were identified if more than 15% of patients scored the lowest or highest possible score on an instrument.[25,26] The proportion of patients with an increase in score, and with no change in score (from admission to discharge) was ascertained to provide additional insights into responsiveness.

The MID is "the smallest amount of change in an outcome that might be considered important by the patient or clinician" and is of significance because it "would mandate, in the absence of troublesome side effects and excessive costs, a change in patient management.[27] The MID for each instrument was determined using distribution-based methods, using 0.5 times the SD of the change scores.[28-30]

Study Measures

The 6-clicks was developed for use in a hospital setting and is part of the AMPAC instrument which expands to a set of 240 functional activities used across health care settings.[31] It is designed to be used in all patient diagnoses and conditions. The mobility component of the instrument is comprised of six mobility tasks: 1) turning in bed, 2) sitting down and standing up from a chair, 3) moving from lying to sitting on side of the bed, 4) moving to and from a bed to chair, 5) walking in a hospital room, and 6) climbing three to five steps with a railing. Each task

is observed and assigned a score from one to four, providing a total raw score from 6 to 24. If an activity is not done, the instrument instructions allow for scores to be estimated if this can be done reliably.[32] Raw scores are converted to t-scale scores,[32] which were used for all data analysis in this study. A higher score indicates greater independence. The 6-clicks has proven reliability,[33,34] validity,[22] and predictive ability for discharge destination.[35,36] This brief instrument is used in more than one thousand hospitals in the United States.[36]

The FSS-ICU was developed to reflect common mobility tasks in a critical care setting.[23] Subsequent investigations showed robust clinical properties and successful use in patients who transitioned out of critical care to acute care floors,[28] and in a long-term acute care setting.[37] The instrument is comprised of five mobility tasks: 1) rolling, 2) coming to sit from a supine position, 3) sitting at edge of bed, 4) sit to stand transfer, and 5) walking or wheelchair locomotion. Each task is observed and assigned a score from zero to seven, providing a total score from 0 to 35. A higher score indicates greater independence. The FSS-ICU has proven reliability,[38,39] validity,[28] predictive ability for discharge setting,[37,38] and is recommended for clinical and research purposes.[29]

We hypothesized that both instruments would be responsive to change in functional mobility, and that both would show increases in score from admission to discharge, as has been observed separately in prior studies in hospitalized patients in several countries.[22,23,28,37] We anticipated that the FSS-ICU would have greater responsiveness and less floor and ceiling effects, for the following reasons: 1) the FSS-ICU has a greater score range (a 36-point spread verses 19-point spread), 2) the FSS-ICU includes a more basic skill of sitting at edge of bed, and 3) the FSS-ICU

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ambulation task stratifies scores based on best walking distance, while the 6-clicks assesses walking ability only within a hospital room.

RESULTS

Within the retrospective study dates 6,825 admitted patients were referred to physical therapy. Evaluations were not performed for 877 patients (common reasons may be not meeting criteria for physical therapy evaluation, medically unstable, or discharged before ability to evaluated). A further 3,155 patients were evaluated but did not have an admission and discharge score for both instruments, and thus were removed from the cohort. The primary reason for absence of scores results from scenarios in which no follow-up physical therapy sessions were conducted (physical therapy goals are met, physical therapy is not indicated, hospital discharge occurs before follow-up, lack of patient cooperation; or therapist non-compliance with instrument administration.

The final number of patients included in the study cohort was 2,793. Mean age was 57 years (44-70), 61.8% were male, and median length of stay was 14.0 days (7.8-27.8). The median time from hospital admission to physical therapy referral was 0.8 days (0.1, 3.1). The median time from hospital admission to the first 6-clicks score was 2.7 days (1.2, 6.0), and to the first FSS-ICU score was 2.8 days (1.3, 6.5). The median time from PT referral to the first record of both the 6-clicks and FSS-ICU was 1.0 days. Refer to Table 1 for complete hospital admission and time metrics. A quarter to a third of physical therapy evaluations each month were done in the intensive care units, and the remainder were completed on acute hospital floors.

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Effect sizes for the 6-clicks and FSS-ICU were 0.97 and 0.87, respectively (Table 2). The smallest effect sizes were observed in patients on the medical service (0.62 and 0.61, respectively), and the largest effect sizes were observed in patients on the heart and vascular service (2.99 and 2.60, respectively). Table 3 illustrates floor and ceiling effects, in which the 6-clicks demonstrated a floor effect on admission among patients diagnosed with stroke and patients discharged from medical floors. The FSS-ICU had no floor effects. Both the 6-clicks and FSS-ICU demonstrated ceiling effects on discharge in the whole group, in patients diagnosed with stroke, and in patients discharged from the heart and vascular floor.

Table 4 shows the proportion of patients with change scores from admission to discharge. An improvement in score (≥ 1 point) was more frequently observed with measurement by the FSS-ICU compared with the 6-clicks, in the whole group (79.6 vs 73.9%) as well as in each subpopulation. Similarly, no change in score from admission to discharge was more frequently observed with measurement by the 6-clicks compared with the FSS-ICU, in the whole group (18.1% vs 11.1%) as well as in each subpopulation.

The 6-clicks MID for the whole group was estimated to be 4.3. Subpopulations had similar findings apart from the heart and vascular population which showed a smaller MID (2.0). The FSS-ICU MID for the whole group was estimated to be 3.9. Again, findings for subpopulations were similar apart from a substantially smaller estimate for the heart and vascular population (1.8). Refer to Table 5 for full data.

DISCUSSION

This is the first report of implementing the 6-clicks and FSS-ICU in the Middle East. It provides novel insights into the clinical properties of these two increasingly common outcome measures and helps us understand their usefulness when administered to hospitalized patients.

In this investigation the ES of the 6-clicks was 0.97, indicating a large degree of responsiveness to change.[24] No prior investigations have reported ES for the 6-clicks, so this is an important milestone for the instrument. In this investigation the ES of the FSS-ICU was 0.87, also indicating a large degree of responsiveness to change.[24] The results complement three prior reports of the responsiveness of the FSS-ICU. Huang et al[28] reported ES based on administration at various hospital milestones, the most similar to this investigation being from ICU discharge to hospital discharge, in which the reported ES was 0.92. Parry et al[29] reported an ES of 0.46 but administered the FSS-ICU at ICU awakening and ICU discharge, and had a small sample size. Thrush et al[37] reported the ES among patients discharged from a long-term acute care hospital, in which the overall ES was small (0.25); however, the ES was large (>0.80) when patients who died or were discharged to long term care or hospice settings were removed.

The MID for the 6-clicks had not previously been reported. This investigation estimated the MID to be 4.3 points. This is useful to clinicians and researchers who desire an estimate for meaningful change in patient function. The MID for the FSS-ICU was estimated to be 3.9 points. This agrees with a previous investigation which reported a range of 2.0–5.0 using similar methods, albeit in a smaller population from several institutions across Western countries.[28]

Analysis of results in the three subgroups offers further insights into instrument performance. As shown in Table 2, compared to the whole group and patient with stroke, patients on the

heart and vascular ward had significantly larger change scores from admission to discharge (mean of +12.3), and patients on the medical ward had significantly smaller change scores from admission to discharge (mean of +5.6). This is most likely an effect of the dominance of the heart and vascular group by patients who are admitted for elective surgeries who have better prior levels of function and independence, and a more rapid recovery after surgery. Conversely, the medical service is dominated by more chronically ill with lower mobility and independence, and thus have less improvement in score during physical therapy management. Evidence of the medical group having lower mobility is seen by it having the highest rate of floor effect on admission and the largest percent of patient who demonstrate no change in score from admission to discharge – as measure by both instruments. These subgroup characteristics have an impact on the effect sizes in which the heart and vascular subgroup has the highest value and the medical subgroup has the lowest value. Similarly, MID estimates are lowest for the heart and vascular group and among the highest for the medical group.

This retrospective investigation provides evidence that both the 6-clicks and FSS-ICU are useful in clinical practice to measure change in physical function in an adult population over the course of hospital admission. Although both may be useful, these findings propose several advantages of the FSS-ICU with respect to responsiveness and floor and ceiling effects. While both instruments show high responsiveness by their ES, this data suggests that the FSS-ICU has superior sensitivity to change because more patients show improvement in score, and less patients show no change in score, with this instrument. While both instruments suffer ceiling effects on discharge, the ceiling effects are higher for 6-clicks across all four groups. The rate of ceiling effect at discharge for the FSS-ICU (23%) was similar to that found by Huang et al[28]

(21%), and higher than that found within an ICU (16%) by Alves et al[40] as would be expected for more critically ill patients. In addition, the 6-clicks suffers floor effects on admission in two subgroups (stroke and medical), while the FSS-ICU does not. These are limiting factors for the 6-clicks ability to detect change. A modified version of the 6-clicks was recently proposed[41] with the intent to accommodate low functioning hospitalized patients and may help to address floor effects, but should be further investigated.

It is important to note that prior investigations have proven both instruments to be predictive of hospital discharge setting in western contexts.[28,35-38] However, the societal and health care context of the United Arab Emirates differ dramatically from Western settings, and physical function is often not one of the primary determinants of discharge setting. Thus, the ability of these instruments to predict discharge setting was not included in this investigation.

Growing evidence show how both instruments are suitable for use across the breadth of a hospitalized adult population, making them useful global physical performance outcome measures. However, it remains important that clinicians use additional outcome measures that have superior performance and value when administered to specific populations and individuals.[42]

An important area for further research is to investigate the impact that increases or decreases in scores during course of hospital admission have on outcomes such as discharge destination, readmissions, quality of life, and mortality. Investigators should seek to confirm the reported MID for each instrument through anchor-based methods and perform additional studies of

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measurement properties in hospital subpopulations, as our results showed variations in metrics in common diagnostics subpopulations.

Study Limitations

This investigation was carried out at a single institution and generalizability should not be assumed, particularly with regard to various geographic contexts and populations. Our data does not indicate how much time elapsed between hospital admission and referral to physical therapy, or between referral to physical therapy and administering of admission scores, or between discharge scores and hospital discharge – which could have provided insights into the timeliness of the instrument measurements. Subjects were included in this study if they had both admission and discharge scores on both instruments, which may present bias when compared to the full population of patients referred to physical therapy in a hospital setting. However, our methodology allowed the comparison of instrument performance among one group of patients, and is likely a better reflection of patients who are participating in an active and ongoing physical therapy episode of care. Finally, a distribution-based method was used to estimate MID because the preferred anchor-based method was not feasible.

CONCLUSIONS

In summary, this investigation is the first to compare the clinical properties of two physical performance outcome measures that are becoming more visible within published research and clinical practice, and it is the first publication of its kind from a hospital setting in the Middle East. The 6-clicks and FSS-ICU both show good responsiveness, and the FSS-ICU shows advantages in performance metrics related to floor effects and responsiveness. The minimal

important difference for each instrument was generated, which has not before been done for the 6-clicks.

Acknowledgments

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Table 1. Hospital Length of Stay, Referral, and Instrument Record Metrics

	Whole Group	Stroke	Heart & Vascular	Medical
Hospital LOS	14.0 (7.8, 27.8)	16.4 (8.1, 32.8)	11.1 (8.0, 16.7)	16.7 (8.7, 35.0)
Days from admission to PT referral	0.8 (0.1, 3.1)	0.1 (0.0, 0.1)	2.0 (0.4, 5.3)	1.0 (0.2, 3.5)
Days from admission to 1st 6-clicks record	2.7 (1.2, 6.0)	1.3 (0.9, 2.8)	4.0 (1.6, 7.5)	3.3 (1.7, 8.0)
Days from admission to 1st FSS-ICU record	2.8 (1.3, 6.5)	1.4 (0.9, 2.8)	4.1 (1.6, 7.8)	3.5 (1.7, 8.5)
Days from PT referral to 1st 6-clicks record	1.0 (0.7, 1.6)	1.0 (0.7, 1.8)	1.0 (0.8, 1.5)	1.1 (0.8, 1.8)
Days from PT referral to 1st FSS-ICU record	1.0 (0.8, 1.8)	1.0 (0.7, 1.9)	1.0 (0.9, 1.9)	1.1 (0.8, 1.9)

*all figures above represent median days, and 1st and 3rd interquartile ranges

Table 2. Responsiveness Metrics

6-clicks	n	mean change (95% CI*) and SD	effect size	p-value
Whole Group	2,793	+8.3 (8.0 – 8.7), 8.6	0.97	<0.001
Stroke	644	+9.0 (8.4 – 9.7), 9.4	0.96	<0.001
Heart & Vascular	642	+12.3 (11.5 – 13.0), 4.1	2.99	<0.001
Medical	554	+5.6 (4.9 – 6.2), 9.1	0.62	<0.001
FSS-ICU	n	mean change (95% CI) and SD	effect size	p-value
Whole Group	2793	+6.8 (6.5 – 7.1), 7.8	0.87	<0.001
Stroke	644	+7.8 (7.3 – 8.4), 8.4	0.93	<0.001
Heart & Vascular	642	+9.1 (8.6 – 9.6), 3.6	2.60	<0.001
Medical	554	+5.2 (4.6 – 5.7), 8.5	0.61	<0.001

*CI = confidence interval

Table 3. Floor Effects and Ceiling Effects

		Floor Effects (%)			
		Whole Group	Stroke	Heart & Vascular	Medical
6-clicks	Admission	11.1	16.9	2.2	19.3
	Discharge	4.9	3.9	0.0	9.4
FSS-ICU	Admission	3.2	5.0	0.5	4.9
	Discharge	1.4	1.1	0.0	1.8
		Ceiling Effects (%)			
		Whole Group	Stroke	Heart & Vascular	Medical
6-clicks	Admission	4.0	4.2	3.4	1.6
	Discharge	25.2	22.8	42.4	9.8
FSS-ICU	Admission	3.4	3.4	3.1	1.1
	Discharge	23.2	22.1	40.5	8.5

Table 4. Proportion of patients with no change in score from admission to discharge.

	Whole Group (%)	Stroke (%)	Heart & Vascular (%)	Medical (%)
6-clicks	**18.1**	**15.5**	**9.8**	**25.8**
FSS-ICU	**11.1**	**8.5**	**6.5**	**15.2**

Table 5. MID estimates

	Whole Group	Stroke	Heart & Vascular	Medical
6-clicks MID	4.3	4.7	2.0	4.5
FSS-ICU MID	3.9	4.2	1.8	4.2