Meaningful Gait Speed Improvement During the First 60 Days Poststroke: Minimal Clinically Important Difference

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Background. When people with stroke recover gait speed, they report improved function and reduced disability. However, the minimal amount of change in gait speed that is clinically meaningful and associated with an important difference in function for people poststroke has not been determined.

Objective. The purpose of this study was to determine the minimal clinically important difference (MCID) for comfortable gait speed (CGS) associated with an improvement in the modified Rankin Scale (mRS) score for people between 20 to 60 days poststroke.

Design. This was a prospective, longitudinal, cohort study.

Methods. The participants in this study were 283 people with first-time stroke prospectively enrolled in the ongoing Locomotor Experience Applied Post Stroke (LEAPS) multi-site randomized clinical trial. Comfortable gait speed was measured and mRS scores were obtained at 20 and 60 days poststroke. Improvement of 1 on the mRS was used to detect meaningful change in disability level.

Results. Mean (SD) CGS was 0.18 (0.16) m/s at 20 days and 0.39 (0.22) m/s at 60 days poststroke. Among all participants, 47.3% experienced an improvement in disability level. The MCID was estimated as an improvement in CGS of 0.16 m/s anchored to the mRS.

Limitations. Because the mRS is not a gait-specific measure of disability, the estimated MCID for CGS was only 73.9% sensitive and 57.0% specific for detecting improvement in mRS scores.

Conclusions. We estimate that the MCID for gait speed among patients with subacute stroke and severe gait speed impairments is 0.16 m/s. Patients with subacute stroke who increase gait speed ≥0.16 m/s are more likely to experience a meaningful improvement in disability level than those who do not. Clinicians can use this reference value to develop goals and interpret progress in patients with subacute stroke.
 Recovery of walking ability is the most frequently stated goal for patients after stroke. In the first week poststroke, 63% of patients are unable to walk independently and 50% cannot walk even with assistance. Patients and therapists naturally focus on improved walking function as a primary goal in acute and subacute stroke rehabilitation.

Gait speed has been shown to be sensitive to change over time and significantly correlated with level of disability in people with stroke. Perry et al identified gait speed categories that correlated with progressive levels of functional walking and disability. People walking at speeds of <0.4 m/s were household ambulators, people walking at speeds of ≥0.4 m/s but <0.8 m/s were limited community ambulators, and people walking at speeds of ≥0.8 m/s were able to walk in the community without substantial limitations. As people with stroke recover gait speed and transition between these categories, they experience substantially better function and quality of life.

Minimal Clinically Important Difference
Gait speed of an individual poststroke can be referenced as a percentage of age- and sex-matched normative values. However, reference values that define clinically meaningful changes in gait speed are lacking. Thus, clinicians lack the reference values needed to answer questions such as, “How much improvement in gait speed is necessary for my patient to achieve a meaningful improvement in level of disability?” The minimal clinically important difference (MCID) is a reference value that addresses this clinical question. The MCID represents the smallest change of score in an outcome measure that a patient would perceive as beneficial. Clinicians can use the MCID to interpret the clinical relevance of changes observed in an individual poststroke. Researchers can use the MCID to determine the magnitude of difference between groups needed to identify an important benefit of one intervention over another. For people with stroke, the MCID has been estimated for the Functional Independence Measure, the Barthel Index, and several upper-extremity measures. Perera et al estimated small meaningful change for gait speed in a cohort of 692 older adults, including 100 people with stroke; however, their study focused on meaningful changes for decline in function. The MCID for gait speed also has been estimated for people with hip fracture. To our knowledge, the MCID has not been estimated for changes in gait speed associated with improved function among people with stroke.

Minimal Detectible Change
Minimal detectible change (MDC) is another commonly reported reference value for interpretation of clinical outcome measures. Whereas the MCID indicates clinically meaningful change, the MDC indicates the amount of change required to exceed measurement variability. That is, the MDC represents the smallest change on an outcome measure that would be considered “real.” The MDC is derived using the distribution, variability, and reliability of an outcome measure when it is studied in a stable population at 2 time points. Thus, for the clinician, knowing the MDC would indicate whether a difference observed between 2 measurements on the same patient represents a true difference in performance or whether the difference could be expected due to individual variability.

MDC = SEM(1.96)\sqrt{2},
where SEM = standard error of the measure, 1.96 represents the z score for a 95% confidence interval, and \sqrt{2} accounts for the difference of 2 variances used to derive SEM. SEM = SD(\sqrt{1—r}), where SD = standard deviation of within-subject test-retest differences and r = measure of reliability (test-retest reliability or Cronbach alpha).

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- eAppendix: Locomotor Experience Applied Post Stroke (LEAPS) Procedures for 10-Meter Walk Test and Modified Rankin Scale
- Video: “Demonstration of a Standardized Procedure for Conducting the 10-Meter Walk Test to Assess Comfortable Gait Speed in a Hospital Setting.”
- Video: In honor of Dr Jacquelin Perry, view art by patients from Rancho Los Amigos National Rehabilitation Center.
- Podcast: “Stepping Forward With Gait Rehabilitation” symposium recorded at APTA Combined Sections Meeting, San Diego.
- Audio Abstracts Podcast

This article was published ahead of print on December 18, 2009, at ptjournal.apta.org.
tristic variability associated with the outcome measure. Because changes smaller than the MDC are likely to be due to measurement variability rather than real change, it is important that the estimated MCID be larger than the MDC for any given outcome measure.

**Estimating MCID**

Whereas the MDC is the value that exceeds the expected internal variability of a measure, the MCID addresses a more complex concept; it is the magnitude of change in an outcome measure that represents a meaningful change to the patient. Because individuals interpret “meaningful change” differently, depending on a multitude of factors (eg, prior level of function, severity of disability, age, physical environment, time since last measurement), the MCID is a dynamic and context-specific concept. Thus, derivations of the MCID only estimate the minimum value likely to represent meaningful change for a specific population at a particular stage of recovery. To gain a clear picture of the MCID for different stroke outcome measures, the MCID will need to be estimated for different stages of recovery and levels of severity (eg, ambulators and nonambulators, chronic and acute). Because estimation of the MCID is an iterative process (ie, evolves from multiple perspectives), it is important to begin to estimate the MCID for key clinical outcome measures such as gait speed among people with stroke.

Numerous methods have been described for deriving the MCID. Traditionally, analysis methods have been divided into 2 broad categories: distribution based and anchor based. Anchor-based analyses are considered a more robust method for estimating clinically meaningful change because the measure of interest, in this case gait speed, is compared with an established measure of meaningful change. By comparing the measure of interest with a gold standard measure with established clinical relevance and responsiveness to change, a reliable estimate of meaningful change can be determined.

In this study, the MCID was estimated for comfortable gait speed (CGS) of people in the first 60 days poststroke using an anchor-based analysis. Because previous work has identified that improved gait speed is associated with reduced disability, we chose an anchor that could detect change in level of disability. The gold standard anchor used to identify minimal clinically important improvement in disability was the modified Rankin Scale (mRS). The mRS is a global index of disability broadly used as an outcome measure in pharmaceutical, epidemiologic, and behavioral studies of stroke recovery.

Although the literature reflects the impact of gait speed on recovery after stroke and its relationship to community ambulation (ie, participation) and level of disability (ie, participation restrictions), there are no studies that have reported the minimal amount of change in gait speed that is expected to improve level of disability for an individual with stroke. Therefore, the purpose of this study was to estimate the MCID of gait speed for ambulatory individuals with subacute stroke using the mRS, an established measure of disability.

**Method**

**Participants**

Participants (N=283) in this study were prospectively enrolled in the multi-site Locomotor Experience Applied Post Stroke (LEAPS) randomized clinical trial between May 2005 and August 2008. Participants were recruited from inpatient rehabilitation hospitals and the surrounding community in 5 different geographic locations across the United States. Inclusion criteria included: (1) age ≥18 years, (2) stroke within 45 days, (3) residual paresis in the lower extremity, (4) ability to walk at least 3 m with maximum assist of one person, (5) ability to follow a 3-step command, (6) CGS of <0.80 m/s, (7) expected to be discharged to home, and (8) ability to travel to the intervention site 3 times per week. Exclusion criteria included living in a nursing home prior to stroke, inability to walk at least 30 m (100 ft) prior to stroke, and medical conditions that contraindicate moderate-intensity exercise. A full list of inclusion and exclusion criteria for the LEAPS study has been published previously. All participants provided written informed consent to participate, as approved by each site’s institutional review board.

**Assessment Protocol and Outcome Measures**

As part of the LEAPS trial, standardized assessments were conducted by trained assessors at approximately 20 days poststroke (T20) and at approximately 60 days poststroke (T60). Between T20 and T60, participants did not participate in a research intervention but were engaged in usual care rehabilitation activities in their community. The assessment protocols and methods used to train assessors were published previously. For this study, stroke impairment severity was characterized using the National Institutes of Health Stroke Scale (NIHSS) and the Fugl-Meyer Sensorimotor Assessment upper-extremity (FM-UE), lower-extremity (FM-LE), and sensory (FM-S) domains.

1 Participants were assessed initially between the 5th and 30th days poststroke; however, the protocol included tolerance for initial assessment up to 45 days poststroke.
Comfortable gait speed. Trained assessors, all licensed physical therapists, measured CGS using a standardized procedure for the 10-Meter Walk Test (10mWT) (see the eAppendix and video at ptjournal.apta.org) previously described in a poststroke walking intervention study.31 High intrarater and interrater reliability have been established for timed walking tests, including the 10mWT.32–34 The walking course consisted of a total of 14 m in a hallway: a 2-m warm-up, 10 m used for the speed measurement, and 2 m for slowing down to a stop. Instructions were provided to the participant to “walk at a comfortable pace.” Participants were provided up to maximum assist by one person for balance and stability (but not for paretic-limb advancement). Participants used the assistive device (eg, cane, walker) or orthotic device (eg, ankle-foot orthosis) that they used “most often” (if any) at each time point. Two trials were conducted in succession, with a brief seated or standing rest as needed by the participant between trials.

Modified Rankin Scale. Modified Rankin Scale scores range from 0 (no symptoms at all) to 5 (severe disability) (Tab. 1). When administered without a structured interview, the mRS has high intrarater reliability (weighted kappa=.94–.99)35 and moderate to high interrater reliability (weighted kappa=.71–.91).35,36 Numerous studies have established mRS content and convergent validity.37 Sensitivity to clinically meaningful change has been established for shifts of mRS scores of ≥1 in large prospective studies.38,39 A standardized procedure was used to determine the mRS score to optimize interrater reliability. Participant mRS scores were determined by the same assessor who conducted the

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
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<tbody>
<tr>
<td>0</td>
<td>No symptoms at all</td>
</tr>
<tr>
<td>1</td>
<td>No significant disability: despite symptoms, able to carry out all usual duties and activities</td>
</tr>
<tr>
<td>2</td>
<td>Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance</td>
</tr>
<tr>
<td>3</td>
<td>Moderate disability: requiring some help but able to walk without assistance</td>
</tr>
<tr>
<td>4</td>
<td>Moderately severe disability: unable to walk without assistance and unable to attend to own bodily needs without assistance</td>
</tr>
<tr>
<td>5</td>
<td>Severe disability: bedridden, incontinent, and requiring constant nursing care and attention</td>
</tr>
</tbody>
</table>

10mWT.35 The mRS score was assigned at the conclusion of a standardized 3- to 4-hour assessment. The assessment included measures of impairment (physical and cognitive), functional activities (physical and cognitive), and life participation, all of which affect the mRS score. Additional information required to accurately determine a participant’s score was obtained from the participant or caregivers at the assessor’s discretion (see the eAppendix at ptjournal.apta.org).

Data Analysis
Descriptive statistics were used to characterize cohort demographics, stroke characteristics, days poststroke, severity of stroke impairment, CGS, and mRS scores. The Student paired t test and the Bowker test40 were used to identify statistically significant differences between continuous and ordinal measures, respectively.

Estimation of MCID
Improvement in mRS score (shift of ≥1) between T20 and T60 served as the gold standard anchor for detecting minimal clinically important change in gait speed. Anchor-based MCID studies can be designed for analysis of data at an individual or group level.15 Individual-level analyses use statistical tests commonly reported in studies of dichotomous diagnostic tests (eg, receiver operating characteristic [ROC] curve, sensitivity, specificity, likelihood ratios).15,17,41

Step 1: receiver operating characteristic curve. To estimate MCID, the sample population was divided into participants who did or did not experience a “true” change in disability (improvement of ≥1 in mRS score). Individual cutoff scores for change in CGS ranging from 0.01 to 0.78 m/s then were tested to determine their sensitivity and specificity for detecting participants who did or did not experience a true change in disability. Sensitivity represents the percentage of participants who experienced an improvement of ≥1 on the mRS and met or exceeded the estimated MCID for CGS. Specificity represents the percentage of participants who did not experience an improvement of ≥1 on the mRS and failed to meet or exceed the estimated MCID for CGS. Figure 1a and the second column of Figure 1c summarize the formulas for the proposed analyses.

A ROC curve was generated by plotting sensitivity against 1 – specificity for each potential cutoff score. The area under the curve (AUC) and 95% confidence interval (CI) were calcu-
lated using the SAS (version 9.1)\textsuperscript{5} \%ROC macro described by Delong et al\textsuperscript{42} to determine the presence of a relationship between change in CGS and shift of mRS score sufficient to estimate MCID.\textsuperscript{43} If the lower limit of the AUC 95% CI was \( >0.5 \), the relationship between change in CGS and mRS was considered sufficient to estimate the MCID for CGS. Identifying a sufficient relationship between the 2 variables was the primary purpose of the ROC curve. Traditionally, if a sufficient relationship existed; the ROC curve could be used to qualitatively estimate MCID by visually determining the point on the curve closest to the upper left-hand corner of the graph, which represents the point of optimal sensitivity and specificity.\textsuperscript{9,43,44} In this study, however, the second step of the analysis provided a more-quantitative method for estimating MCID.

\textbf{Step 2: Classification and Regression Tree.} The second step of the analysis used CART analysis (version 6)\textsuperscript{45} to provide a more quantitative estimate of the best cutoff score to estimate MCID. For this analysis, potential cutoff scores were defined by the minimum and maximum values for change in CGS between T\textsubscript{20} and T\textsubscript{60} in our sample population.

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|}
\hline
\textbf{Property} & \textbf{Formula} & \textbf{Result for 0.16 m/s} \\
\hline
\textbf{Sensitivity} & \( \frac{A}{A + B} \) & 99/99 + 35 = 73.9\% \\
\textbf{Specificity} & \( \frac{D}{C + D} \) & 85/64 + 85 = 57.0\% \\
\textbf{Likelihood Ratio Positive} & \( \frac{Sensitivity}{1 - Specificity} \) & \( \frac{0.739}{1 - 0.57} \) = 1.72 \\
\textbf{Likelihood Ratio Negative} & \( \frac{1 - Sensitivity}{Specificity} \) & \( \frac{1 - 0.739}{0.57} \) = 0.46 \\
\hline
\end{tabular}
\caption{(a) A 2 \times 2 table traditionally used to calculate sensitivity and specificity. The sample population is divided into 4 groups (cells A, B, C, and D). Cell A represents the number of participants who had a positive result on both the gold standard test and the new test (true positives). Cell B represents the number of participants who had a positive result on the gold standard test but a negative result on the new test (false negatives). Cell C represents the number of participants who had a positive result on the gold standard test but a positive result on the new test (false positives). Cell D represents the number of participants who had a negative result on both the gold standard test and the new test (true negatives). (b) A 2 \times 2 table of actual data from this study for the gold standard anchor (the modified Rankin Scale) and the minimal clinically important difference (MCID) of 0.16 m/s for comfortable gait speed. (c) Formulas used to calculate sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio and actual data used to calculate values for the MCID of 0.16 m/s for comfortable gait speed.}
\end{table}
Within that range, cutoff scores were tested at 0.01-m/s increments. Each cutoff score served as a metric for splitting the data into 2 groups: participants whose change in CGS exceeded the cutoff score and participants whose change in CGS did not exceed the cutoff score. A heterogeneity value (ie, impurity) associated with each cutoff score was computed. The cutoff score with the largest heterogeneity represented the score with the best discrimination of the data (ie, the best MCID candidate). Thus, the cutoff score with the highest heterogeneity value was identified as the estimated MCID.

Next, tenfold cross validation was used to substantiate this estimate. This process involved development of an ancillary cross-validation learning tree (ie, computational modeling) using a randomly selected 90% of our data set. The remaining 10% of the data served as a pseudo-independent data set that was used to validate the estimate generated from the initial 90% (by calculation of a classification error). This procedure was repeated 10 times. The results of the 10 cross-validation procedures were combined to compute a statistical score for determining the significance of the estimated MCID. The CART program will provide a result only if it is statistically significant. Thus, the CART analysis produces a more-quantitative result than the ROC curve analysis.

CART analysis is not probabilistic and, therefore, provides a point estimate but not a CI. Results from the CART analysis were compared with the ROC curve to ensure that the computer-generated cutoff score corresponded to a visual representation of the data. If the 2 models were in general agreement, the cutoff score identified by CART would be considered the preferred method to estimate MCID.

Likelihood Ratios
Finally, to facilitate clinical interpretation and utilization of the MCID value, positive and negative likelihood ratios (LR+, LR-) were calculated to characterize the value of the MCID for identifying a meaningful change in level of disability for individual patients. Likelihood ratios combine sensitivity and specificity and were used to determine the likelihood, based on change in CGS, that an individual would experience a meaningful change in level of disability. Specifically, LR+ was used to estimate the likelihood that a participant who met or exceeded the estimated MCID would actually experience a meaningful improvement in level of disability, and LR- was used to estimate the likelihood that a participant who did not exceed the estimated MCID would experience a meaningful improvement in level of disability. Formulas used to calculate LR+ and LR- are illustrated in the second column of Figure 1c.

Once likelihood ratios were calculated, a likelihood ratio nomogram was used to determine the probability that an individual similar to the participants of our cohort would experience an improvement in level of disability based upon whether he or she did or did not achieve the estimated MCID for CGS. A nomogram, in this case a likelihood ratio nomogram, is a graphical calculating device. Whenever possible, 95% CIs were calculated to demonstrate the precision of statistical analyses (AUC, sensitivity and specificity, likelihood ratios).

Role of the Funding Source
This work was supported by funding from National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research (RO1 NS050506). The funding source had no role in the design, conduct, or reporting of this study.

Results
Participants
A total of 283 participants (age: mean [SD] = 63.5 [12.5] years, range = 29–98 years) completed assessments T20 and T60. Scores for stroke impairment severity at T20, based on the NIHSS, ranged from 0 to 20 out of 42 (mean [SD] = 7.5 [4.0]) (Tab. 2). Significant increases in CGS, FM-UE, FM-LE, FM-S, and mRS scores (P < .001) associated with natural recovery and participation in therapeutic rehabilitation programs were evident (Tab. 3).
Comfortable Gait Speed

Individual gait speeds at T20 and T60 met the LEAPS inclusion criterion of a CGS of 0.80 m/s, ranging from 0.00 to 0.79 m/s. At T20 and T60, 67 and 7 participants, respectively, met the inclusion criterion of ability to walk 3 m but were unable to walk 10 m due to fatigue and, therefore, were considered to have a gait speed of 0.0 m/s. For the purposes of this study, these cases were not considered missing data. At T20, only 14% of the participants (n=41) were classified as limited community ambulators (≥0.4 to <0.8 m/s), whereas the remainder (n=242, 86%) were classified as household ambulators (<0.4 m/s). At T60, the proportion of limited community ambulators increased to 49% (n=139). Mean (SD) CGS increased 0.21 (0.17) m/s, from 0.18 (0.16) m/s at T20 to 0.39 (0.22) m/s at T60 (P<.001); change in gait speed ranged from −0.21 m/s to 0.75 m/s. Between assessments, 15 participants (5%) experienced a decline in CGS (median 0.04 m/s).
represented in cells below (and to the left of) the blue boxes (n=134, 47.3%) experienced a clinically meaningful improvement in function (≥1 improvement of mRS scores) between T20 and T60. There was a statistically significant shift of mRS category from T20 to T60 (P<.001).

MCID–ROC Curve
To derive the CGS MCID, the best match between a change in CGS and a change in the gold standard anchor (mRS) was identified. The ROC curve is illustrated in Figure 2, and the AUC was calculated as 0.69 (95% CI=0.63–0.75). The shape of the ROC curve is relatively smooth and difficult to interpret with regard to cutoff scores. Having established a substantial relationship between CGS and mRS scores (AUC >0.5), we proceeded to CART analysis to derive a specific cutoff score.

MCID–CART Analysis
The CART analysis showed that a CGS of ≥0.16 m/s produced the optimal combination of sensitivity (73.9%, 95% CI=65.9–80.6%) and specificity (57.0%, CI=49.0–64.7%) for detecting improvement in mRS scores among our participants (Fig. 1b and columns 3 and 4 of Fig. 1c). This cutoff score produced the strongest association to the anchor compared with all other potential cutoff scores. This finding is consistent with the trend presented in the ROC curve.

Likelihood Ratios
The LR+ for the CGS MCID of 0.16 m/s was 1.72 (95% CI=1.39–2.12), and the LR– was 0.46 (0.33–0.63). Overall, 47.3% of the participants in the cohort experienced a meaningful improvement in disability level. The overall prevalence rate of improved disability (47.3%) served as the estimated pretest probability that a participant would experience a meaningful change in disability. Using a likelihood ratio nomogram, we determined that a participant who met or exceeded a 0.16-m/s change in CGS had a posttest probability of 60% for experiencing a meaningful change in disability (Fig. 3). In contrast, those who did not meet or exceed a 0.16-m/s CGS change had a posttest probability of only 29% for experiencing a meaningful change in disability.

Discussion
For people between 20 and 60 days after first-time stroke who are ambulatory but have severe gait impairment (eg, mean gait speed=0.18 m/s), we estimate the MCID for gait speed to be 0.16 m/s. We anchored our MCID analysis to the mRS, an
accepted and reliable indicator of disability level. From the patient perspective, walking at faster speeds results in higher levels of participation such as going out of the home for family, recreational, or occupational outings. For the clinician, this reference for meaningful change in gait speed can be used to interpret clinical outcomes, particularly the effectiveness of walking rehabilitation programs.

The mRS is a robust measure of global disability that has convergent validity with the Barthel Index (BI), another common measure of disability poststroke, while avoiding the ceiling effect observed in the BI. Additionally, the mRS is more sensitive than the BI for distinguishing between mild and moderate disability. A recent survival analysis by Huybrechts et al demonstrated the importance of a 1-point shift on the mRS. They found that mRS scores at 3 months poststroke are not only predictive of long-term functional independence but also highly predictive of mortality. For every 1-point improvement on the mRS, participants’ life expectancy was statistically significantly longer. Further support that the relationship between CGS and mRS scores is justified and sound is provided by the ROC curve and the associated AUC, which was substantial (>0.50).

A requirement of valid, longitudinal, anchor-based MCID studies is that time between assessments is sufficient for individuals in the study cohort to experience a clinically meaningful change. We chose to evaluate the time points of 20 and 60 days poststroke because this is a critical time of change when most indi-
individuals are involved in some form of rehabilitation (ie, inpatient rehabilitation, home health care, outpatient therapy). Indeed, across the 20- to 60-day period poststroke, the participants in our study had a mean improvement in gait speed of 0.21 (0.17) m/s. This represents greater than 100% improvement in mean gait speed from T20 to T60. However, not all participants experienced an improvement in speed or disability level, providing sufficient diversity within the population for a difference to be detected between those who experienced at least a minimal clinically important improvement and those who did not.

Clinical Interpretation of MCID
By defining the threshold for clinically important change, we improve our ability to interpret the value of rehabilitation efforts in clinical settings and randomized clinical trials of intervention effectiveness. Thus, an MCID reference value of 0.16 m/s for gait speed could serve as an explicit therapeutic goal for rehabilitation interventions aimed at improving participation levels for inpatients. Not only are higher gait speeds associated with improved function poststroke, but gait speed also is associated with reduced mortality in older adults. Improvement in usual gait speed has been shown to predict a substantial reduction in mortality, whereas a decline in gait speed predicts increased risk for hospitalization and onset of disability among older adults. Another important aspect of maintaining gait speed and high levels of participation is the established benefits of physical activity to reduce stroke risk. Clearly, people with stroke who are at risk for secondary stroke need to be involved in physical activities such as walking to maintain health and wellness. A valid MCID for gait speed improves not only the clinical interpretation of individual rehabilitation programs but also the clinical significance of intervention studies that may find statistical improvements in gait speed but may not achieve a threshold that is clinically meaningful.

Likelihood ratios incorporate sensitivity and specificity and typically are used to describe diagnostic tests. However, in our study, they provided valuable insight into the interpretation of our results by estimating how likely an individual with subacute stroke is to experience an improvement in level of disability based solely on change in gait speed. Of all participants in our study, 47.3% experienced an improvement in level of disability. For an individual with stroke who has characteristics similar to those of our cohort and achieves an improvement in CGS of ≥0.16 m/s, a nomogram and the LR+ of 1.72 estimate that this individual has a 60% probability of experiencing a meaningful change in disability level (Fig. 3). Conversely, an individual who fails to meet or exceed a 0.16-m/s change in CGS has only a 29% probability of experiencing a meaningful change in disability level. Thus, although our MCID estimate for CGS is not a perfect indicator of meaningful change, it provides a valuable reference for identifying meaningful change in clinical and research settings.

What Is the Difference Between MCID and MDC?
Both MCID and MDC provide reference values for interpreting magnitude of change on an outcome measure. The MCID indicates the magnitude of change required to achieve a clinically meaningful change. The MDC indicates the magnitude of change required to exceed test-retest reliability. As mentioned previously, it is important to interpret estimates of MCID in light of random measurement error represented by the MDC. Unfortunately, these 2 measurement constructs may be confusing for the clinician to use and interpret. This confusion is further confounded by studies that do not adhere to optimal design methods for derivation of MDC.

For example, the MDC for CGS among patients with stroke was reported in 3 studies, all during the inpatient subacute phase of recovery (number of subjects ranged from 24 to 35 individuals poststroke). The MDC was reported as 0.12 m/s, 0.17 m/s, and 0.30 m/s. The limitation of these studies is that the test-retest coefficient, an integral component of MDC derivation, was derived during a time of rapid recovery. Deviation of test-retest reliability in a changing population potentially overestimates variability, causing inflation of the MDC. The smallest real difference (SRD) is considered the same construct as the MDC. Perera et al estimated SRD to be 0.05 m/s for decline in gait speed among older adults, 14% of whom were people with chronic stroke. Similarly, among individuals following a hip fracture, the MDC for gait speed was determined to be 0.08 m/s. Thus, it appears that the MDC for gait speed in older adults and most likely in people with stroke is more in the range of 0.05 to 0.08 m/s, rather than the reported range of 0.12 to 0.30 m/s. Additional study of MDC in people with stroke who are not expected to make gains through natural recovery and are not participating in a rehabilitation program is needed.

Magnitude of change for MCID is driven by characteristics of the population studied. The MCID of 0.16 m/s found in our study is similar to, although slightly larger than, findings in other populations. Palombo et al estimated an MCID of 0.10 m/s for habitual gait speed among elderly people after hip fracture with a mean (SD) initial CGS of 0.66 (0.28) m/s (range = 0.14 – 1.33 m/s). Perera et al estimated “substantial mean-
Meaningful Gait Speed Improvement Poststroke

ingful change” for decline in gait speed among older adults to be 0.10 m/s in a population with initial mean (SD) gait speeds ranging from 0.65 (0.28) m/s to 0.88 (0.24) m/s. Participants in the present study, with a mean (SD) CGS of 0.18 (0.16) m/s at T20, had relatively severe initial gait speed impairments. It may be that a larger magnitude of change in speed is required to produce meaningful change in people with more-severe deficits. Future analyses of patients with mild impairment secondary to stroke are needed and may produce smaller values for MCID.

Strengths and Limitations

This study had several strengths. We were able to prospectively follow a large cohort of participants recruited from 5 distinct geographic locations during a time of rapid change in walking recovery poststroke.258 Data for outcome measures were collected using a standardized protocol by therapists who had completed rigorous training and competency testing. Our analysis included the traditional method of ROC curve analysis combined with a quantitative CART analysis. Finally, the mRS is a robust measure that captures small, but clearly important, changes in global disability. By using the mRS, we are able to understand the smallest magnitude of CGS improvement likely to contribute a meaningful change in disability level for individual patients during the subacute phase poststroke.

Our MCID estimate was 73.9% sensitive and 57.0% specific to improvement in mRS scores. The lack of precision (sensitivity and specificity) of our MCID estimate may be considered a limitation. However, the mRS does not directly correlate with gait speed because it is a global measure of disability. Disability from the individual perspective is a complex and multivariate phenomenon that encompasses more than gait speed. Thus, gait speed, an activity-level measure of mobility, is one of many variables (eg, arm and hand function, cognition level, emotional impairment, bowel and bladder control, pain) that contribute to mRS score.59 We consider improvement on the mRS to be a robust anchor for determining CGS MCID because it reflects change on a participation level that is important from the individual perspective.

Another possible limitation is that participants were allowed to use different assistive devices at the 2 time points. Due to the acuity of our participants (mean = 21.9 days poststroke at T20), we expect that spontaneous neurologic recovery and response to therapeutic interventions are occurring simultaneously. Thus, an ecologically valid (ie, real-life) MCID for CGS would reflect both the expected changes associated with time poststroke (ie, acute, subacute, chronic)60 and the beneficial effects expected of therapy. That is, we are interested in the real-life change in gait speed regardless of assistive device.

Additional studies are needed to expand our understanding of MCID for gait speed among individuals with stroke. Other anchors also should be used to develop additional estimates of MCID, including measures that directly assess patients’ perspective of change. Ideally, over time a relatively narrow range of MCID estimates will emerge that clinicians can use to more definitively understand the minimal amount of change in gait speed likely to represent clinically meaningful change for individual patients. Other subsets of people with stroke also should be studied. For example, in this study, there were insufficient participants with moderate gait speed deficits (≥ 0.4 to 0.8 m/s) at initial evaluation to support subanalysis by gait speed severity. Likewise, people who were able to walk at speeds of >0.8 m/s were excluded from the study. The MCID needs to be determined for people with stroke across various time frames and levels of severity.

Conclusion

We estimate that the MCID for gait speed among patients with subacute stroke and severe gait speed impairments is 0.16 m/s. Thus, patients with similar characteristics who increase their gait speed ≥0.16 m/s are more likely to experience a meaningful improvement in disability level than those who do not. This reference value can be used by clinicians to develop goals and interpret progress in patients with subacute stroke. The MCID estimate also is useful for interpretation of walking intervention effectiveness studies.

The authors acknowledge the participants who dedicated their time to this study and the contributions of the following members of the LEAPS investigative team: Brooks Rehabilitation Hospital, Jacksonville, Florida: Trevor Paris, MD, Deborah Stewart, MD, and Joann Gallicchio, PT; Florida Hospital Rehabilitation and Sports Medicine, Orlando, Florida: Mitchell Freed, MD, Michelle Dolske, PhD, Craig Moore, PT, and Bettina Brutsch, PT; Long Beach Memorial Medical Center, Long Beach, California: H. Richard Adams, MD, Demha Hoang, MD, and Anita Correa, PT; Sharp Memorial Rehabilitation Center, San Diego, California: Jerome Stenehjem, MD, Roxanne Hon, MD, and Molly McLeod, PT; USC PT Associates, Los Angeles, California: David Alexander, MD, Julie Hershberg, PT, DPT, and Samneang Ith-Chang, PT, DPT. Locomotor Experience Applied Post-Stroke
Meaningful Gait Speed Improvement Poststroke


Meaningful Gait Speed Improvement Poststroke

60 Sullivan KJ. Letter to the editor on “Modified constraint-induced therapy in patients with chronic stroke exhibiting minimal movement ability in the affected arm.” Phys Ther. 2007;87:1560.