Agreement and Accuracy of Ambulatory Definitions in Duchenne Muscular Dystrophy: A Cross-Sectional Analysis

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Introduction

- Duchenne muscular dystrophy (DMD) is a rare, X-linked neuromuscular disease that results in progressive muscle weakness[1,2]
- While there is no standard definition of "ambulatory" in DMD, loss of ambulation (LOA) is a critical milestone in the progression of DMD[3,4]
- Different metrics for categorization of ambulatory ability are used across a variety of settings (research, clinical trials, registries) and stakeholders (researchers, clinicians, patients, payers):
  - Physician- or patient/caregiver-reported attestation,
  - Patient/caregiver-reported continuous wheelchair use,[5] and/or
  - Physician-verified functional metric (eg, inability to complete the 10-meter walk/run [10MWR] test, the 6-minute walk test [6MWT], or the North Star Ambulatory Assessment [NSAA])[6-8]
- Payers often restrict access to approved DMD therapies based on ambulatory status[9-11]
- Therefore, it is important to understand whether heterogeneous definitions used to describe LOA are indirectly impacting patient access to therapies covered by different plans

Objective

To evaluate the agreement and accuracy of various functional assessments used to categorize ambulatory status in patients with DMD (**scan QR code for details**)

Methods

- Data were collected from the Cooperative International Neuromuscular Research Group Duchenne Natural History Study (CINRG DNHS), a prospective cohort of patients with DMD (aged 2–28 years) enrolled at 20 centers around the world from 2006–2016
- Patients were followed up for 10 years, with assessments obtained every 3 months for 1 year, at 18 months, and annually thereafter
- In this analysis, patients were required to have at least 1 result recorded for the 10MWR and 6MWT at the same visit (index date) and to be at least 7 years of age at index date
- A second analysis was completed in patients who had results available for NSAA and wheelchair frequency variables
- The method for determining sensitivity, specificity, and predictive values is in **Supplemental Table 1**; the inability to complete a functional test was considered a negative result (**scan QR code for additional methods details**)

Results

Baseline characteristics

- 121 patients with DMD were included in the 10MWR/6MWT analysis; 127 were included in the NSAA/CINRG DNHS analysis (**Table 1**)
- At index, patients in both analyses had been observed for a median of ~3 years
- Most patients were ambulatory per the CINRG DNHS definition (no or part-time wheelchair use); median age at LOA was 10 years

Table 1 *Population and Patient Demographics at Index Date*

Population	10MWR/6MWT	NSAA/CINRG DNHS
Patients enrolled in CINRG DNHS registry 2006–2016	440 (100%)	440 (100%)
Both test results at same visit	149 (33.9%)	156 (35.5%)
At least 7 years of age at index date	121 (27.5%)	127 (28.9%)
Patient demographics at index date		
Age at DMD diagnosis, years	N=118[a]	N=124[a]
Mean (SD)	4.4 (2.10)	4.4 (2.10)
Observation time up to index date, days	N=121	N=127
Mean (SD)	1596.0 (1122.58)	1660.2 (1132.23)
Median (min–max)	1106.0 (0–3311)	1112.0 (0–3311)
Age at index date, years	N=121	N=127
Mean (SD)	10.8 (3.47)	11.0 (3.54)
Median (min–max)	9.3 (7–22)	9.4 (7–22)
Ambulation status (CINRG DNHS); n (%)	N=121	N=127
Ambulatory	109 (90.1)	114 (89.8)
Nonambulatory[b]	12 (9.9)	13 (10.2)
Age at LOA, years	N=12	N=12
Mean (SD)	10.3 (2.48)	10.2 (2.37)
Median (min–max)	10.0 (5–14)	10.0 (5–14)

Note: Values are n (%) unless otherwise stated. [a]Data for 3 patients were not available at index date. [b]Patients in the CINRG DNHS population who met the inclusion/exclusion criteria for the study and experienced LOA beforehand.
6MWT=6-minute walk test; 10MWR=10-meter walk/run; CINRG DNHS=Cooperative International Neuromuscular Research Group Duchenne Natural History Study; DMD=Duchenne muscular dystrophy; LOA=loss of ambulation; NSAA=North Star Ambulatory Assessment.

LOA using 6MWT vs 10MWR

- There was weak to moderate agreement between the 10MWR and 6MWT, with the greatest agreement for the 6MWT ≥180-meter threshold of ambulatory (**Table 2A**)
- Compared with the 10MWR 30-second threshold, the 6MWT 300-meter threshold identified 71% of the same ambulatory (sensitivity) and 100% of the same nonambulatory (specificity) patients (**Table 2B; Supplemental Table 2**)
- The sensitivity of the 6MWT to correctly identify the same ambulatory patients improved to 90% when the threshold was lowered to 180 meters; there was no effect of a lower threshold on specificity (**Table 2B; Supplemental Table 2**)

Table 2 *Agreement of 6MWT Compared With 10MWR Test and Accuracy Compared With 10MWR Test <30-Second Threshold for Ambulatory*

		Reference Standard	
A	**6MWT Threshold for Ambulatory**	**10MWR Test, <30-Second Threshold Kappa Coefficient (95% CI)**	**Level of Agreement**
	≥300 meters	0.41 (0.26–0.56)	Weak
	≥250 meters	0.61 (0.44–0.77)	Moderate
	≥200 meters	0.70 (0.54–0.86)	Moderate
	≥180 meters	0.73 (0.57–0.88)	Moderate

B	**6MWT Threshold for Ambulatory**	**Parameter**	**Estimate**	**95% CI**	
	≥300 meters	Sensitivity	0.71	0.62–0.80	~29% of patients might be denied therapy coverage if an ambulatory requirement uses a 6MWT ≥300-meter threshold instead of a 10MWR <30-second threshold
		Specificity	1.00	1.00–1.00	
		PPV	1.00	1.00–1.00	
		NPV	0.36	0.22–0.50	
	≥180 meters	Sensitivity	0.90	0.85–0.96	~10% of patients might be denied therapy coverage if an ambulatory requirement uses a 6MWT ≥180-meter threshold instead of a 10MWR <30-second threshold
		Specificity	1.00	1.00–1.00	
		PPV	1.00	1.00–1.00	
		NPV	0.63	0.45–0.81	

6MWT=6-minute walk test; 10MWR=10-meter walk/run; NPV=negative predictive value; PPV=positive predictive value.

LOA using 10MWR vs CINRG DNHS

- There was strong agreement between the CINRG DNHS definition of ambulatory and the 10MWR <30-second threshold for ambulatory (**Table 3A; Supplemental Table 2**)
- Compared with the CINRG DNHS definition, the 10MWR <30-second threshold correctly identified 95% of the same ambulatory (sensitivity) and 100% of the same nonambulatory (specificity) patients (**Table 3B**)

Table 3 *Agreement/Accuracy of 10MWR Compared With CINRG DNHS Definition*

A	**10MWR Test Threshold for Ambulatory**	**CINRG DNHS Definition of Ambulatory Kappa Coefficient (95% CI)**	**Level of Agreement**
	<30 seconds	0.80 (0.64–0.97)	Strong

B	**10MWR <30-Second Threshold for Ambulatory Compared With CINRG DNHS Definition**			
	Parameter	**Estimate**	**95% CI**	
	Sensitivity	0.95	0.91–0.99	This represents ~5% of patients who could potentially be denied coverage for a therapy if required to be "ambulatory" by the 10MWR <30-second threshold rather than the CINRG DNHS definition
	Specificity	1.00	1.00–1.00	
	PPV	1.00	1.00–1.00	
	NPV	0.71	0.49–0.92	

10MWR=10-meter walk/run; CINRG DNHS=Cooperative International Neuromuscular Research Group Duchenne Natural History Study; NPV=negative predictive value; PPV=positive predictive value.

LOA using 6MWT vs CINRG DNHS

- There was weak agreement beyond chance alone between the CINRG DNHS definition and the 6MWT definition of ambulatory at any threshold (**Table 4A**)
- Compared with the CINRG DNHS definition, the 6MWT 180-meter threshold correctly identified 86% of the same ambulatory (sensitivity) and 100% of the same nonambulatory (specificity) patients (**Table 4B**)

Table 4 *Agreement/Accuracy of 6MWT Compared With CINRG DNHS Definition*

A	**6MWT Threshold for Ambulatory**	**CINRG Definition of Ambulatory Kappa Coefficient (95% CI)**	**Level of Agreement**
	≥300 meters	0.30 (0.16–0.44)	Minimal
	≥250 meters	0.45 (0.28–0.63)	Weak
	≥200 meters	0.54 (0.35–0.72)	Weak
	≥180 meters	0.55 (0.37–0.74)	Weak

B	**Threshold**	**Parameter**	**Estimate**	**95% CI**	
	≥300 meters	Sensitivity	0.71	0.62–0.80	This represents ~32% and ~14% of patients who could potentially be denied coverage for a therapy if required to be "ambulatory" by the 6MWT ≥300-meter threshold or ≥180-meter threshold, respectively, rather than the CINRG DNHS definition
		Specificity	1.00	1.00–1.00	
		PPV	1.00	1.00–1.00	
		NPV	0.36	0.22–0.50	
	≥180 meters	Sensitivity	0.90	0.85–0.96	
		Specificity	1.00	1.00–1.00	
		PPV	1.00	1.00–1.00	
		NPV	0.63	0.45–0.81	

6MWT=6-minute walk test; CINRG DNHS=Cooperative International Neuromuscular Research Group Duchenne Natural History Study; NPV=negative predictive value; PPV=positive predictive value.

LOA using NSAA vs CINRG DNHS

- There was moderate agreement between the CINRG DNHS definition of ambulatory and the NSAA threshold of total score ≥1, but minimal and no agreement with the NSAA threshold of total score ≥17 and all domains ≥1, respectively (**Table 5**)
- The sensitivity of NSAA to correctly identify ambulatory patients improved to 89% with a threshold of total score ≥1

Table 5 *Agreement/Accuracy of NSAA Compared With CINRG DNHS Definition*

A	**NSAA Score Threshold for Ambulatory**	**CINRG DNHS Definition of Ambulatory Kappa Coefficient (95% CI)**	**Level of Agreement**
	All domains ≥1	0.12 (0.05–0.19)	None
	Total score ≥17	0.25 (0.13–0.36)	Minimal
	Total score ≥1	0.64 (0.45–0.82)	Moderate

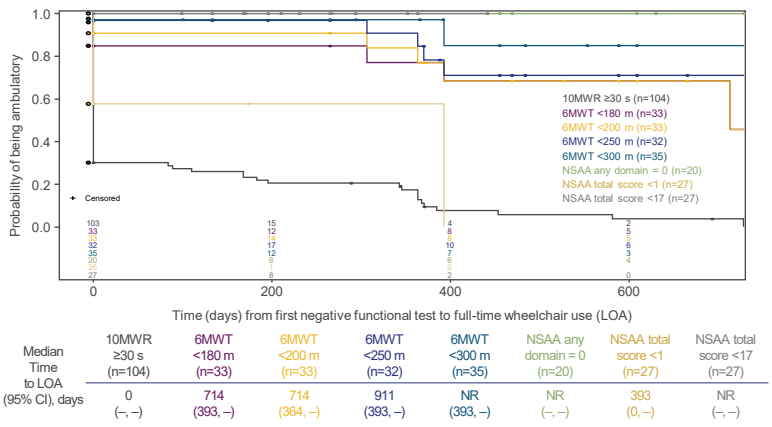
B	**NSAA Threshold for Ambulatory**	**Parameter**	**Estimate**	**95% CI**	
	All domains ≥1	Sensitivity	0.40	0.31–0.49	This represents ~60%, ~39%, and ~11% of patients who could potentially be denied coverage for a therapy if required to be "ambulatory" by all NSAA domains ≥1, total score ≥17, or total score ≥1 thresholds, respectively, rather than the CINRG DNHS definition
		Specificity	1.00	1.00–1.00	
		PPV	1.00	1.00–1.00	
		NPV	0.16	0.08–0.24	
	Total score ≥17	Sensitivity	0.61	0.52–0.70	
		Specificity	1.00	1.00–1.00	
		PPV	1.00	1.00–1.00	
		NPV	0.23	0.12–0.34	
	Total score ≥1	Sensitivity	0.89	0.84–0.95	
		Specificity	1.00	1.00–1.00	
		PPV	1.00	1.00–1.00	
		NPV	0.52	0.32–0.72	

CINRG DNHS=Cooperative International Neuromuscular Research Group Duchenne Natural History Study; NPV=negative predictive value; NSAA=North Star Ambulatory Assessment; PPV=positive predictive value.

Time from LOA by 10MWR, 6MWT, and NSAA to LOA by CINRG DNHS definition

- While sample sizes were small, this analysis indicated:
  - If 6MWT thresholds were used by payers to determine ambulation, >50% of patients would be classified as nonambulatory ≥2 years before they report full-time wheelchair use (**Figure 1**)
  - If NSAA total score of <17 or any domain = 0 thresholds were used, all patients would be classified as nonambulatory >2 years before full-time wheelchair use; with NSAA total score <1, over 50% would be classified as nonambulatory >1 year before full-time wheelchair use (**Figure 1**)

Figure 1 *Time Between First Results of 10MWR, 6MWT, and NSAA Used to Categorize Nonambulatory and First Record of Nonambulatory in CINRG DNHS[a]*



Median Time to LOA (95% CI), days	10MWR ≥30 s (n=104)	6MWT <180 m (n=33)	6MWT <200 m (n=33)	6MWT <250 m (n=32)	6MWT <300 m (n=35)	NSAA any domain = 0 (n=20)	NSAA total score <1 (n=27)	NSAA total score <17 (n=27)
	0 (–, –)	714 (393, –)	714 (364, –)	911 (393, –)	NR (393, –)	NR (–, –)	393 (0, –)	NR (–, –)

[a]Data shows thresholds for nonambulatory whereas the rest of the poster shows thresholds for ambulatory.
6MWT=6-minute walk test; 10MWR=10-meter walk/run; CINRG DNHS=Cooperative International Neuromuscular Research Group Duchenne Natural History Study; m=meter(s); NR=not reached; NSAA=North Star Ambulatory Assessment; s=second(s).

Results from additional analyses in patients who physicians viewed as having enough ambulatory function to attempt additional assessments after a negative 6MWT result are shown in Supplemental Table 3 (scan QR code for details)

Key Finding(s)

While physician attestation of ambulatory ability should be sufficient documentation of medical necessity, there is a need for standard criteria to identify ambulatory vs nonambulatory patients with DMD when a specific test is needed to anchor the data, such as research or policy eligibility screening

Conclusions

Across the 10MWR, 6MWT, and NSAA, the specificity of the tests was better than the sensitivity values

- This means that no participant considered nonambulatory by the reference test was falsely considered ambulatory by the screening test, regardless of the threshold evaluated

The various levels of misclassification of patients with DMD as ambulatory may result in patients being denied access to treatment should a payer policy use quantitative measures to define ambulatory rather than nonambulatory, resulting in unequal access to treatment

The use of the 10MWR <30-second threshold was the best-suited definition for ambulation after physician attestation

Regardless of the comparator or threshold, the 6MWT performed especially poorly as a measure of ambulation in patients with DMD, with up to approximately one third of ambulatory patients misclassified as nonambulatory

After a negative 6MWT result, physicians view up to 80% of patients as having enough ambulatory function to attempt additional assessments at subsequent visits

NSAA, even at a threshold of total score ≥1, was less accurate than the 10MWR; NSAA total score ≥17 or all domains ≥1 performed more poorly than any thresholds of the 6MWT

Use of 6MTW or NSAA to define LOA would classify patients as nonambulatory years before physicians would consider them nonambulatory

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October 8–12, 2024; Prague, Czech Republic

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Methods (cont)

Supplemental Table 1

Method for Determining Sensitivity, Specificity, and Predictive Values

	Reference Standard		
Comparator Metric	**Ambulatory**	**Nonambulatory**	
Ambulatory	True positives (TP)	False positives (FP)	← Positive predictive value (PPV): Proportion of TP if test positive
Nonambulatory	False negatives (FN)	True negatives (TN)	← Negative predictive value (NPV): Proportion of TN if test negative
	↑ Sensitivity (Se): Proportion of TP	↑ Specificity (Sp): Proportion of TN	

Note: The inability to complete a functional test was considered a negative result.

Outcomes assessed:

Primary

- Assuming the 10MWR as the reference standard to categorize patients with DMD as ambulatory vs nonambulatory:
  - Agreement between the 10MWR and the 6MWT
  - Estimated accuracy (ie, sensitivity, specificity, and predictive values) of the 6MWT compared with the 10MWR

Secondary

- Assuming the definition of ambulation (no or not full-time wheelchair use) used in the CINRG DNHS[5] as the reference standard to categorize DMD as ambulatory vs nonambulatory:
  - Accuracy (ie, sensitivity, specificity, and predictive values) of the 10MWR and the 6MWT compared with the CINRG DNHS definition
  - Time from LOA by 6MWT/10MWR test to LOA by CINRG DNHS definition
  - Estimated accuracy of different cutpoints for the NSAA compared with the CINRG DNHS definition
  - Estimated receiver operating characteristic (ROC) curves by varying thresholds of the NSAA
  - Time gap between the results of the NSAA used to categorize ambulatory and the first record of nonambulatory in CINRG DNHS

Exploratory

- Exploratory analyses of whether additional tests (10MWR or 6MWT) are performed after a recorded 10MWR and/or 6MWT result that categorizes a patient with DMD as nonambulatory

Results (cont)

Accuracy measures

- Among patients who would be denied access to therapies based on payer policies that cite 6MWT as a measure of ambulation, a range of 56% to 74% do not report full-time wheelchair use in this study (**Supplemental Table 2**)

Supplemental Table 2 *Accuracy Measures: Sensitivity, Specificity, and Predictive Values*

	Reference Standard CINRG DNHS Self-Reported Wheelchair Use			Reference Standard 10MWR Test Result		
6MWT Result	**None or Not Full-Time Ambulatory (N=109)**	**Full-Time Nonambulatory (N=12)**		**<30 Seconds Ambulatory (N=104)**	**≥30 Seconds or UTC Nonambulatory (N=17)**	
≥300 meters (ambulatory), n (%)	74 (68)	0	PPV 1.00 (1.00–1.00)	74 (71)	0	PPV 1.00 (1.00–1.00)
<300 meters or UTC (nonambulatory), n (%)	35 (32)	12 (100)	NPV 0.26 (0.13–0.38)	30 (29)	17 (100)	NPV 0.36 (0.22–0.50)
	Se 0.68 (0.59–0.77)	**Sp 1.00 (1.00–1.00)**		**Se 0.71 (0.62–0.80)**	**Sp 1.00 (1.00–1.00)**	
≥250 meters (ambulatory), n (%)	88 (81)	0	PPV 1.00 (1.00–1.00)	88 (85)	0	PPV 1.00 (1.00–1.00)
<250 meters or UTC (nonambulatory), n (%)	21 (19)	12 (100)	NPV 0.36 (0.20–0.53)	16 (15)	17 (100)	NPV 0.52 (0.34–0.69)
	Se 0.81 (0.73–0.88)	**Sp 1.00 (1.00–1.00)**		**Se 0.85 (0.78–0.92)**	**Sp 1.00 (1.00–1.00)**	
≥200 meters (ambulatory), n (%)	93 (85)	0	PPV 1.00 (1.00–1.00)	93 (89)	0	PPV 1.00 (1.00–1.00)
<200 meters or UTC (nonambulatory), n (%)	16 (15)	12 (100)	NPV 0.43 (0.25–0.61)	11 (11)	17 (100)	NPV 0.61 (0.43–0.79)
	Se 0.85 (0.79–0.92)	**Sp 1.00 (1.00–1.00)**		**Se 0.89 (0.84–0.95)**	**Sp 1.00 (1.00–1.00)**	
≥180 meters (ambulatory), n (%)	94 (86)	0	PPV 1.00 (1.00–1.00)	94 (90)	0	PPV 1.00 (1.00–1.00)
<180 meters or UTC (nonambulatory), n (%)	15 (14)	12 (100)	NPV 0.44 (0.26–0.63)	10 (10)	17 (100)	NPV 0.63 (0.45–0.81)
	Se 0.86 (0.80–0.93)	**Sp 1.00 (1.00–1.00)**		**Se 0.90 (0.85–0.96)**	**Sp 1.00 (1.00–1.00)**	

10MWR Result	**None or Not Full-Time Ambulatory (N=109)**	**Full-Time Nonambulatory (N=12)**	
<30 seconds (ambulatory), n (%)	104 (95)	0	PPV 1.00 (1.00–1.00)
≥30 seconds or UTC (nonambulatory), n (%)	5 (5)	12 (100)	NPV 0.71 (0.49–0.92)
	Se 0.95 (0.91–0.99)	Sp 1.00 (1.00–1.00)	

NSAA Result	**None or Not Full-Time Ambulatory (N=114)**	**Full-Time Nonambulatory (N=13)**	
Total score ≥1 (ambulatory), n (%)	102 (89)	0	PPV 1.00 (1.00–1.00)
Total score 0 or UTC (nonambulatory), n (%)	12 (11)	13 (100)	NPV 0.52 (0.32–0.72)
	Se 0.89 (0.84–0.95)	**Sp 1.00 (1.00–1.00)**	
Total score ≥17 (ambulatory), n (%)	70 (61)	0	PPV 1.00 (1.00–1.00)
Total score <17 or UTC (nonambulatory), n (%)	44 (39)	13 (100)	NPV 0.23 (0.12–0.34)
	Se 0.61 (0.52–0.70)	**Sp 1.00 (1.00–1.00)**	
All domains ≥1 (ambulatory), n (%)	46 (40)	0	PPV 1.00 (1.00–1.00)
Any domain 0 or UTC (nonambulatory), n (%)	68 (60)	13 (100)	NPV 0.16 (0.08–0.24)
	Se 0.40 (0.31–0.49)	**Sp 1.00 (1.00–1.00)**	

NOTE: Values are median (range), unless otherwise stated. A missing value following a completed test was considered UTC.
6MWT=6-minute walk test; 10MWR=10-meter walk/run; CINRG DNHS=Cooperative International Neuromuscular Research Group Duchenne Natural History Study; NPV=negative predicted value; NSAA=North Star Ambulatory Assessment; PPV=positive predicted value; Se=sensitivity; Sp=specificity; UTC=unable to complete the test due to disease progression.

Additional tests after classification of nonambulatory by payer

- After a first negative 10MWR test result (≥30 seconds), only 3.8% (n=3/80) of patients with DMD who had subsequent study visits had additional functional tests (10MWR or 6MWT) performed (**Supplemental Table 3**)
- After a first negative 6MWT result (<180 meters), 64.3% (n=9/14) of patients with DMD who had subsequent study visits had additional functional tests (10MWR or 6MWT) performed
- This proportion increased to 80% for the 6MWT threshold of 300 meters

Supplemental Table 3 *Additional Tests After Classification of Nonambulatory by Payer*

Additional Testing, n (%)	10MWR ≥30 seconds (N=104)	6MWT <180 meters (N=33)	6MWT <200 meters (N=33)	6MWT <250 meters (N=32)	6MWT <300 meters (N=35)
No	77 (74.0)	5 (15.2)	6 (18.2)	7 (21.9)	3 (8.6)
10MWR only	2 (1.9)	1 (3.0)	1 (3.0)	1 (3.1)	1 (2.9)
10MWR and 6MWT	1 (1.0)	8 (24.2)	9 (27.3)	12 (37.5)	11 (31.4)
No subsequent visits	24 (23.1)	19 (57.6)	17 (51.5)	12 (37.5)	20 (57.1)

6MWT=6-minute walk test; 10MWR=10-meter walk/run.