TDIS™

User Guide

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Tardive Dyskinesia Impact Scale

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Introduction

Tardive dyskinesia (TD) is an involuntary, hyperkinetic, persistent, and potentially disabling movement disorder in which individuals experience abnormal involuntary movements. It results from long-term exposure to dopamine receptor-blocking agents used to treat psychiatric conditions such as schizophrenia, major depressive disorder, and bipolar disorder.[1,2] These uncontrolled movements can have profound negative impacts on physical, cognitive, and psychosocial functioning.[3]

Historically, the burden of TD has been underrecognized, as it was primarily associated with long-term schizophrenia and first-generation antipsychotic use. However, the expanding use of antipsychotics for bipolar disorder, major depressive disorder, and off-label indications may increase TD prevalence and underscores the need for improved recognition and understanding of its impact on health-related quality of life.[4,5]

In addition to motor symptoms, TD can negatively affect daily functioning as well as socioemotional well-being, highlighting the importance of assessing its broader impact. As such, the Tardive Dyskinesia Impact Scale (TDIS), a novel, TD-specific, fit-for-purpose, patient-reported outcome (PRO), was developed with patient and caregiver input.[6]

Overview of the Tardive Dyskinesia Impact Scale (TDIS)

The TDIS is the first and only psychometrically validated PRO specific for TD developed to measure the physical, social, and emotional impacts of TD symptoms in adults with moderate to severe TD lasting ≥ 3 months and a diagnosis of a psychotic or mood disorder. Its measurement properties have been evaluated in accordance with the principles outlined in the FDA's Patient-Focused Drug Development guidance documents.[7–10] The questionnaire contains 11 items assessing the effect of uncontrollable movements on the respondent's life, with a recall period of the past 7 days. There are 3 sets of response options: (1) Not at all, Slightly, Moderately, Very, and Extremely; (2) Never, Rarely, Sometimes, Most of the time, and All the time; and (3) Never, Rarely, Sometimes, Most times, and Every time. The questionnaire is scored to produce 2 domains. The Physical Impact domain includes 8 items, and the Socioemotional Impact domain includes 3 items. Total scores range from 0 to 44, with higher scores representing greater impairment.

Administration Guidelines

The TDIS is designed to be self-administered by individuals with TD. The questions are written at an eighth-grade reading level. Please ensure individuals have the basic cognitive abilities necessary to provide reliable data. When handing the TDIS to the participant to complete, please use the following guidelines:

DOs

- Become familiar with the TDIS.
- Ask patients to complete the TDIS before undergoing any clinical procedures or physical exams.
- Provide patients with a private room (ideally) or at least a clipboard with the TDIS to complete while in the waiting room.
- Provide patients with ample time to complete the TDIS. It should take less than 10 minutes to complete.
- Address any questions the patient may have about completing the TDIS, but don't tell them how they should respond to any of the questions.
- Visually scan the completed TDIS to make sure no responses were unintentionally omitted or that more than one response was provided. If the response to a question is missing, confirm that the patient intended not to provide a response.

DON'Ts

- Don't interpret or answer any of the TDIS questions on behalf of the patient. Instead, restate the question and ask the patient to answer it the best he or she can.
- Don't interview the the patient to gather their responses. The TDIS should be self-administered by the patient.

Reminders for Patients

- Answer each question to the best of their ability.
- There are no right or wrong answers.
- Pay close attention to the timeframe of interest (the past 7 days).
- Only provide one response per question.
- There is no need to provide any additional text in the margins of the TDIS to explain their responses.

Scoring Instructions

The TDIS consists of 11 items, each scored on a 5-point scale ranging from 0 to 4, where higher scores indicate worse symptom impact. Item responses are used in the calculation as recorded, and no reverse scoring is required. **Table 1** presents the response options by item.

Table 1. Response options by item

Response value	Items 1, 3-6 (Intensity)	Items 2, 7-8 (Frequency)	Items 9-11 (Frequency)
0	Not at all	Never	Never
1	Slightly	Rarely	Rarely
2	Moderately	Sometimes	Sometimes
3	Very	Most of the time	Most times
4	Extremely	All the time	Every time

Two domain scores and one Total Score are calculated by summing item responses. The **Physical Impact** score is computed as the sum of items 1 to 8, with a possible score range of 0 to 32. The **Socioemotional Impact** score is the sum of items 9 to 11, with a possible score range of 0 to 12. The **Total Score** is the sum of all 11 items and ranges from 0 to 44.

All items contributing to a score must be completed in order to calculate that score. No imputation or prorating of missing items is permitted.

Higher scores on the domains of Physical Impact and Socioemotional Impact and the Total Score indicate greater symptom impact. Domain scores reflect impact within their respective areas (physical or socioemotional), and the Total Score reflects overall symptom impact across the instrument.

Table 2 presents a summary of the scoring instructions, theoretical range, and interpretation for each domain score and the Total Score.

Table 2. Summary of scoring and interpretation

Scale	Items	Scoring	Theoretical Score Range and Interpretation
Domain 1: Physical Impact	1-8	Sum items 1-8	0-32; higher scores reflect greater physical impact
Domain 2: Socioemotional Impact	9-11	Sum items 9-11	0-12; higher scores reflect greater socioemotional impact
Total Score	1-11	Sum items 1-11	0-44; higher scores reflect greater physical and socioemotional impact

Summary of TDIS Development

The TDIS was developed from the Tardive Dyskinesia Rating Scale (TDRS), which was an adaptation of both the Unified Dyskinesia Rating Scale and the Abnormal Involuntary Movement Scale (AIMS). The TDRS contains 23 items assessing the severity of dyskinesia, impairment, and disability. Limitations of the TDRS include its length (>20 items), the requirement for both patient/caregiver and clinician completion, and overlap with items assessed in the AIMS.

The TDIS was developed in accordance with available FDA Patient-Focused Drug Development guidance documents.[9,10] This included undertaking a focused literature review in PubMed and conducting qualitative research with patients and caregivers. The first qualitative research study sought to understand which symptoms and impacts of TD were most important to patients and caregivers. Using information gained from that study, a second qualitative research study involved debriefing interviews with patients with TD to determine if the TDIS was relevant and if it was being interpreted as intended.

Participants in both studies included adults diagnosed with a psychotic or mood disorder with dopamine receptor-blocking agent-induced TD who were aware of their abnormal movements (score ≥ 1 [aware, no distress through severe distress] on the AIMS item 10: Patient's awareness of abnormal movements). To be eligible, individuals with TD were required to have a score of 3 (moderate) or 4 (severe) on question 8 (Severity of abnormal movements) of the AIMS. Caregivers had to be caring for someone with TD for > 6 months. A total of 22 individuals with TD and 11 caregivers from 8 clinical sites in the US were enrolled and took part in the interview. The purpose of the first half of the interview was to understand the main symptoms, signs, and impacts experienced. In the second half of the interview, specific parts of the TDRS were cognitively debriefed with participants. The most common impacts of TD were unwanted social attention (76%), difficulty speaking (64%), and social isolation (55%). The most common movements reported were in the tongue (61%) and jaw (58%), which were also reported to be the most bothersome movements. Concepts in the TDRS endorsed by more than half the participants included difficulty chewing and swallowing, dressing, handwriting, participating in hobbies, hygiene, dyskinesia pain, difficulty in public/social settings, speech, and walking and balance. Saturation of concepts was reached, and the results of this first study were used to inform the development of the TDIS items.

In the second study, the draft TDIS was cognitively debriefed with 20 individuals identified from 4 clinical sites in the US. Ninety percent of participants found the instructions to be clear, with the exception of 7 individuals who found the word "dyskinesias" to be unclear; therefore, the term was revised to "uncontrollable movements." Most participants found the recall period of the "past 7 days" to be easy to consider. The concepts participants found to be most relevant included receiving unwanted attention (75%), difficulty speaking (70%), and feeling embarrassed (70%). Based on the feedback obtained during these interviews, minor revisions were made to the TDIS.

The finalized version of the TDIS (Farber et al, 2024)[6] contains the following 11 items:

Question
Over the past 7 days, how difficult was it for you to **speak** due to the uncontrollable movements of your tongue, jaw, lips or mouth?
Over the past 7 days, how often have you **made noises with your mouth** (for example, lip smacking, tongue clicking) due to uncontrollable movements of your tongue, jaw or lips?
Over the past 7 days, how difficult was it for you to **swallow** due to the uncontrollable movements of your tongue, jaw, lips or mouth?
Over the past 7 days, how difficult was it for you to **grip objects** (for example, a zipper, buttons, fork or knife, cup or glass, toothbrush) due to the uncontrollable movements of your hands, arms, or fingers?
Over the past 7 days, how difficult was it for you to **write or type** due to the uncontrollable movements of your hands, arms, or fingers?
Over the past 7 days, how difficult was it for you to **walk** due to the uncontrollable movements of your legs, feet or toes? Only consider difficulty **due to uncontrollable movements of your legs, feet or toes**.
Over the past 7 days, how often did you lose your **balance** due to the uncontrollable movements?
Over the past 7 days, how often have you experienced any **pain** due to the uncontrollable movements?
Over the past 7 days, when you were around other people, how often did you receive **unwanted attention from others** (for example, looks or comments from others), due to the uncontrollable movements?
Over the past 7 days, when you were around other people, how often did you feel **embarrassed** due to the uncontrollable movements?
Over the past 7 days, when you were around other people, how often did you feel **self-conscious** due to the uncontrollable movements?

Measurement Properties and Meaningful Change

The minimal clinically important difference (MCID) for the TDIS has been evaluated and are documented in the published literature; readers are referred to these publications for detailed methodology and results.[11,12] These analyses, conducted using data from several clinical trials in psychotic disorders and mood disorders, provide evidence supporting the reliability, validity, and interpretability of the instrument, including the estimation of a threshold for meaningful change in the TDIS Total Score. A summary of key findings is provided below.

Reliability

The TDIS demonstrated strong reliability in individuals participating in the KINECT® 3 and KINECT® 4 clinical trials.[11,12] Internal consistency reliability was high, indicating that the items consistently measure a common underlying construct, with no items identified as problematic. Test–retest reliability was also strong, supporting the stability of scores over time in participants whose condition had not changed.

Validity

The TDIS demonstrated a clear and interpretable 2-domain structure, capturing both physical and socioemotional impacts of TD, with model fit statistics supporting the adequacy of this structure. Changes in TDIS scores over time were generally aligned with changes in clinician- and patient-reported global impressions, supporting longitudinal validity.

TDIS scores differentiated between groups defined by patient- and clinician-reported severity and change, with higher scores observed among participants reporting greater symptom burden and lower scores among those reporting improvement. TDIS scores were also associated with the severity of participants' TD movements at baseline, supporting the ability of the TDIS to reflect meaningful differences in disease impact.

Responsiveness

TDIS scores demonstrated sensitivity to change over time in individuals participating in the KINECT® 3 and KINECT® 4 clinical trials. Improvements in TDIS scores were observed during treatment, with worsening during washout periods, consistent with patterns seen in clinician-assessed outcomes. These findings indicate that the TDIS is responsive to changes in disease impact.

Meaningful Change

The MCID represents the smallest change in score that is considered meaningful by patients and clinicians. For the TDIS Total Score, MCID was estimated using data from the KINECT® 3 and KINECT® 4 clinical trials, including participants with baseline and post-baseline assessments at Weeks 6 and 8.

Both anchor-based (primary) and distribution-based (supportive) methods were used. Anchor-based estimates were based on Patient- and Clinical Global Impression of Change ratings corresponding to "minimally improved." Distribution-based estimates incorporated statistical indices of change and measurement precision.

Across methods, results consistently supported an MCID of 4 points for the Total Score (range: 0-44). This indicates that a reduction of approximately 4 points may be interpreted as a meaningful improvement in symptom impact.

Frequently Asked Questions (FAQs)

Patients may have questions when completing the TDIS. Please refer to these FAQs to assist in answering their questions.

TDIS Administration

What if the patient questions why they are completing this questionnaire?

- You might respond to this question with something like, "These questions focus on your experience living with tardive dyskinesia (TD) and how your symptoms may affect your daily life. As someone living with TD, you are the expert on your own symptoms and their impact. This information is helpful to understand how TD affects your life and the impact of treatment."
- Remind the patient to consider their TD symptoms and whether they have noticed any changes over time or with treatment.

What if the patient asks why the same questions are being asked multiple times?

- Explain that the same questions are asked more than once to help understand whether the patient's TD symptoms and their impact on daily life have changed over time.

What if a patient doesn't want to answer a question?

- Ideally, patients should answer every question. However, if a patient does not feel comfortable answering a particular question, they may skip it.

What if a patient does not understand a specific question and asks what it means?

- Remind the patient that the question should be answered based on their own interpretation and experience. Avoid interpreting or explaining the question for them.
- Ask them to re-read the question and provide the answer that best reflects their experience.
- If they are still unable to understand the question, the patient is free to skip the question. However, please encourage the patient to answer each question when possible.

What if a patient asks if someone else can complete the TDIS on their behalf?

- The TDIS is intended to be self-administered by the patient and should not be completed on their behalf by family members, friends, or others.
- The patient's responses should reflect their own thoughts and feelings.

What if a patient does not speak English and wants their friend/family member to translate it for them?

- Only approved translations should be used.

TDIS Development and Interpretation

How was the TDIS developed and tested?

- The development of the TDIS was informed by principles outlined in the US Food and Drug Administration Patient-Focused Drug Development (PFDD) guidance documents,[9,10] including incorporation of patient input to ensure content relevance, as well as an evaluation of the instrument's measurement properties.

Who was the TDIS instrument tested in?

- The measurement properties of the TDIS were evaluated in adults with moderate to severe TD lasting ≥ 3 months and a diagnosis of a psychotic or mood disorder. The TDIS has also been used in patients with mild TD movement severity.

Are there impact severity cut-points, e.g., mild, moderate, severe, for interpreting scores?

- At this time, there are no established cut-points to classify impact severity, e.g., mild, moderate, severe, for either TDIS domain scores or Total Score.

Are meaningful change thresholds available for sub-domains?

- The MCID have been established for the Total Score only. Domain scores are intended to support interpretation of specific areas of impact and are not currently associated with standalone meaningful change thresholds.

References:

1. Caroff SN. *Neuropsychiatr Dis Treat*. 2019;15:785-794. **2.** Kane JM, et al. *J Clin Psychiatry*. 2018;79(3):17cs11959. **3.** Jackson R, et al. *Neuropsychiatr Dis Treat*. 2021;17:1589-1597. **4.** Carbon M, et al. *J Clin Psychiatry*. 2017;78(3):e264-e278. **5.** Alabaku O, et al. *PLoS One*. 2023;18(4):e0284389. **6.** Farber RH, et al. *J Patient Rep Outcomes*. 2024;8(1):2. **7.** Bron M, et al. *J Clin Psychiatry*. 2026;87(2):25nr16047. **8.** Zigler CK, Coles T. *Value Health*. 2024;27(11):1494-1496. **9.** US Food and Drug Administration. Updated April 5, 2023. Accessed June 8, 2026. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-incorporating-clinical-outcome-assessments-endpoints-regulatory **10.** US Food and Drug Administration. December 2009. Accessed June 8, 2026. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims **11.** Hauser RA, et al. *Am J Psychiatry*. 2017;174(5):476-484. **12**. Marder SR, et al. *J Clin Psychopharmacol*. 2019;39(6):620-627.

Addendum: Scoring Worksheet

Instructions

1. Record responses to each item in the **Response** column.
2. If all items within a domain are non-missing, sum items to obtain domain score.
3. If both domain scores are non-missing, sum them to calculate the Total Score.
4. Higher scores indicate greater symptom impact.

Domain 1	Item	Response (range 0–4)
Physical Impact	**1**	
	2	
	3	
	4	
	5	
	6	
	7	
	8	
	Domain 1 score = sum of item responses *Range: 0–32* *(All items must be non-missing)*	

Domain 2	Item	Response (range 0–4)
Socioemotional Impact	**9**	
	10	
	11	
	Domain 2 score = sum of item responses *Range: 0–12* *(All items must be non-missing)*	

Total Score	Domain	Domain Score
	Domain 1: Physical Impact	
	Domain 2: Socioemotional Impact	
	Total Score = sum of domain scores *Range: 0–44* *(All domain scores must be non-missing)*	

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