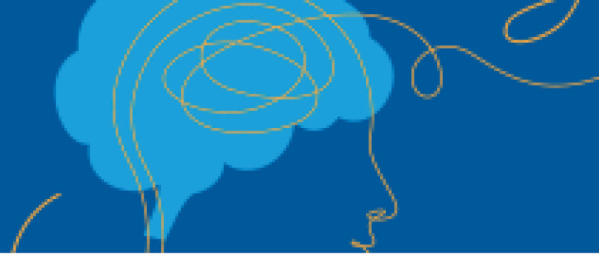
tardive dyskinesia 360

Addressing Persistent Myths & Misconceptions in Tardive Dyskinesia

This activity has been supported through independent educational grants from Neurocrine Biosciences, Inc. and Teva Pharmaceuticals.

Faculty



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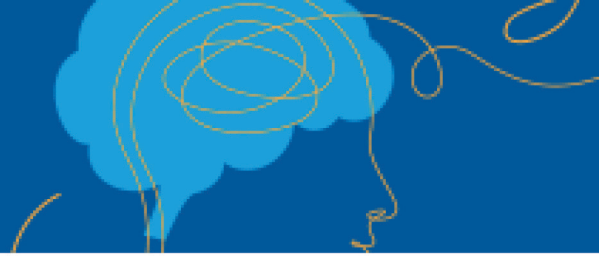
Faculty Disclosure



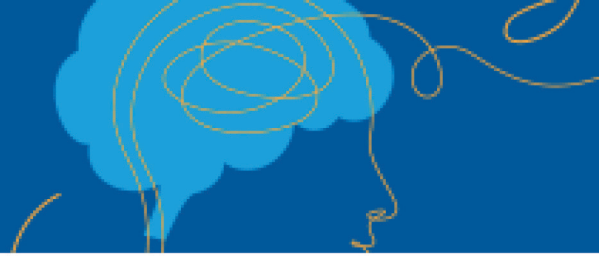
- **Dr. Craig Chepke:** Advisory Board—Abbvie, Acadia, Alkermes, Corium, Eisai, Idorsia, Intracellular, Ironshore, Janssen, Jazz, Karuna, Lundbeck, Neurocrine, Noven, Otsuka, Takeda, Teva; Advisory Board (Spouse)—Otsuka; Consultant—AbbVie, Alkermes, Corium, Eisai, Intracellular, Janssen, Jazz, Karuna, Lundbeck, Neurocrine, Noven, Otsuka, Takeda, Teva; Grant Research/Support—Acadia, Axsome, Biohaven, Harmony, Neurocrine, Teva; Speaker's Bureau—AbbVie, Acadia, Alkermes, Eisai, Intracellular, Ironshore, Janssen, Jazz, Lundbeck, Merck, Neurocrine, Noven, Otsuka, Sunovion, Takeda, Teva.

- **Mr. Kevin Williams:** Speakers Bureau—Myriad, Neurocrine Biosciences, Inc., Teva Pharmaceuticals.

- **Bethany Yeiser:** Advisory Board—Alkermes; Grant/Research Support—Cadent Therapeutics, Janssen, Karuna Therapeutics, Neurocrine Biosciences; Speaker—Alkermes, Neurocrine Biosciences.

- **David Yeiser**: No disclosures

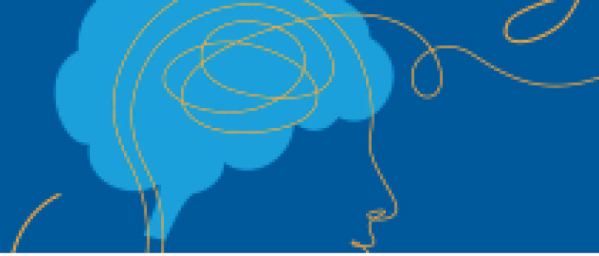
Disclosure



- The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational use(s) of drugs, products, and/or devices (any use not approved by the US Food and Drug Administration)
- Applicable CME staff have no relationships to disclose relating to the subject matter of this activity
- This activity has been independently reviewed for balance

CME = continuing medical education.

Learning Objectives



- Discuss with patients the quality of life impact that even low AIMS scores may have in addition to stigma associated with TD
- Describe the clinical risk factors for the development of TD, the prevalence of TD in patients currently taking antipsychotic medication, and the impact on patient quality of life
- Utilize MOA, key clinical trial data and current guideline recommendations to appropriately implement and/or adjust therapy for TD symptom management without specialist referral
- Describe why anticholinergics are not recommended for TD treatment
- Implement strategies to ensure appropriate novel VMAT-2 dosage for each individual patient

TD = tardive dyskinesia; MOA = mechanism of action

Myth: TD Is Not a Problem for Most Patients

TD Is a Common Presence and It Lurks in Every Practice With Psychiatric Patients

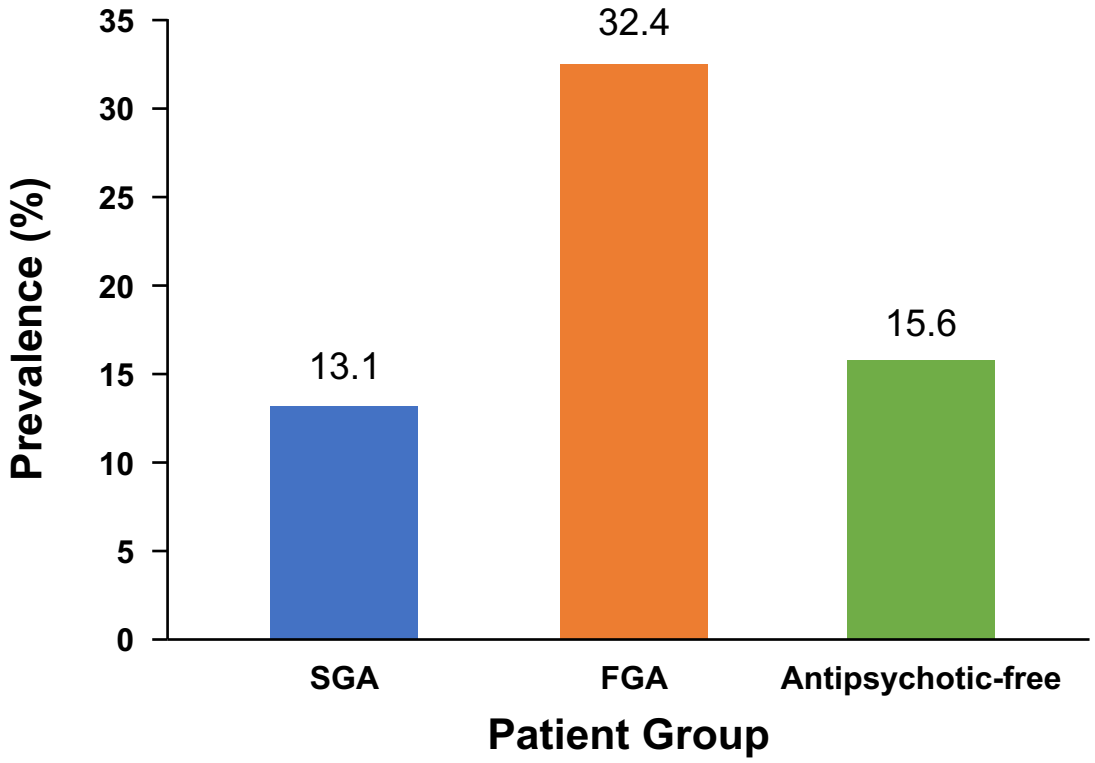
- **We clinicians see TD patients in multiple clinical settings**
  - Outpatient practices
  - Inpatient practices
  - PHP
  - State hospital setting
  - Long Term Care setting
  - Multiple others
- **TD is frequent. A recent study found it in 36% of patients with chronic schizophrenia**
- **It is also commonly found in patients with mood disorders**

PHP = partial hospitalization program.

Uludag K, et al. *Asian J Psychiatr.* 2021;66:102877.

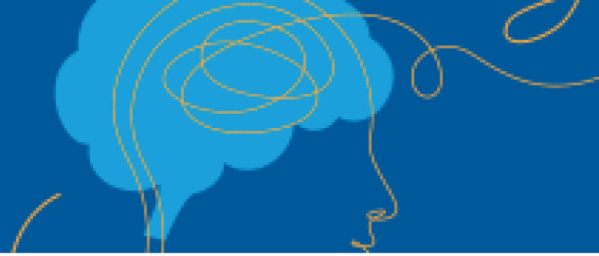
There are ~ 600,000 People Living with TD in the United States

Prevalence of TD
(from 4 adult studies, n=2008)



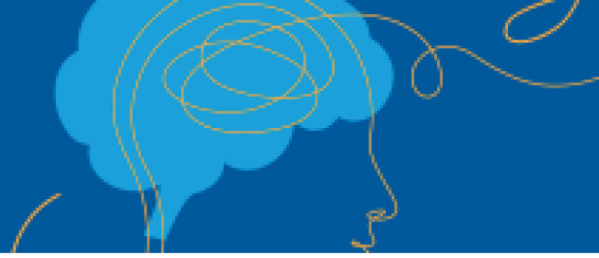
Cities with Approx. 600,000 People in Them:
Milwaukee, Tucson, Baltimore

Correll CU, et al. *J Clin Psychiatry.* 2017;78(8):1136-1147.



Definition of Tardive Dyskinesia

Definition of Tardive Dyskinesia



A type of dyskinesia that typically emerges after long-term use of antipsychotic drugs (DRBAs)

Tardive

Appearing or tending to appear late

Dyskinesia

Distortion or impairment of voluntary movement

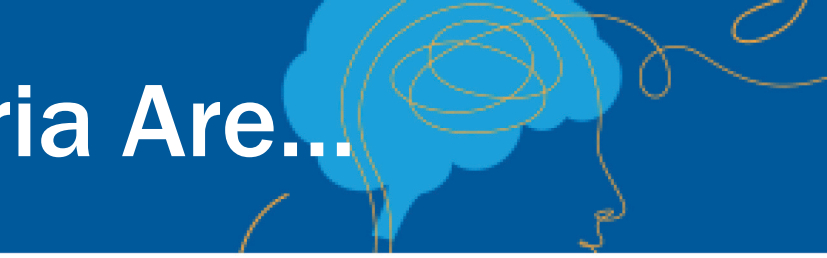
DSM Dx (highlights)

- Involuntary movements of the tongue, jaw, trunk, or extremities have developed in association with the use of neuroleptic medication
- The involuntary movements are present over a period of at least 4 weeks and occur in any of the following patterns: 1) choreiform movements (ie, rapid, jerky, nonrepetitive); 2) athetoid movements (ie, slow, sinuous, continual); 3) rhythmic movements (ie, stereotypes)
- Symptoms develop during exposure to a neuroleptic medication or within 4 weeks of withdrawal from an oral neuroleptic medication or within 8 weeks of withdrawal from a depot
- There has been exposure to neuroleptic medication for at least 3 months (1 month, if age ≥ 60 years)

DRBA = dopamine receptor blocking agent; DSM = Diagnostic and Statistical Manual of Mental Disorders; Dx = diagnosis.

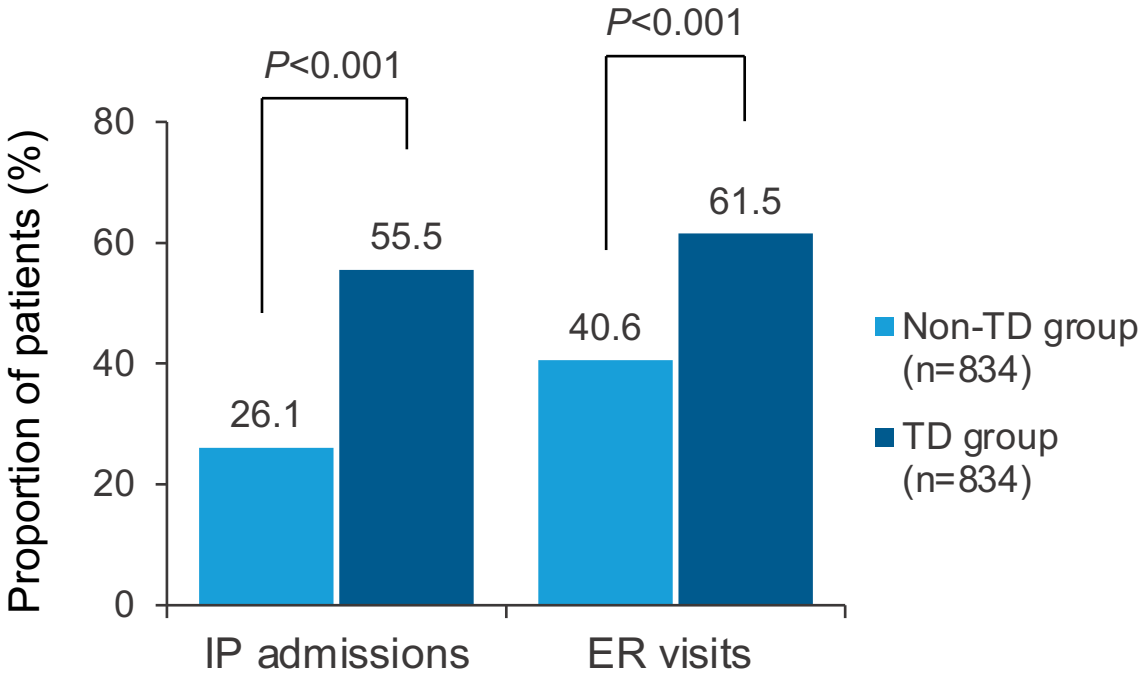
Lerner PP, et al. *Psychiatry Clin Neurosci.* 2015;69(6):321-334.

Significant Weakness of These Criteria Are...

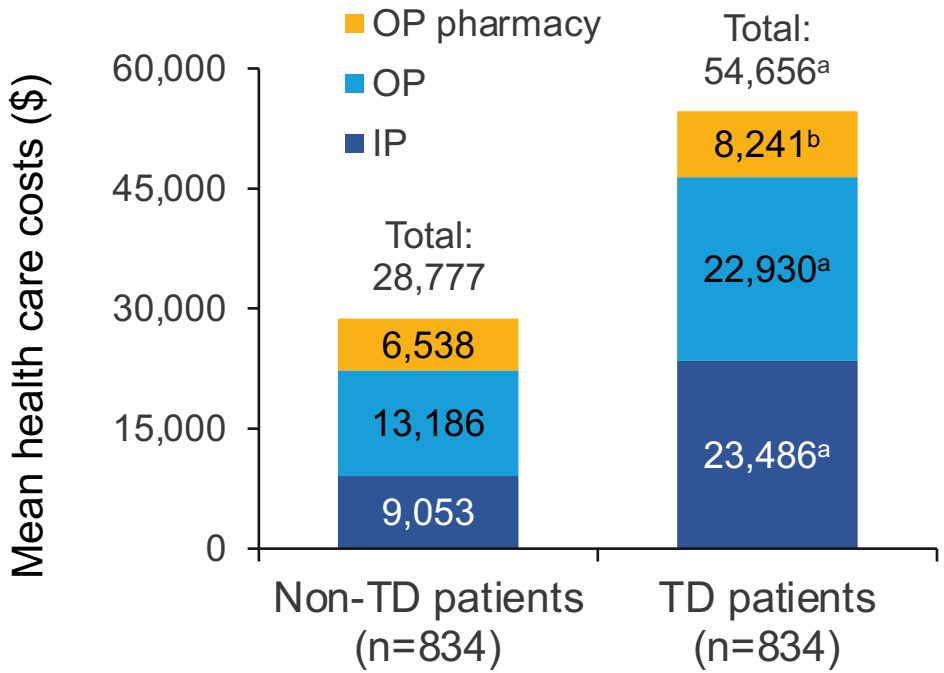


QoL = quality of life.

Health Care Utilization Costs Are Elevated in Patients With TD



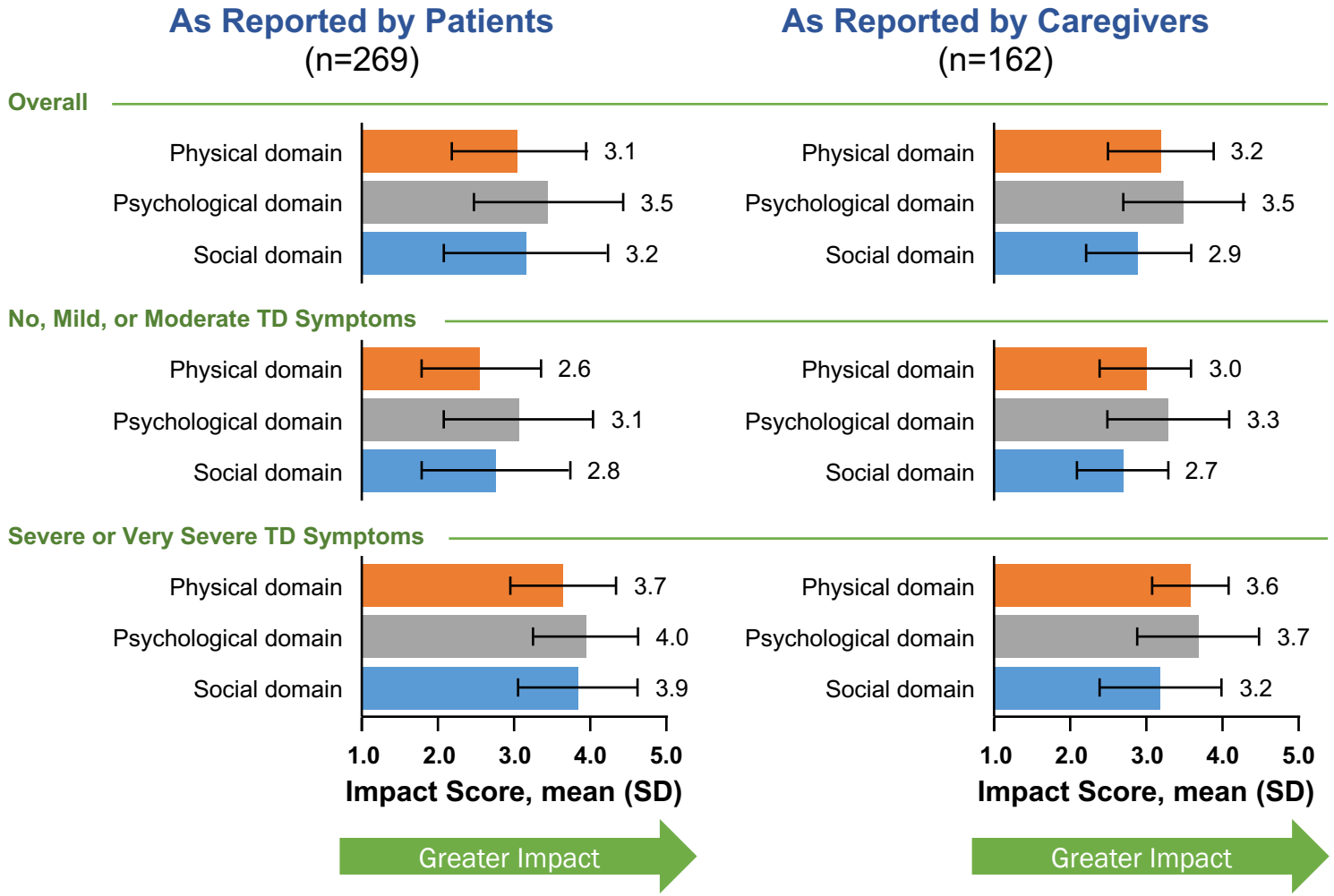
Note: Percentage of patients with any ER visit pre-index vs post-index. Mean ER visits for individual patients, pre-index vs post-index.



Note: Mean total healthcare costs subdivided into costs for OP pharmacy; OP and IP admissions per patient of matched TD vs matched non-TD cohorts. Any discrepancy in the total mean healthcare costs is due to rounding.

[a]*P*<0.001 compared with non-TD patients; [b]*P*<0.01.
ER = emergency room; IP = inpatient; OP = outpatient.
Carroll B, et al. *J Manag Care Spec Pharm.* 2019;25(7):810-816.

TD Is a Highly Impairing Disorder Impacting Physical, Psychological, and Social Domains



- TD imposes substantial burden on the patient's well-being and their psychosocial function, along with their physical functioning
- TD also impacts how patients manage the underlying condition, suggesting that better TD symptom control may reduce patient burden by reducing antipsychotic treatment disruptions and nonadherence
- These results reinforce the need for healthcare providers to assess impact to patients when assessing TD movements

Jain R, et al. Poster presented at: Psych Congress; October 29-November 1, 2021; San Antonio, Texas.

Caregivers Are Often the Other Victims of TD

Figure 1. Burden of Caregiving Tasks

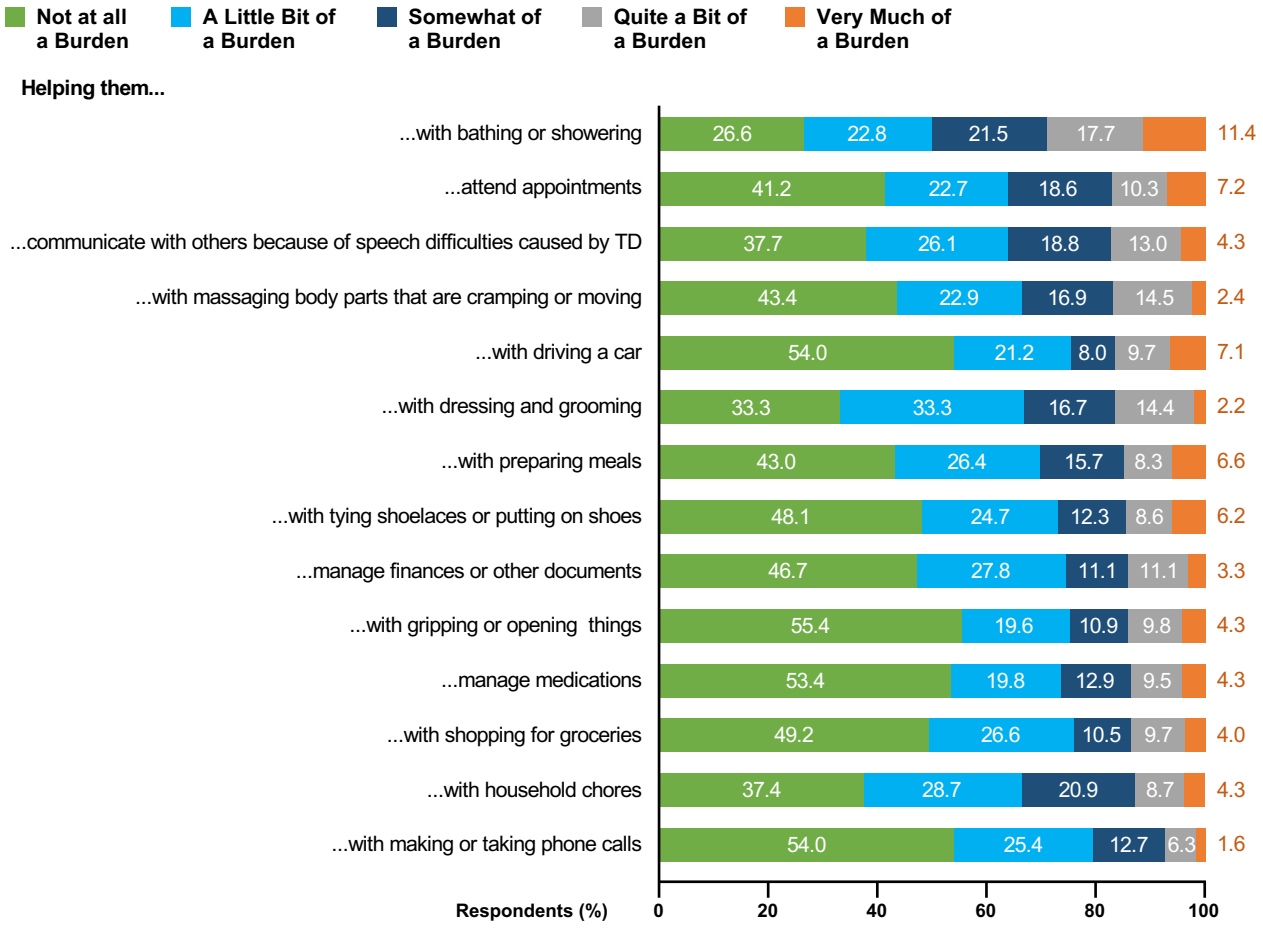
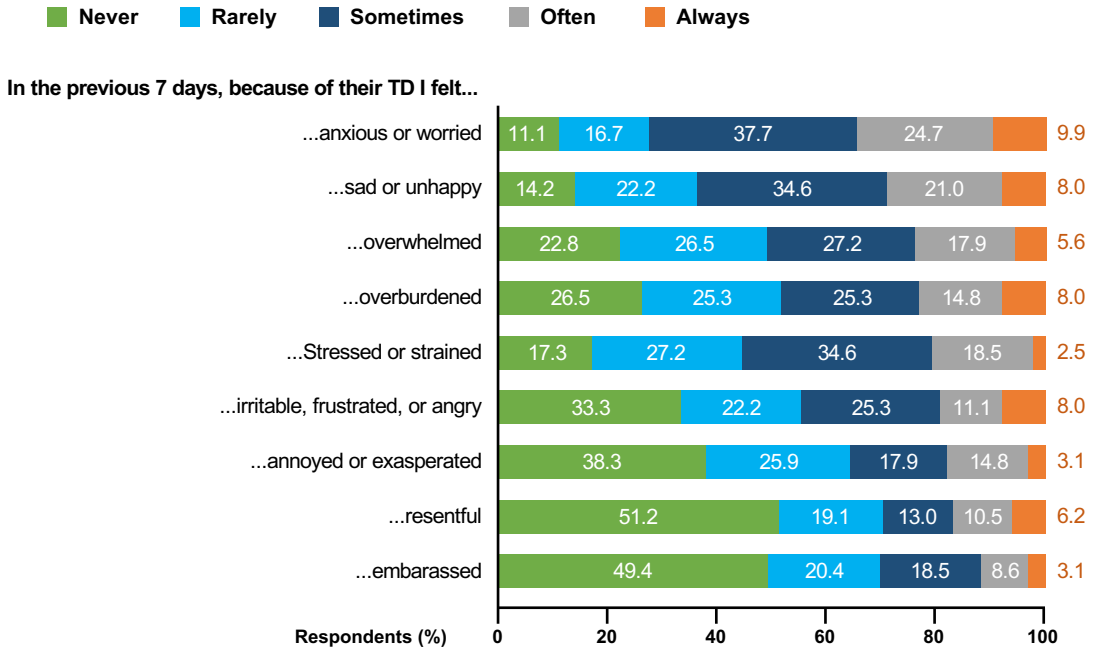


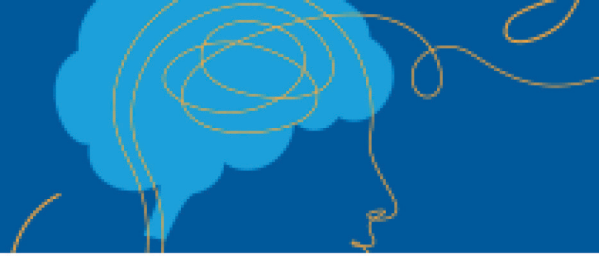
Figure 2. Impact on Caregiver Psychological Well-Being



- The surveyed caregivers (N=162) represented the diversity of races/ethnicities present in United States
- Caregivers experienced 46.4% activity impairment because of caring for the patient
- Caregivers who were employed missed 13.8% of work time (i.e., absenteeism) and experienced 44.0% impairment while working (i.e., presenteeism)

Jain R, et al. Poster presented at: Psych Congress; October 29-November 1, 2021; San Antonio, Texas.

An Additional Consequence of Having TD - A Major, Negative Impact on Medication Adherence



48.4%
Skipped doses of an antipsychotic medication or took less than the doctor instructed[a]

39.3%
Stopped taking antipsychotic medication altogether[a]

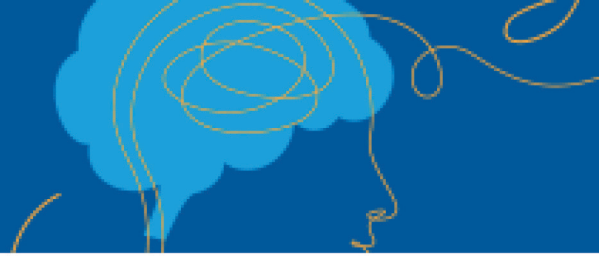
35.7%
Stopped going to the doctor treating their underlying condition

20.8%
Advised someone else not to take an antipsychotic medication

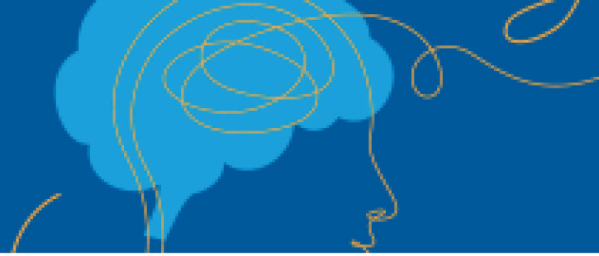
21.9%
None of the above

Jain R, et al. Poster presented at: Psych Congress; October 29-November 1, 2021; San Antonio, Texas.

Deep Learning Point for All of Us



If optimum outcomes are desired, then it is important to control **TD symptoms** AND focus on **functional impairment** in patients with TD.



Meet Bethany

Myth: AIMS is Too Difficult and Takes Too Much Time

Abnormal Involuntary Movement Scale (AIMS): The Standard of Care

- Observer-rated 12-item anchored scale that **takes only 5-10 minutes**
- Adopted by many agencies for routine clinical use **– baseline and periodically**
- With FGAs, examine for TD at least every 6 months
- With SGAs and no concomitant FGAs, examine for TD annually
- With patients at high risk for EPS (e.g., older age, history of dystonic reactions, akathisia, clinically significant parkinsonism), examine every 3 months with FGAs or 6 months with SGAs
- Is the ***primary outcome measure*** in research of drugs for TD

		CIRCLE ONE				
FACIAL AND ORAL MOVEMENTS	1. **Muscles of Facial Expression** e.g., Movements of forehead, eyebrows, peri-orbital area, cheeks, include frowning, blinking, smiling, grimacing	0	1	2	3	4
	2. **Lips and Peri-oral Area** e.g., puckering, pouting, smacking	0	1	2	3	4
	3. **Jaws** e.g., biting, clenching, chewing, mouth opening, lateral movement	0	1	2	3	4
	4. **Tongue** Rate only increase in movement both in and out of mouth, **NOT** inability to sustain movement	0	1	2	3	4
EXTREMITY MOVEMENTS	5. **Upper (arms, wrists, hands, fingers)** Include choreic movements (i.e., rapid objectively, purposeless, irregular spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine) Do **NOT include tremor (i.e., repetitive, regular, rhythmic)**	0	1	2	3	4
	6. **Lower (legs, knees, ankles, toes)** e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot	0	1	2	3	4
TRUNK MOVEMENTS	7. **Back, shoulders, hips** e.g., rocking, twisting, squirming, pelvic gyrations	0	1	2	3	4
GLOBAL JUDGMENTS	8. Severity of abnormal movements	None, Normal ...0 Minimal 1		Mild .....2 Moderate 3		Severe 4
	9. Incapacitation due to abnormal movements	None, Normal ...0 Minimal 1		Mild .....2 Moderate 3		Severe 4
	10. Patient's awareness of abnormal movements ***RATE ONLY PATIENT'S REPORT***	No Awareness .....0 Aware, Mild distress 2		Aware, No distress .....1 Aware, Severe distress ...4		
DENTAL STATUS	11. Current problems with teeth and/or dentures	No.....0		Yes 1		
	12. Does patient usually wear dentures?	No.....0		Yes 1		

Guy W (ed): ECDEU Assessment Manual for Psychopharmacology, revised ed. DHEW Publ No ADM 76-338. Washington, DC, US Department of Health, Education, and Welfare, 1976; Citrome L. J Neurol Sci. 2017;383:199-204.

Yes, AIMS Takes Time, But... Three More Reasons To Do This

Some payers require it for VMAT2 inhibitor coverage

	DATE 4/26/17	DATE 5/30/17	DATE 6/14/17	DATE 7/31/17	DATE 8/28/17
1. **Muscles of Facial Expression** e.g. movements of forehead, eyebrows, periorbital area, cheeks, including frowning, blinking, smiling, grimacing	0 (1) 2 3 4	0 (1) 2 3 4	0 (1) 2 3 4	0 (1) 2 3 4	0 (1) 2 3 4
2. **Lips and Perioral Area** e.g. puckering, pouting, smacking	0 (1) 2 3 4	0 (1) 2 3 4	0 (1) 2 3 4	0 1 (2) 3 4	0 (1) 2 3 4
3. **Jaw** Biting, clenching, chewing, mouth opening , lateral movement	0 1 (2) 3 4	0 (1) 2 3 4	0 (1) 2 3 4	0 1 (2) 3 4	0 (1) 2 3 4
4. **Tongue** Rate only increases in movement both in and out of mouth. NOT inability to sustain movement. Darting in and out of mouth	0 (1) 2 3 4	0 (1) 2 3 4	0 1 2 3 4	0 (1) 2 3 4	(0) 1 2 3 4
5. **Upper (arms, wrists, hands, fingers)** Include choreic movements (i.e. rapid objectively purposeless, irregular, spontaneous) athetoid movements. DO NOT INCLUDE TREMOR (i.e. repetitive, regular, rhythmic)	0 (1) 2 3 4	0 1 2 3 4	0 1 2 3 4	0 1 2 (3) 4	(0) 1 2 3 4
6. **Lower (legs, knees, ankles, toes)** Lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot	0 1 2 (3) 4	0 (1) 2 3 4	0 (1) 2 3 4	0 1 2 (3) 4	0 (1) 2 3 4
7. **Neck, shoulders and hips** Rocking, twisting, squirming, pelvic gyrations	0 1 2 (3) 4 12	0 (1) 2 3 4 16	(0) 1 2 3 4 14	0 1 (2) 3 4 14	(0) 1 2 3 4 14

Enables measurement-based care

Helps us slow down and use a systematic thought process

VMAT = vesicular monoamine transporter.

McEvoy JP. *J Clin Psychiatry*. 2020;81(6):NU19047BR4C. Munetz MR, et al. *Hosp Community Psychiatry*. 1988;39(11):1172-1177.

Abnormal Involuntary Movement Scale (AIMS): The Standard of Care

- Observer-rated 12-item anchored scale that **takes 5-10 minutes**
- Adopted by many agencies for routine clinical use – **baseline and periodically**

Items 1 to 7:
4 items dedicated to the face, lips, jaws, tongue.
Only 1 item each for the upper extremities, lower extremities, and trunk.
The sum of the score of these 7 items is the dyskinesia score and is used as the *primary outcome measure* for TD studies

		CIRCLE ONE				
FACIAL AND ORAL MOVEMENTS	1. **Muscles of Facial Expression** e.g., Movements of forehead, eyebrows, peri-orbital area, cheeks, include frowning, blinking, smiling, grimacing	0	1	2	3	4
	2. **Lips and Peri-oral Area** e.g., puckering, pouting, smacking	0	1	2	3	4
	3. **Jaws** e.g., biting, clenching, chewing, mouth opening, lateral movement	0	1	2	3	4
	4. **Tongue** Rate only increase in movement both in and out of mouth, **NOT** inability to sustain movement	0	1	2	3	4
EXTREMITY MOVEMENTS	5. **Upper (arms, wrists, hands, fingers)** Include choreic movements (i.e., rapid objectively, purposeless, irregular spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine) Do **NOT include tremor (i.e., repetitive, regular, rhythmic)**	0	1	2	3	4
	6. **Lower (legs, knees, ankles, toes)** e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot	0	1	2	3	4
TRUNK MOVEMENTS	7. **Back, shoulders, hips** e.g., rocking, twisting, squirming, pelvic gyrations	0	1	2	3	4
GLOBAL JUDGMENTS	8. Severity of abnormal movements	None, Normal ...0 Minimal 1		Mild .....2 Moderate 3		Severe 4
	9. Incapacitation due to abnormal movements	None, Normal ...0 Minimal 1		Mild .....2 Moderate 3		Severe 4
	10. Patient's awareness of abnormal movements ***RATE ONLY PATIENT'S REPORT***	No Awareness .....0 Aware, Mild distress 2		Aware, No distress .....1 Aware, Severe distress ...4		
DENTAL STATUS	11. Current problems with teeth and/or dentures	No.....0		Yes 1		
	12. Does patient usually wear dentures?	No.....0		Yes 1		

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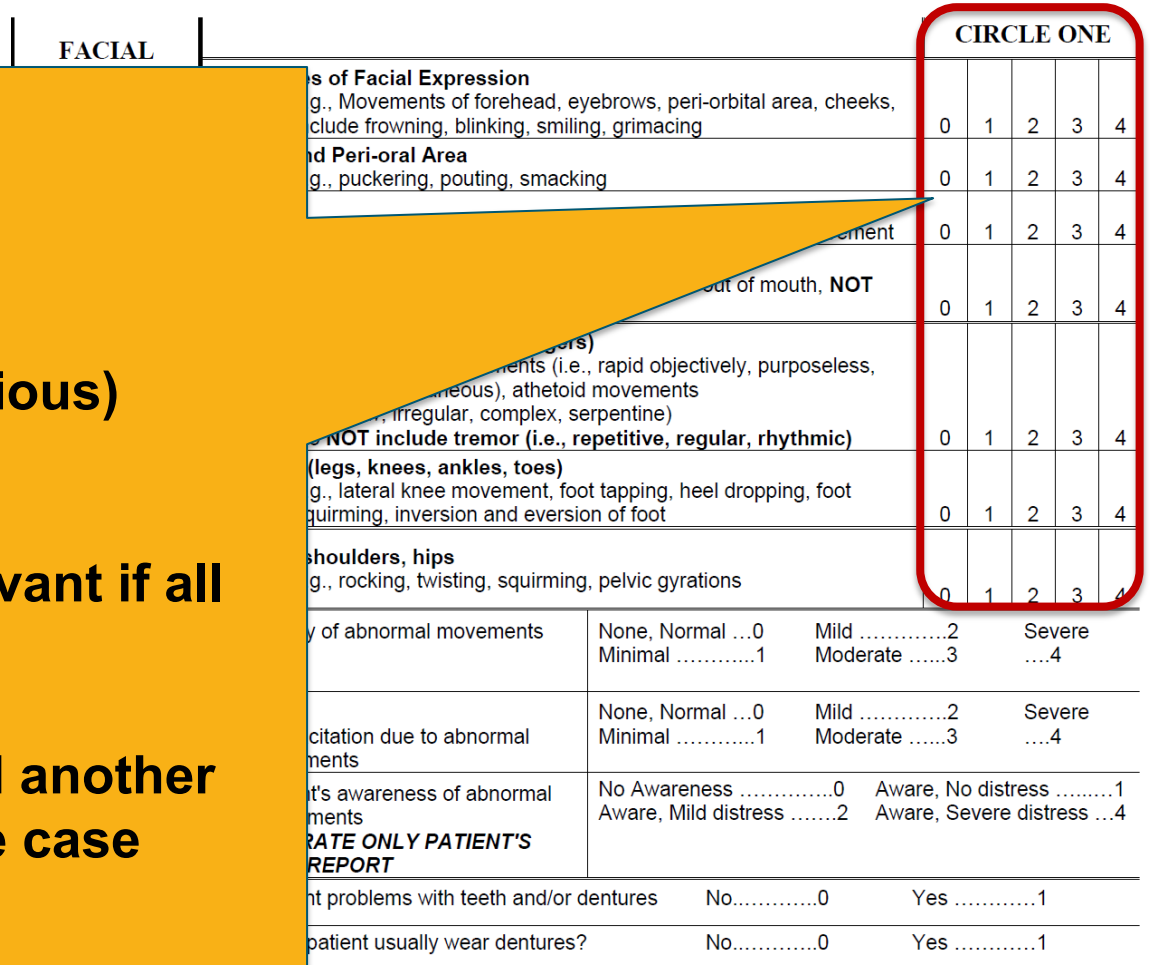
Abnormal Involuntary Movement Scale (AIMS): The Standard of Care

- Observer rated 12-item psychiatric scale that takes **5-10 min**
- Adopted
- With FGA
- With SGA
- With pat
- With pat
- Is the ***pri***

0 = no movements
1 = minimal or extreme normal
2 = mild
3 = moderate (and usually quite obvious)
4 = severe

Sum can equal 7 but would be irrelevant if all items scored as a "1"

Sum of 7 when one item is a "4" and another item is a "3" would indicate a severe case



FACIAL					CIRCLE ONE				
s of Facial Expression g., Movements of forehead, eyebrows, peri-orbital area, cheeks, clude frowning, blinking, smiling, grimacing					0	1	2	3	4
d Peri-oral Area g., puckering, pouting, smacking					0	1	2	3	4
ement					0	1	2	3	4
out of mouth, **NOT**					0	1	2	3	4
gers) nents (i.e., rapid objectively, purposeless, neous), athetoid movements ; irregular, complex, serpentine) **NOT include tremor (i.e., repetitive, regular, rhythmic)**					0	1	2	3	4
(legs, knees, ankles, toes) g., lateral knee movement, foot tapping, heel dropping, foot quirming, inversion and eversion of foot					0	1	2	3	4
shoulders, hips g., rocking, twisting, squirming, pelvic gyrations					0	1	2	3	4
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- With SGAs and no concomitant FGAs, examine for TD annually
- With patients at high risk for EPS (e.g.
- with FGAs or 6 months with SGAs
- Is the ***primary outcome measure*** in research of drugs for TD

Global severity: based on the highest single score in the first 7 items

		CIRCLE ONE
FACIAL AND ORAL MOVEMENTS	1. **Muscles of Facial Expression** e.g., Movements of forehead, eyebrows, peri-orbital area, cheeks, include frowning, blinking, smiling, grimacing	0 1 2 3 4
	2. **Lips and Peri-oral Area** e.g., puckering, pouting, smacking	0 1 2 3 4
	3. **Jaws** e.g., biting, clenching, chewing, mouth opening, lateral movement	0 1 2 3 4
	4. **Tongue** Rate only increase in movement both in and out of mouth, **NOT** inability to sustain movement	0 1 2 3 4
EXTREMITY MOVEMENTS	5. **Upper (arms, wrists, hands, fingers)** Include choreic movements (i.e., rapid objectively, purposeless, irregular spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine) Do **NOT include tremor (i.e., repetitive, regular, rhythmic)**	0 1 2 3 4
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TRUNK MOVEMENTS	7. **Back, shoulders, hips** e.g., rocking, twisting, squirming, pelvic gyrations	0 1 2 3 4
GLOBAL JUDGMENTS	8. Severity of abnormal movements	None, Normal ...0 Minimal .....1 Mild .....2 Moderate .....3 Severe 4
	9. Incapacitation due to abnormal movements	None, Normal ...0 Minimal .....1 Mild .....2 Moderate .....3 Severe 4
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Abnormal Involuntary Movement Scale (AIMS): The Standard of Care

Degree of incapacitation due to abnormal movements - the patient will need to be asked to what extent any movements interfere with activities such as eating, drinking, speaking, breathing, dressing oneself, writing, working, leisure activities, being with others, etc.

with FGAs or 6 months with SGAs

- Is the ***primary outcome measure*** in research of drugs for TD

		CIRCLE ONE
FACIAL AND ORAL MOVEMENTS	1. **Muscles of Facial Expression** e.g., Movements of forehead, eyebrows, peri-orbital area, cheeks, include frowning, blinking, smiling, grimacing	0 1 2 3 4
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TRUNK MOVEMENTS	7. **Back, shoulders, hips** e.g., rocking, twisting, squirming, pelvic gyrations	0 1 2 3 4
GLOBAL JUDGMENTS	8. Severity of abnormal movements	None, Normal ...0 Minimal .....1 Mild .....2 Moderate .....3 Severe 4
	9. Incapacitation due to abnormal movements	None, Normal ...0 Minimal .....1 Mild .....2 Moderate .....3 Severe 4
	10. Patient's awareness of abnormal movements ***RATE ONLY PATIENT'S REPORT***	No Awareness .....0 Aware, Mild distress .....2 Aware, No distress .....1 Aware, Severe distress ...4
DENTAL STATUS	11. Current problems with teeth and/or dentures	No.....0 Yes 1
	12. Does patient usually wear dentures?	No.....0 Yes 1

Guy W (ed): ECDEU Assessment Manual for Psychopharmacology, revised ed. DHEW Publ No ADM 76-338. Washington, DC, US Department of Health, Education, and Welfare, 1976; Citrome L. J Neurol Sci. 2017;383:199-204.

Abnormal Involuntary Movement Scale (AIMS):

Patient's awareness (and distress level) of the abnormal movements (0–4, with 0 noting no awareness, 1 noting being aware with no distress, and 2–4 noting awareness and distress rating from mild to moderate to severe)

It is not unusual for persons with schizophrenia to have little insight into their dyskinetic movements; however, patients with mood disorders may be better able to articulate their distress

	CIRCLE ONE
1. **Muscles of Facial Expression** e.g., Movements of forehead, eyebrows, peri-orbital area, cheeks, include frowning, blinking, smiling, grimacing	0 1 2 3 4
2. **Lips and Peri-oral Area** e.g., puckering, pouting, smacking	0 1 2 3 4
3. **Jaws** e.g., biting, clenching, chewing, mouth opening, lateral movement	0 1 2 3 4
4. **Tongue** Rate only increase in movement both in and out of mouth, **NOT** inability to sustain movement	0 1 2 3 4
5. **Upper (arms, wrists, hands, fingers)** Include choreic movements (i.e., rapid objectively, purposeless, irregular spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine) Do **NOT include tremor (i.e., repetitive, regular, rhythmic)**	0 1 2 3 4
6. **Lower (legs, knees, ankles, toes)** e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot	0 1 2 3 4
7. **Back, shoulders, hips** e.g., rocking, twisting, squirming, pelvic gyrations	0 1 2 3 4
8. Severity of abnormal movements	None, Normal ...0 Minimal .....1 Mild .....2 Moderate .....3 Severe 4
9. Incapacitation due to abnormal movements	None, Normal ...0 Minimal .....1 Mild .....2 Moderate .....3 Severe 4
10. Patient's awareness of abnormal movements ***RATE ONLY PATIENT'S REPORT***	No Awareness .....0 Aware, Mild distress .....2 Aware, No distress .....1 Aware, Severe distress ...4
11. Current problems with teeth and/or dentures	No.....0 Yes 1
12. Does patient usually wear dentures?	No.....0 Yes 1

Guy W (ed): ECDEU Assessment Manual for Psychopharmacology, revised ed. DHEW Publ No ADM 76-338. Washington, DC, US Department of Health, Education, and Welfare, 1976; Citrome L. J Neurol Sci. 2017;383:199-204

Abnormal Involuntary Movement Scale (AIMS): The Standard of Care

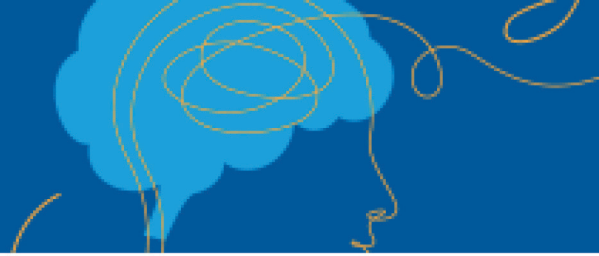
- Observer-rated 12-item anchored scale that **takes 5-10 minutes**
- Adopted by many agencies for routine clinical use – **baseline and periodically**
- with FGAs or 6 months with SGAs
- Is the ***primary outcome measure*** in researc
  drugs for TD

The last 2 items of the AIMS are yes/no questions regarding dentition status and the use of dentures. Note that people with TD who wear dentures often have problems with them

		CIRCLE ONE
FACIAL AND ORAL MOVEMENTS	1. **Muscles of Facial Expression** e.g., Movements of forehead, eyebrows, peri-orbital area, cheeks, include frowning, blinking, smiling, grimacing	0 1 2 3 4
	2. **Lips and Peri-oral Area** e.g., puckering, pouting, smacking	0 1 2 3 4
	3. **Jaws** e.g., biting, clenching, chewing, mouth opening, lateral movement	0 1 2 3 4
	4. **Tongue** Rate only increase in movement both in and out of mouth, **NOT** inability to sustain movement	0 1 2 3 4
EXTREMITY MOVEMENTS	5. **Upper (arms, wrists, hands, fingers)** Include choreic movements (i.e., rapid objectively, purposeless, irregular spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine) Do **NOT include tremor (i.e., repetitive, regular, rhythmic)**	0 1 2 3 4
	6. **Lower (legs, knees, ankles, toes)** e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot	0 1 2 3 4
TRUNK MOVEMENTS	7. **Back, shoulders, hips** e.g., rocking, twisting, squirming, pelvic gyrations	0 1 2 3 4
GLOBAL JUDGMENTS	8. Severity of abnormal movements	None, Normal ...0 Minimal .....1 Mild .....2 Moderate .....3 Severe 4
	9. Incapacitation due to abnormal movements	None, Normal ...0 Minimal .....1 Mild .....2 Moderate .....3 Severe 4
	10. Patient's awareness of abnormal movements ***RATE ONLY PATIENT'S REPORT***	No Awareness .....0 Aware, Mild distress .....2 Aware, No distress .....1 Aware, Severe distress ...4
DENTAL STATUS	11. Current problems with teeth and/or dentures	No.....0 Yes 1
	12. Does patient usually wear dentures?	No.....0 Yes 1

Guy W (ed): ECDEU Assessment Manual for Psychopharmacology, revised ed. DHEW Publ No ADM 76-338. Washington, DC, US Department of Health, Education, and Welfare, 1976; Citrome L. J Neurol Sci. 2017;383:199-204

Tips on Scoring



- Thumb-finger tapping, arm extension and walking are “activation” maneuvers used to elicit abnormal movements in other body areas
  - Score **activated movements** the same way; do not lower those numbers as was proposed at one time
  - An additional activation maneuver that can be used is a **cognitive task** such as asking the patient to count backwards from 100 or to recite the months of the year in reverse order
- Score the **highest amplitude or frequency** in a movement on the 0-4 scale, not the average
- The instructions for the AIMS also include an assessment of upper extremity **rigidity** by flexing and extending the patient's left and right arms, as well as observation of **gait**, but these are not rated
  - Nevertheless, findings from these actions may be helpful when determining if the patient has drug-induced parkinsonian side effects

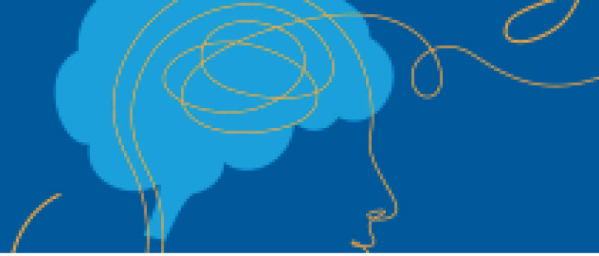
Guy W (ed): ECDEU Assessment Manual for Psychopharmacology, revised ed. DHEW Publ No ADM 76-338. Washington, DC, US Department of Health, Education, and Welfare, 1976; Citrome L. J Neurol Sci. 2017;383:199-204.

TD Differential Diagnosis: Key Points

- TD movements are distinctly different from the rhythmic (3-6 Hz) tremors commonly seen in medication-induced parkinsonism
- It is imperative to distinguish medication-induced parkinsonism from tardive dyskinesia because the treatments commonly used to manage medication-induced parkinsonism (i.e., anticholinergic medications) may worsen the abnormal motor movements associated with tardive dyskinesia
- Moreover, treatments used to manage tardive dyskinesia (i.e., VMAT2 inhibitors) may worsen the symptoms of medication-induced parkinsonism

American Psychiatric Association. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision. American Psychiatric Association Publishing, Washington, DC, 2022

Practice Makes Perfect!



- Visit the Exhibit Hall on Sunday from 1:45 PM – 3:15 PM and attend the **AIMS Exam Workshop**!
- Practice administering the AIMS exam and discuss your questions and concerns with expert faculty
- Located in the back of the Exhibit Hall, at the end of the 900 aisle

RE-Kinect: Real World TD Screening Study

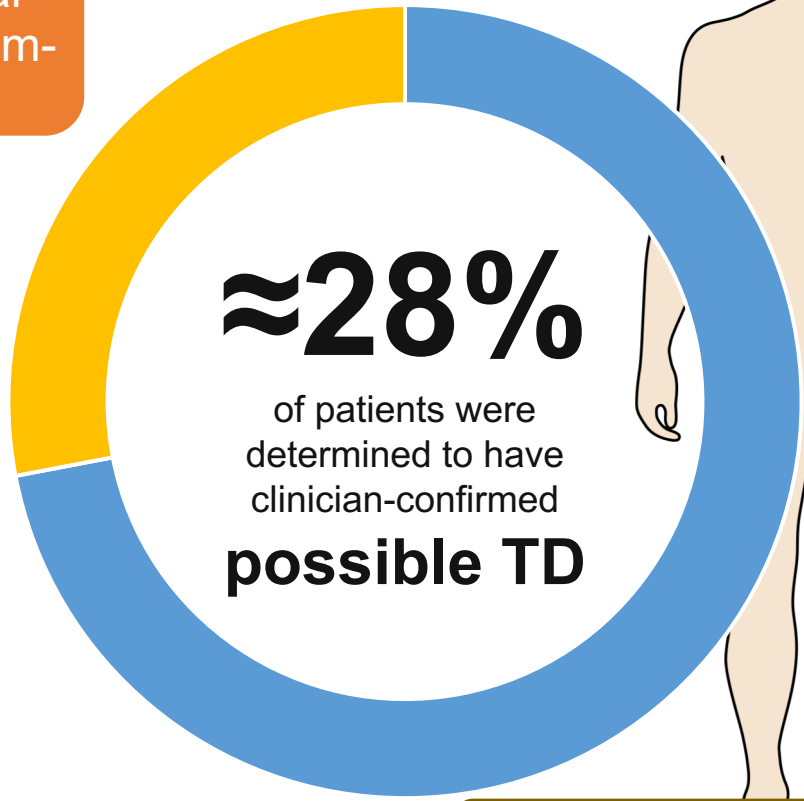
739 patients taking antipsychotics at CMHCs, private practices, and hospital-based clinics were assessed with a team-based approach simplified exam:

Intake staff

Visual observation during intake at usual care visit

Clinician

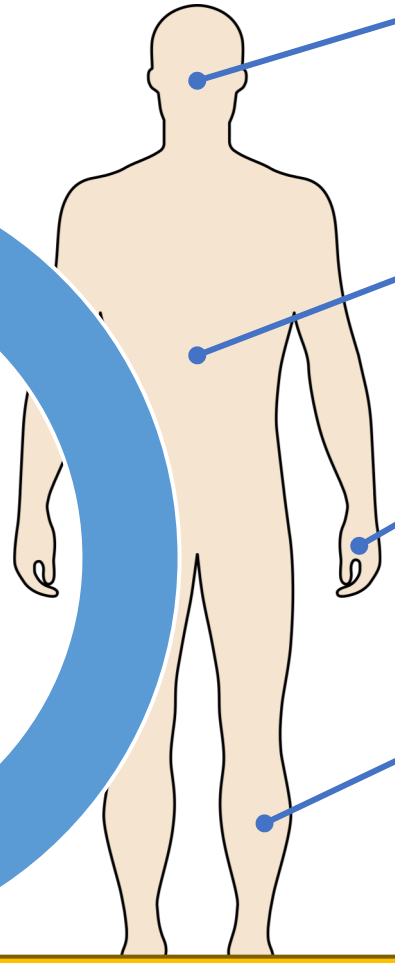
Assess presence and severity of movements



≈28%

of patients were determined to have clinician-confirmed

possible TD



Facial muscles, lips, tongue, jaw

None	34%
Some	46%
A lot	20%

Neck, shoulders, chest, hips

None	78%
Some	16%
A lot	4%

Arms, hands, fingers

None	41%
Some	49%
A lot	10%

Legs, feet, toes

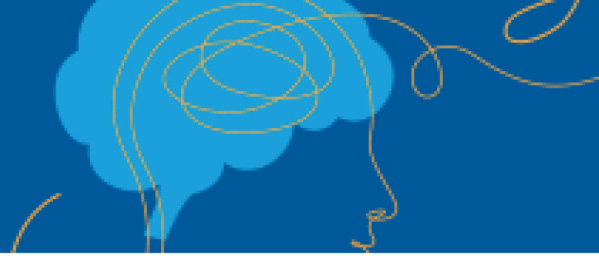
None	57%
Some	34%
A lot	8%

2 of 3 had movements above the neck

RE-Kinect = Real-World Evaluation Screening Study and Registry of Dyskinesia in Patients Taking Antipsychotic Agents; CMHC = Community Mental Health Center.

Caroff SN, et al. *J Clin Psychopharmacology.* 2020;40(3):259-268.

Top Telemedicine AIMS Tips



Assessing the lower body

- They can sit further back from the camera, or a helper can hold the device if present
- Angle camera downwards or place device on coffee table or on floor

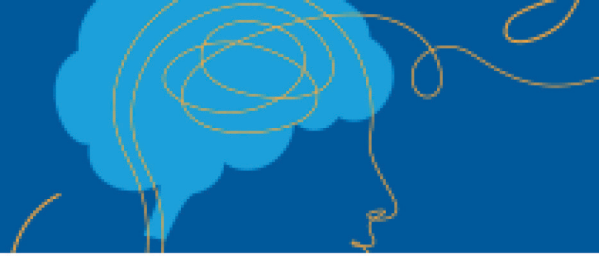
Asynchronous AIMS is an option

- Teach procedures (and give instruction sheets) so patients can record themselves
- Symptoms are variable and may wax and wane, so patients can catch “bad days”
- Saves time and can overcome low speed connection issues

Advantages to remote AIMS

- Can stare directly at their face for 10-15 seconds without awkwardness
- No fear/embarrassment of smell when observing feet without socks and shoes

Boes CJ, et al. *Neurol Clin Pract.* 2021;11(2):e157-e164. Srinivasan R, et al. Tremor Other Hyperkinet Mov (NY). 2020;17(10). Cubo E, et al [www.movementdisorders.org]. Accessed February 5, 2021. https://www.movementdisorders.org/MDS-Files1/Education/Webinars/Webinar_FINAL2.pdf.



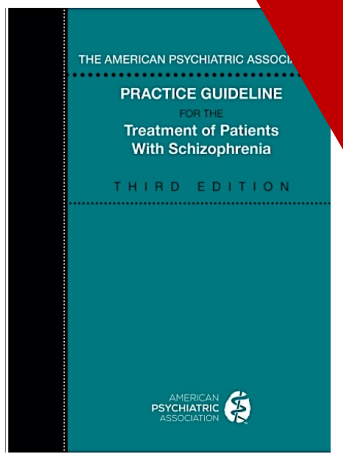
AIMS Screening and Diagnosis

APA Guideline Recommendations on Anticholinergics in DIMDs

The long-term benefits and harms of anticholinergic medications are less clear, and harms may outweigh benefits

Drinking high-calorie fluids in response to dry mouth from anticholinergics can contribute to weight gain

Akathisia tends not to respond to anticholinergics



DIMD = drug-induced movement disorder. APA=American Psychiatric Association

APA *Practice Guideline for the Treatment of Patients with Schizophrenia.* 3rd ed. APA; 2021.

Benztropine PI on its Use in Tardive Dyskinesia

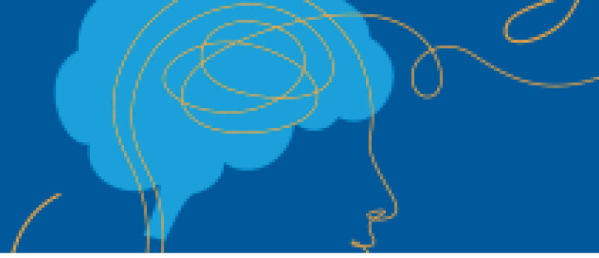
"Benztropine is not recommended for use in patients with tardive dyskinesia."

"Useful also in the control of extrapyramidal disorders (except tardive dyskinesia)"

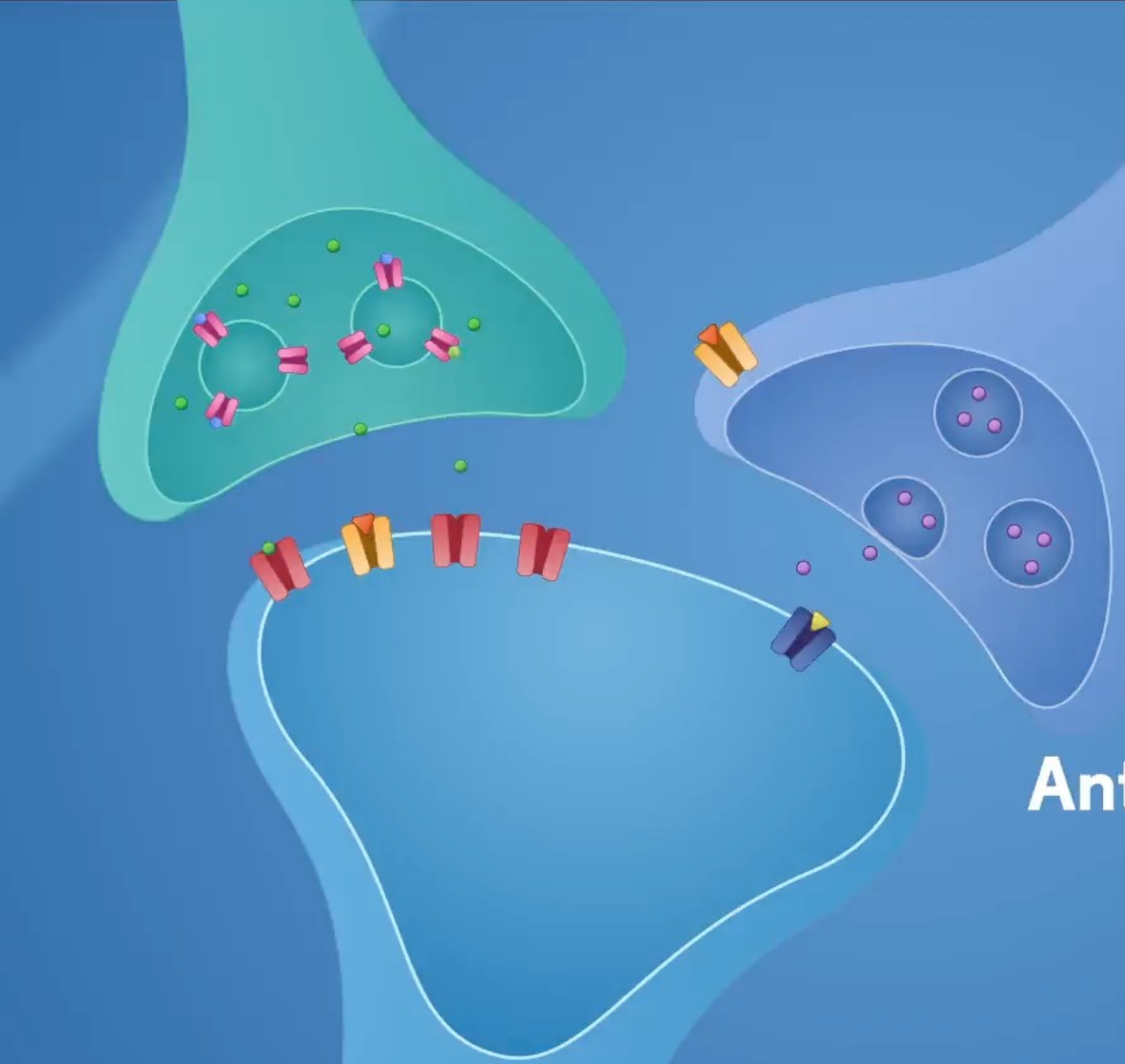
"Antiparkinsonism agents do not alleviate the symptoms of tardive dyskinesia, and in some instances may aggravate them."

PI = prescribing information

US Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. www.accessdata.fda.gov/scripts/cder/daf/index.cfm.



MOA of Anticholinergics and VMAT2 Video



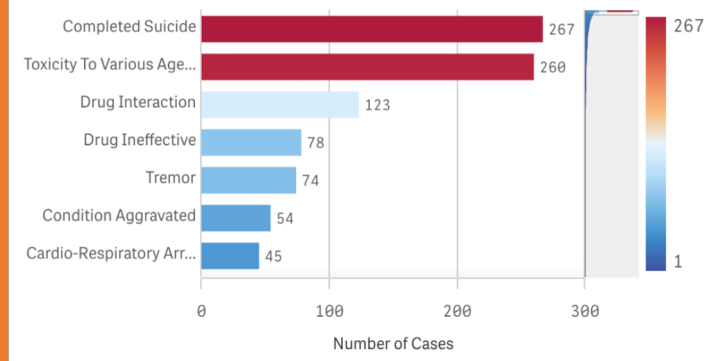
Anticholinergics and VMAT-2 Inhibitors:

Different MOAs, Different Results

Adverse Events Associated with the Use of Benztropine Reported to the FDA, 2017-2021

Case Count by Reaction

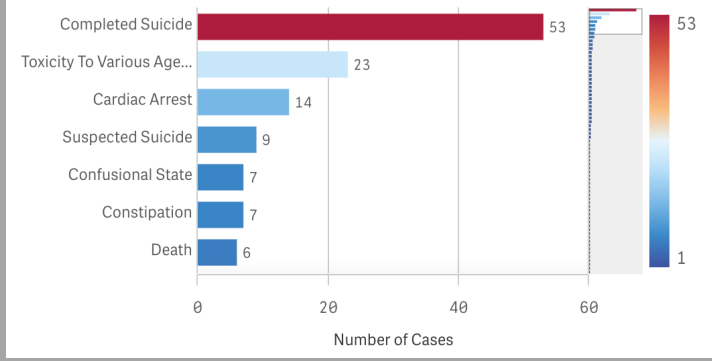
Category	Number of Cases	Percentage
Completed Suicide	267	22.46%
Toxicity To Various Agents	260	21.87%
Drug Interaction	123	10.34%
Drug Ineffective	78	6.56%
Tremor	74	6.22%
Condition Aggravated	54	4.54%
Cardio-Respiratory Arrest	45	3.78%
Confusional State	44	3.70%
Acute Kidney Injury	44	3.70%
Totals	**1,189**	**100.00%**



All ages

Case Count by Reaction

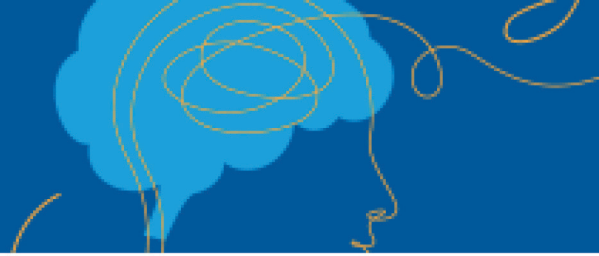
Category	Number of Cases	Percentage
Completed Suicide	53	42.06%
Toxicity To Various Agents	23	18.25%
Cardiac Arrest	14	11.11%
Suspected Suicide	9	7.14%
Confusional State	7	5.56%
Constipation	7	5.56%
Death	6	4.76%
Dysuria	6	4.76%
Abdominal Pain Lower	4	3.17%
Totals	**126**	**100.00%**



≥ 65 years

FAERS = FDA Adverse Event Reporting System.
US Food and Drug Administration. FAERS Public Dashboard. Accessed February 5, 2022.

Deprescribing Anticholinergics: Use a Gentle Hand



Studies in patients with schizophrenia/schizoaffective disorder on long-term anticholinergics

Study of 20 patients in Canada	Study of 34 patients in Japan
Weekly taper: 100%→75%→50%→25%→12.5%→0%	Tapered by 1mg of benztropine-equivalents every 2-4 weeks
90% successfully tapered	96% successfully tapered
20% with TD at baseline no longer met criteria	Mean length of taper 4.5 (±1.6) weeks
Improvement in cognitive measures (p<0.001, ES=0.34)	Improvement in cognitive measures (p=0.002, ES=0.42)

Desmarais, JE, et al. *Therapeutic advances in psychopharmacology* 4.6 (2014): 257-267. Ogino, S, et al. *Progress in Neuro-Psychopharmacology and Biological Psychiatry* 35.1 (2011): 78-83. De Leon, J, et al. *Psychiatric Services* 45.6 (1994): 606-607.

When to Use Anticholinergics in the Setting of TD

Anticholinergics <u>are</u> indicated in treatment of Parkinsonism and dystonia

If TD **<u>and</u>** Parkinsonism or dystonia are present, anticholinergics could be an appropriate choice

Dyskinetic movements could worsen, but the trade-off may be worthwhile in their quality of life

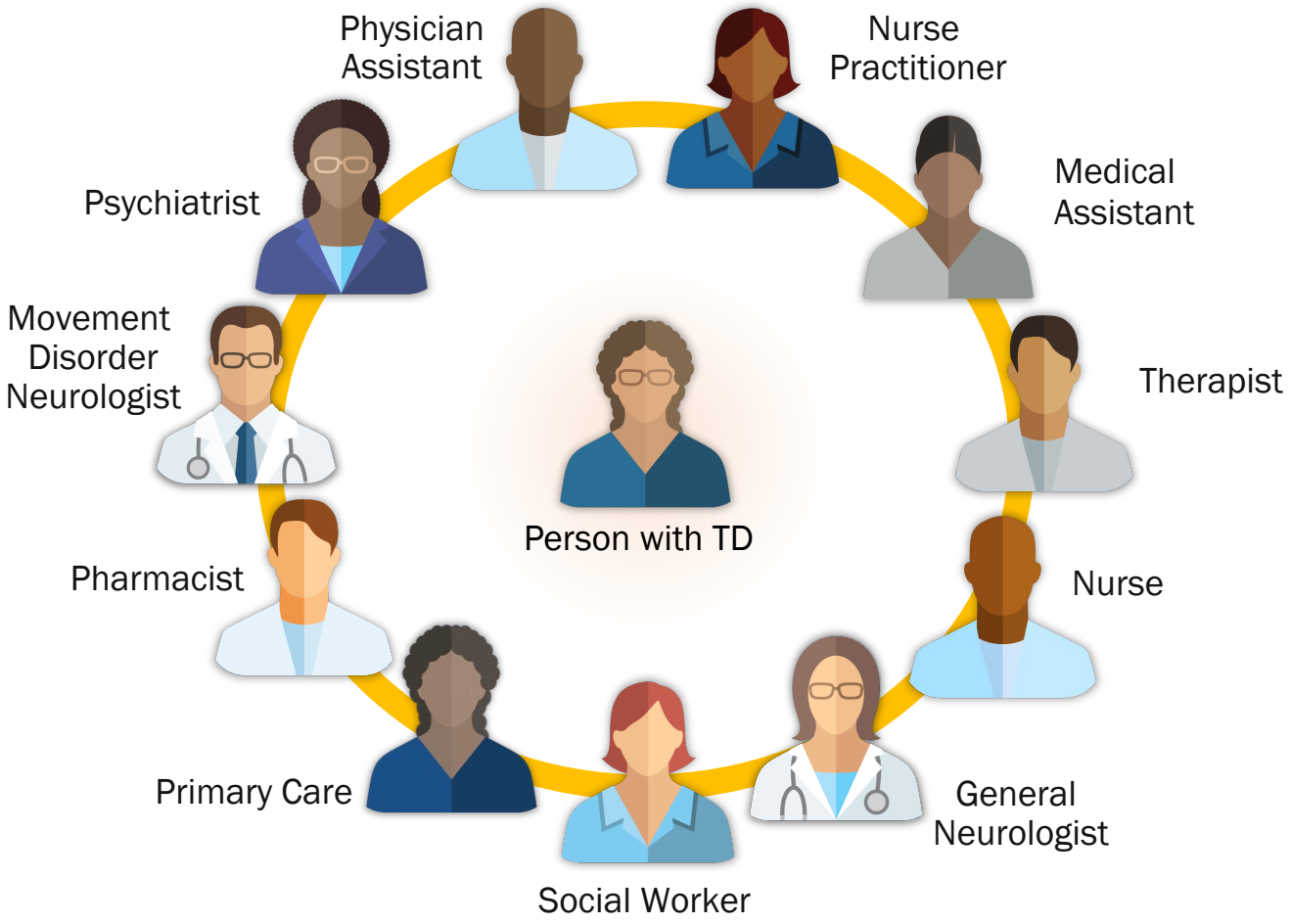
Patients with this kind of mixed presentation may be good candidates for MDS referral

DIP = drug-induced Parkinsonism. MDS = movement disorders specialist.

American Psychiatric Association. *Practice Guideline for the Treatment of Patients with Schizophrenia.* 3rd ed. American Psychiatric Association; 2021. Ward KM, et al. *Neurol Ther.* 2018;7(2):233-248.

Myth: Only Movement Disorder Specialists Can Treat TD

You may say I'm a dreamer...

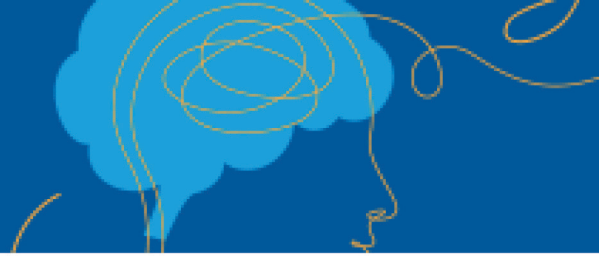


When to Consider Consultation with a Movement Disorder Specialist:

- Family history of other movement disorders (e.g., Huntington's disease)
- Pre-existing movement disorder now coexisting with or complicating TD
- Persistent parkinsonism despite antipsychotic discontinuation
- Prominent dystonia, which may respond to botulinum toxin
- Unresponsive to multiple treatments and may be a Deep Brain Stimulation candidate

Psychiatric clinicians can diagnose and treat ~95% of patients with TD

Caroff, SN, et al. The Journal of Clinical Psychiatry 81.2 (2020): 19042.



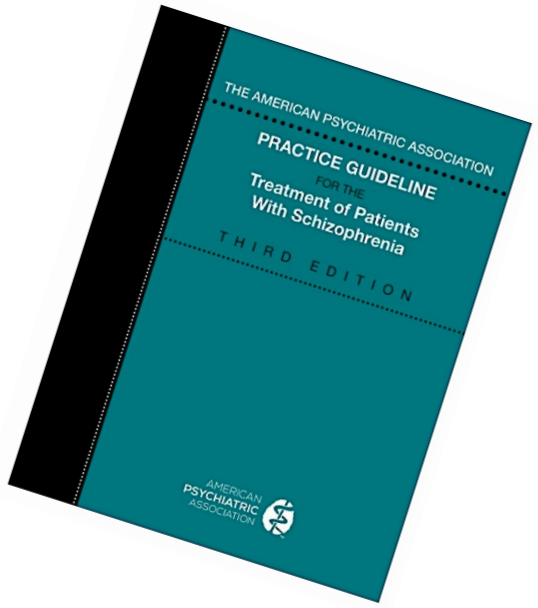
What Do the Guidelines Say About the Treatment of TD?

APA Guideline Recommendations for Treatment of TD

APA recommends that patients who have moderate to severe or disabling tardive dyskinesia associated with antipsychotic therapy be treated with a reversible inhibitor of the vesicular monoamine transporter 2 (VMAT2).

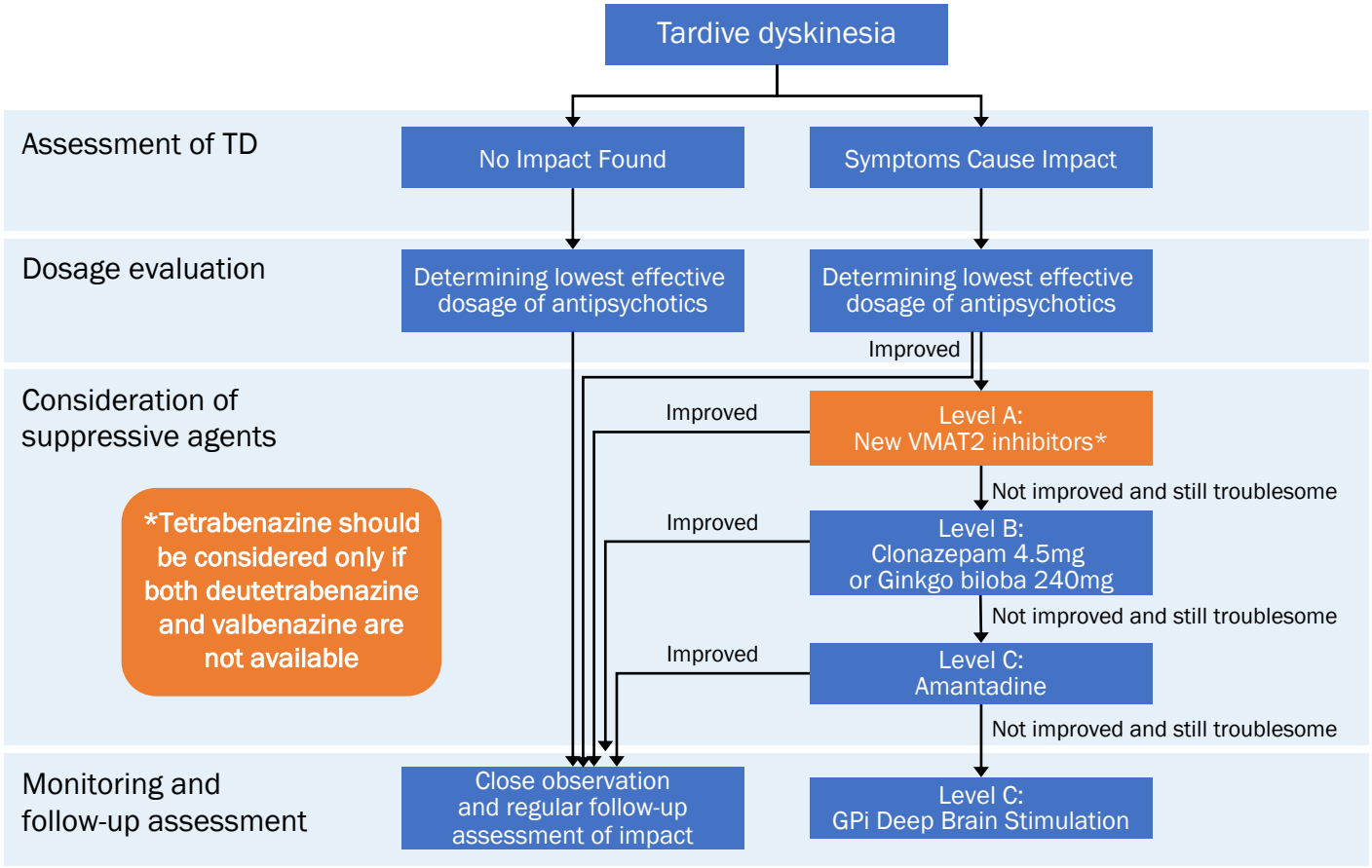
Disability is in the eye of the beholder.
Severity is defined by the impact of functional or quality of life impairment.

- **Treatment with a VMAT2 inhibitor can also be considered for patients with mild TD** based on patient preference, associated impairment, or effect on psychosocial functioning
- **Deutetrabenazine or valbenazine are preferred over tetrabenazine** because of the greater evidence base supporting their use
- **Anticholinergics do not improve and may even worsen tardive dyskinesia** in addition to producing significant side effects.



APA Practice Guideline for the Treatment of Patients with Schizophrenia, Third Edition. 2021. APA Publishing.

Modified 2018 AAN Guideline Updates for Treatment of TD



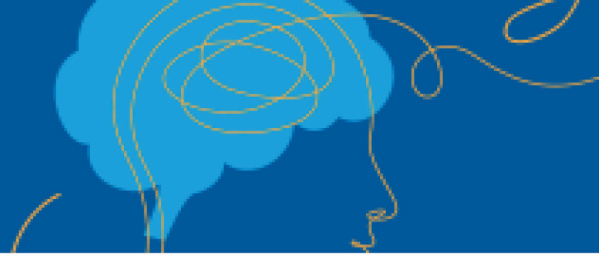
Deutetrabenazine and valbenazine are established as effective treatments of TD (Level A) and ***must*** be recommended as treatment.

The recommendations for DRBA withdrawal and switching from typical to atypical DRBAs remain unchanged at level U (insufficient evidence)

There was no role for anticholinergics (e.g. benztropine) in the algorithm

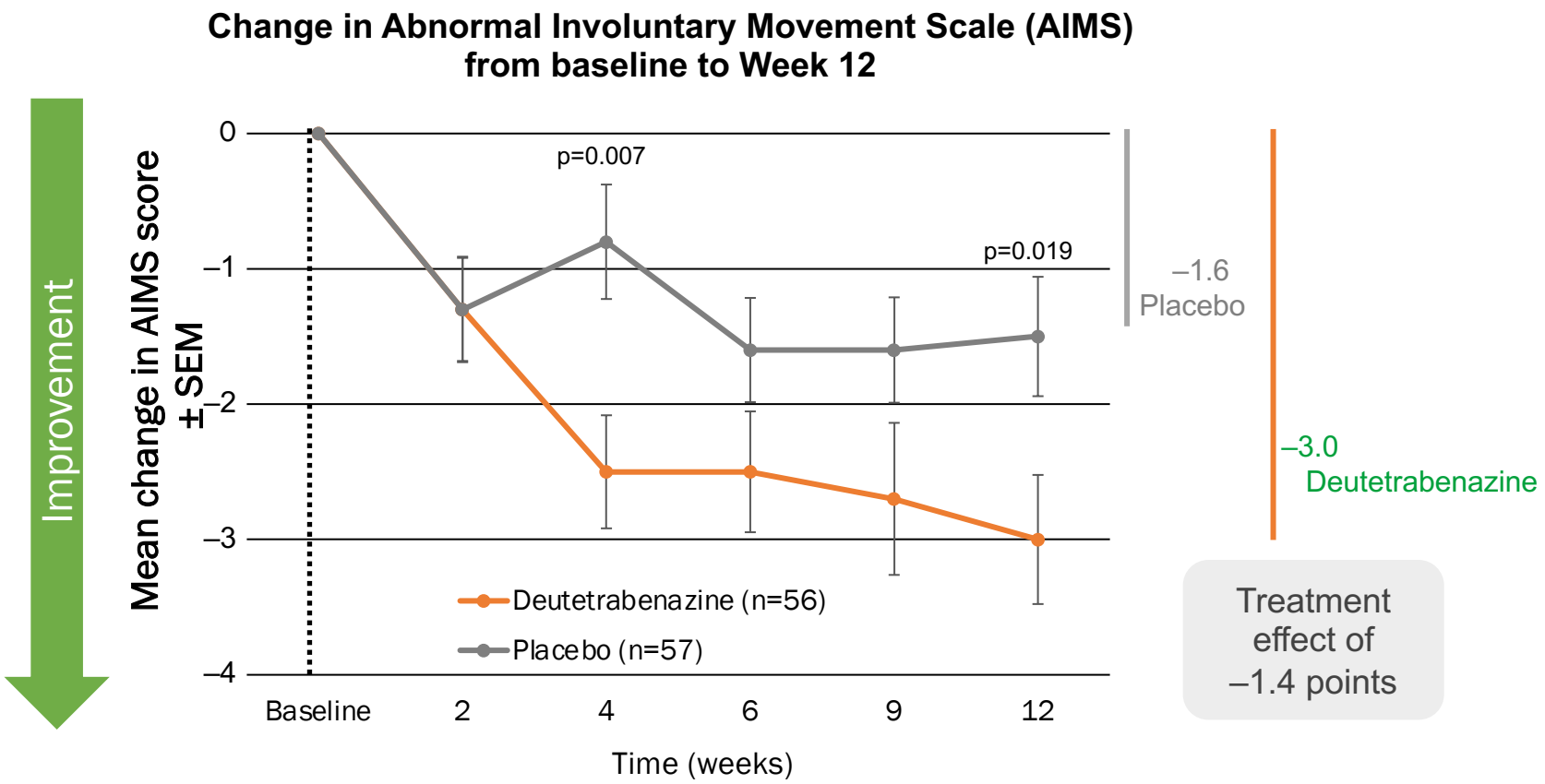
GPi = globus pallidus interna deep brain stimulation; DRBAs=Dopamine Receptor-Blocking Agents

Bhidayasiri R, et al. *J Neurol Sci*. 2018;389:67-75.



Key Clinical Trial Findings of Novel VMAT2 Inhibitors

Flexible-dose study of Deutetrabenazine (ARM-TD)



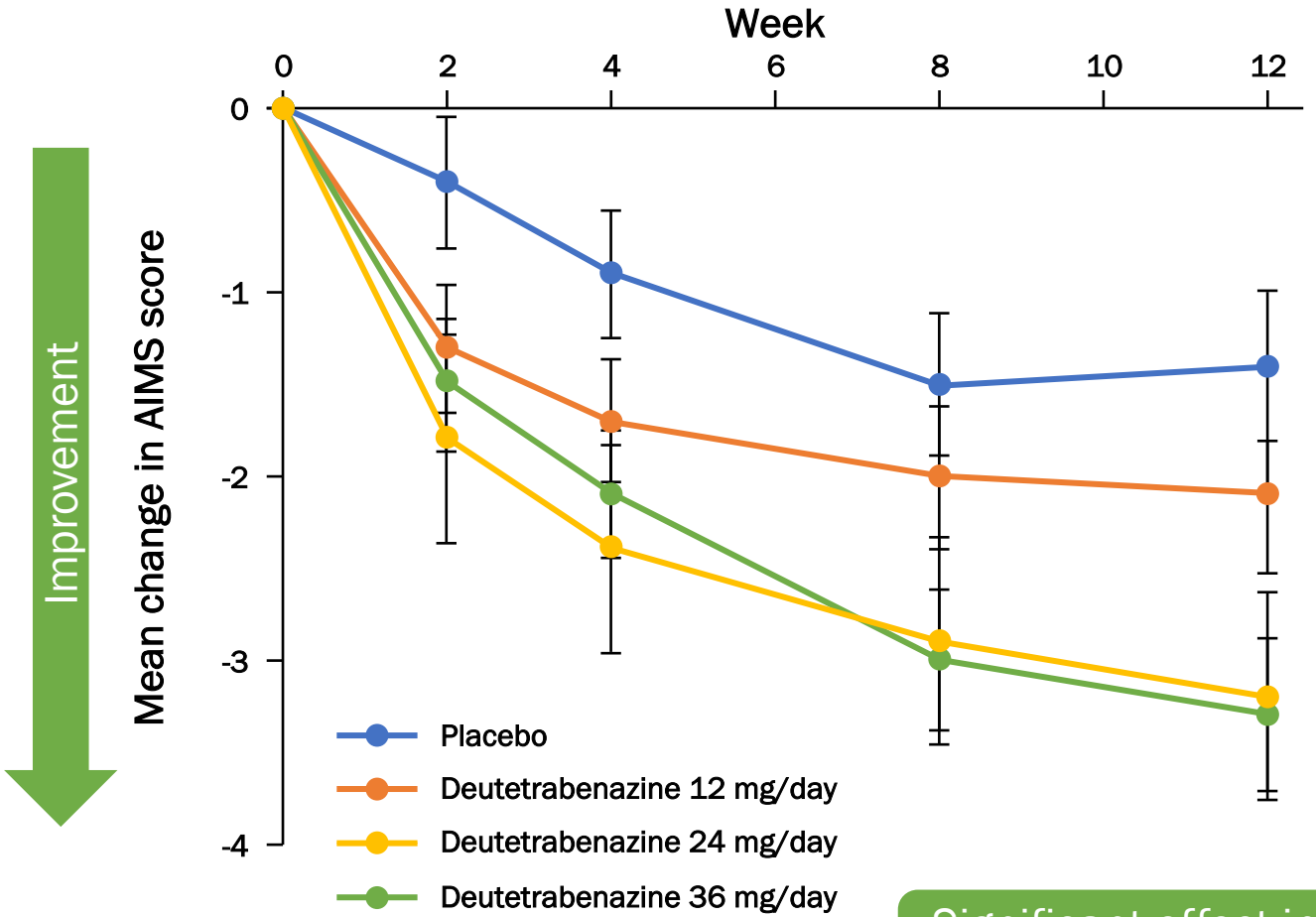
Deutetrabenazine significantly reduced AIMS total score by at Week 12 compared with placebo (p=0.019)

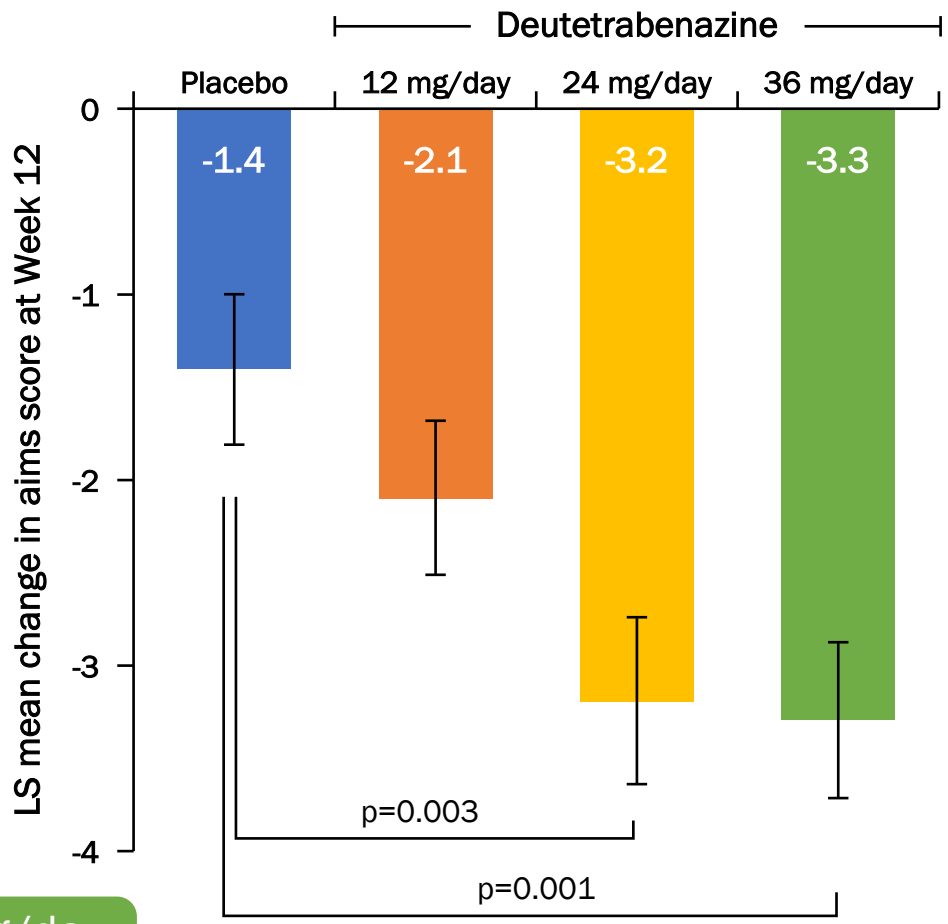
Mean dose at the end of titration was 38.8 mg/day

AIMS, Abnormal Involuntary Movement Scale; ARM-TD, Aim to Reduce Movements in Tardive Dyskinesia; SEM, standard error of the mean.

Fernandez HH, et al. Neurology 2017;88:2003–10.

Fixed-dose study of Deutetrabenazine (AIM-TD)





Significant effect in 36 mg/day and 24 mg/day groups

AIM-TD, Involuntary Movements in Patients with Tardive Dyskinesia; AIMS, Abnormal Involuntary Movement Scale; LS, least squares.

Anderson KE, et al. Lancet Psychiatry 2017;4:595–604.

Deutetrabenazine Safety and Tolerability in Short-Term Studies

Placebo-Controlled TD Studies: Adverse Reactions Reported in ≥ 2% of Patients Treated with deutetrabenazine

Adverse Reaction	Deutetrabenazine (n=279)	Placebo (n=131)
Headache	5%	8%
Somnolence	4%	7%
Diarrhea	4%	4%
Nasopharyngitis	4%	2%
Fatigue	4%	5%
Insomnia	4%	1%
Anxiety	4%	5%
Upper respiratory tract infection	3%	4%
Dry mouth	3%	5%
Nausea	2%	7%
Weight increased	2%	3%
Urinary tract infection	2%	2%
Depression/Dysthymic Disorder	2%	1%
Akathisia/Agitation/Restlessness	2%	1%
Arthralgia	2%	1%

Only highlighted AEs occurred at a greater rate in patients taking deutetrabenazine than in patients taking placebo

Discontinuation due to AEs occurred in 4% of patients taking deutetrabenazine vs 3% of patients taking placebo

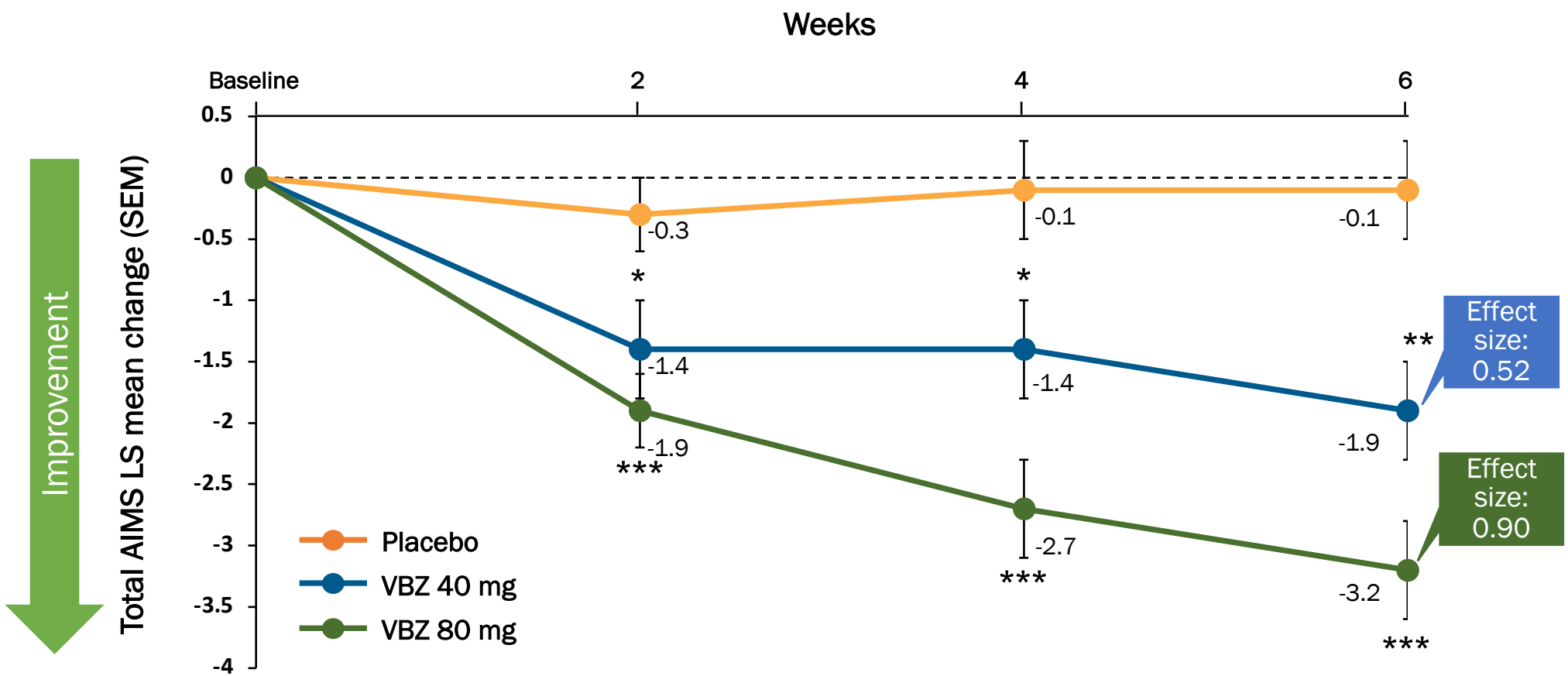
Anderson KE, et al. *Lancet Psychiatry*. 2017;4(8):595-604. Fernandez HH, et al. *J Neurol Neurosurg Psychiatry*. 2019;90(12):1317-1323.

Fixed-dose study of Valbenazine in North America (KINECT 3)

Mean baseline AIMS total score: 10.0± 4.0

DBPC Change From Baseline

VBZ 80 mg: -3.2***
VBZ 40 mg: -1.9**
Placebo: -0.1



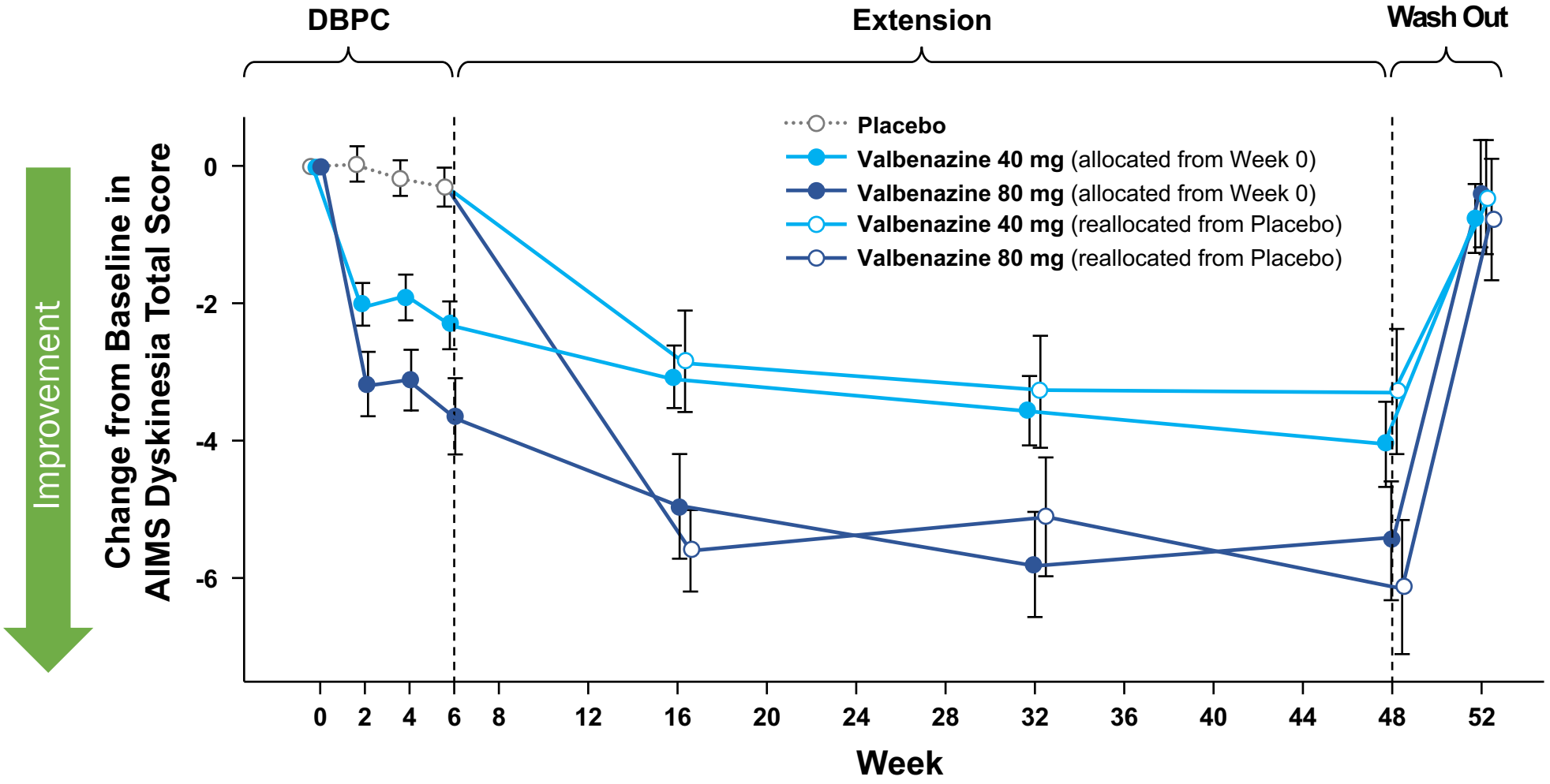
*P<0.05. **P<0.01. ***P≤0.001.
SEM = standard error of the mean; VBZ = valbenazine
Hauser RA, et al. *Am J Psychiatry*. 2017;174(5):476-484.

Phase 3 Fixed-Dose Study of Valbenazine in Japan (J-KINECT)

Mean baseline AIMS total score: 7.6 ± 4.1

DBPC Change From Baseline

VBZ 80 mg: -3.7*
VBZ 40 mg: -2.3*
Placebo: -0.1

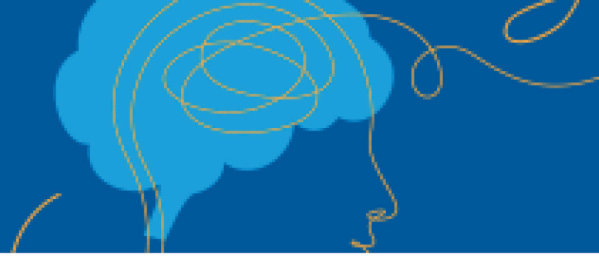


*P<0.001

DBPC = double-blind placebo controlled; AIMS = Abnormal Involuntary Movement Scale; VBZ = valbenazine

Horiguchi, J., et al. Psychiatry Clin. Neurosci. Accepted Author Manuscript. (2022).

Valbenazine Safety and Tolerability in Short-Term Studies



Adverse Events in 6-Week Valbenazine DBPC Studies in North America Reported at ≥ 2% and > Placebo

Adverse Event	Valbenazine (n=262) (%)	Placebo (n=183) (%)
Somnolence	10.9%	4.2%
Anticholinergic effects	5.4%	4.9%
Balance disorders/fall	4.1%	2.2%
Headache	3.4%	2.7%
Akathisia (akathisia, restlessness)	2.7%	0.5%
Vomiting	2.6%	0.6%
Nausea	2.3%	2.1%
Arthralgia	2.3%	0.5%

Discontinuation due to AEs occurred in 3% of patients taking valbenazine vs 2% of patients taking placebo

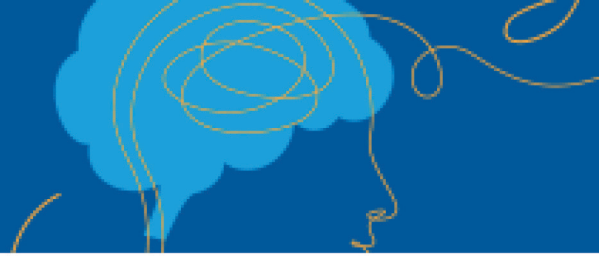
[a]somnolence, fatigue, sedation
[b]dry mouth, constipation, disturbance in attention, vision blurred, urinary retention
[c]fall, gait disturbance, dizziness, balance disorder

Treatment-Emergent Adverse Events in J-KINECT DBPC Reported at ≥ 2% and > Placebo

	Placebo (n=84)	VBZ 40 mg (n=85)	VBZ 80 mg (n=84)
Somnolence	2 (2.4%)	10 (11.8%)	21 (25.0%)
Salivary hypersecretion	1 (1.2%)	3 (3.5%)	9 (10.7%)
Nasopharyngitis	6 (7.1%)	6 (7.1%)	4 (4.8%)
Malaise	0 (0.0%)	5 (5.9%)	4 (4.8%)
Akathisia	1 (1.2%)	4 (4.7%)	5 (6.0%)
Insomnia	1 (1.2%)	2 (2.4%)	5 (6.0%)
Schizophrenia	1 (1.2%)	7 (8.2%)	0 (0.0%)
Tremor	0 (0.0%)	0 (0.0%)	5 (6.0%)

TEAE leading to discontinuation:
Placebo: 3.6%, VBZ 40 mg: 7.1%, VBZ 80 mg: 16.7%

US Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. Accessed 4/19/22. www.accessdata.fda.gov/scripts/cder/daf/index.cfm.
Horiguchi, J., et al. Psychiatry Clin. Neurosci. Accepted Author Manuscript. (2022).

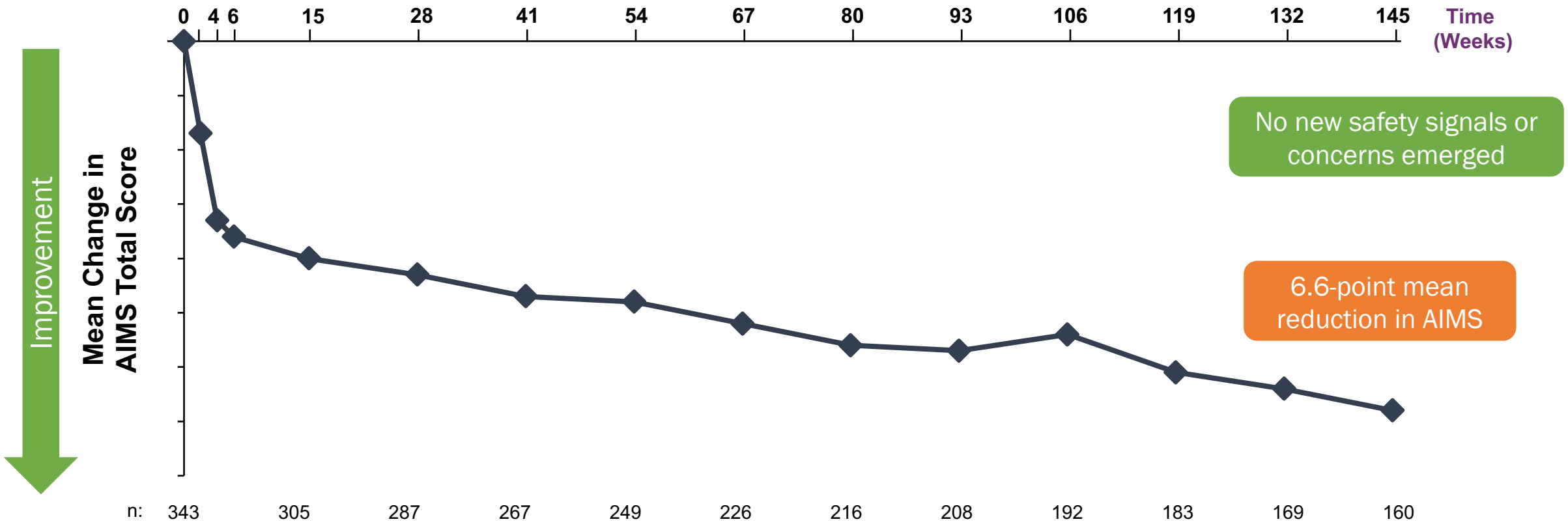


Deutetrabenazine and Valbenazine Long-Term Data

Long-Term Study of Deutetrabenazine (RIM-TD)

Baseline mean AIMS score: 8.8

Open-Label Extension Study of Patients from ARM-TD and AIM-TD



No new safety signals or concerns emerged

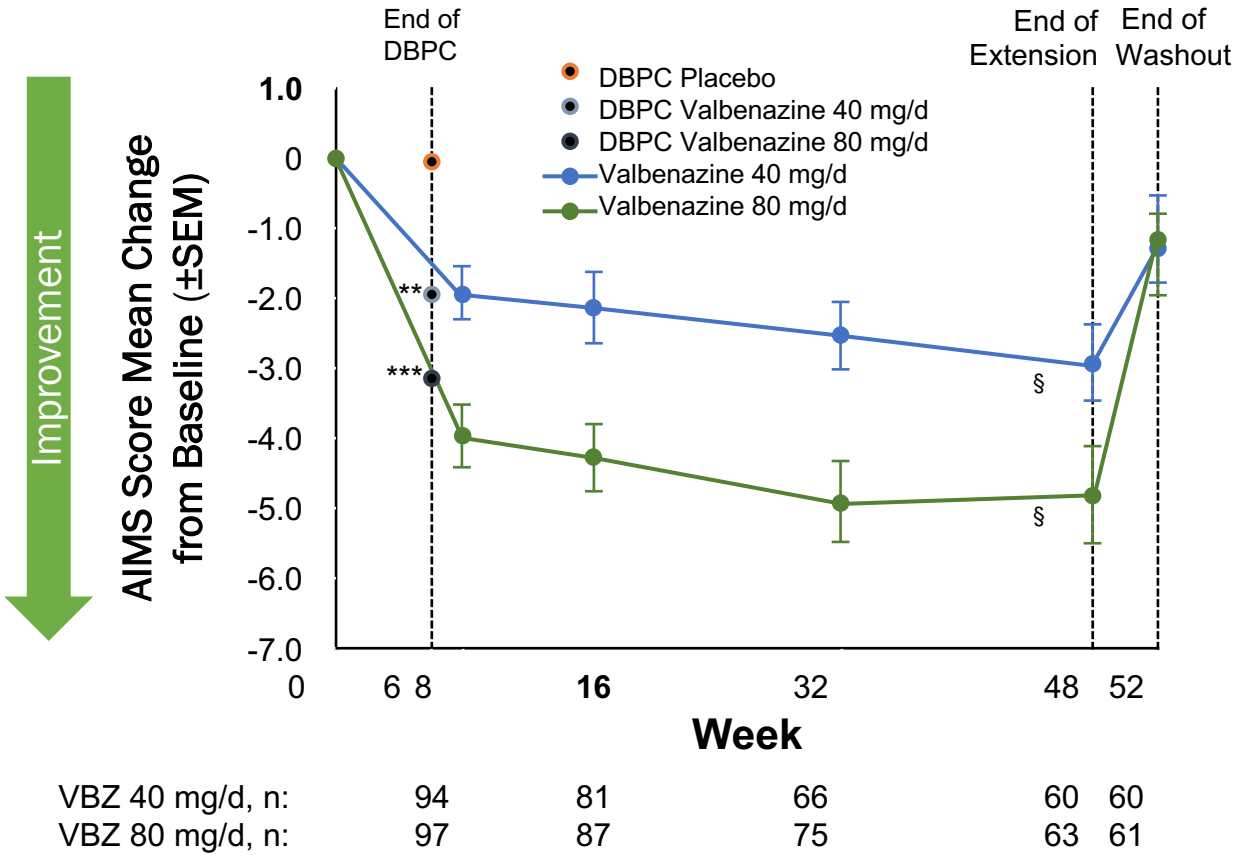
6.6-point mean reduction in AIMS

Mean total daily dose (mg):	38.7	39.3	39.4

Hauser RA, et al. Long-Term Treatment with Deutetrabenazine is Associated with Continued Improvement in Tardive Dyskinesia: Results from the Completed, 3-Year Open-Label Extension Study. Presented at: 2020 Psych Congress Virtual Experience; September 10–13, 2020.

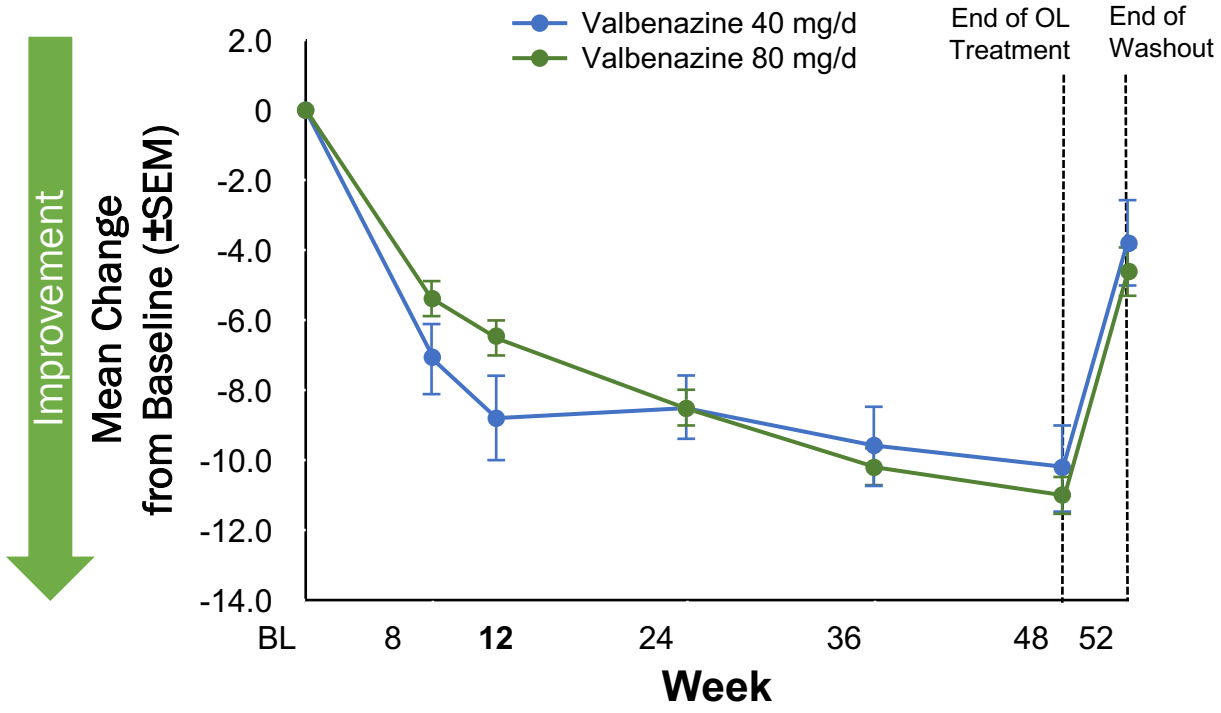
Long-Term Valbenazine Data

KINECT-3 Extension



VBZ 40 mg/d, n:	94	81	66	60	60
VBZ 80 mg/d, n:	97	87	75	63	61

KINECT-4



VBZ 40 mg/d, n:45	33	30	25	20	20	20
VBZ 80 mg/d, n:107	105	97	87	79	74	74

No new safety signals or concerns emerged in either study

DBPC = Double-blind placebo control
*****P*<.01 vs placebo. ****P*<.001 vs placebo. § *P*<.001 vs baseline.**
Factor SA, et al. *J Clin Psychiatry*. 2017;78(9):1344-1350. Marder SR, et al. *J Clin Psychopharmacol*. 2019;39(6):620-627.

Effects of Deutetrabenazine in Older Individuals Through 145 Weeks

Mean ages	AE leading to discontinuation after 145 weeks	Mean changes from baseline in total AIMS at week 145	≥50% AIMS response at week 145
45.6 years (range 21–54) in the younger subgroup	<55 years = 8%	<55 years = −6.7	<55 years = 76%
63.1 years (range 55–81) in the older subgroup	≥55 years = 14%	≥55 years = −6.5	≥55 years = 62%

Mean dose ~39.5 mg/d in both groups

In a post-hoc analysis of a 145-week open-label study, long-term treatment with deutetrabenazine was *well-tolerated* and associated with *sustained improvements* in AIMS score and *treatment success* in both younger and older adults

AIMS = Abnormal Involuntary Movement Scale

Sajatovic, M, et al. The American Journal of Geriatric Psychiatry 30.3 (2022): 360-371.

Effects of Valbenazine in Older Individuals Through 48 weeks

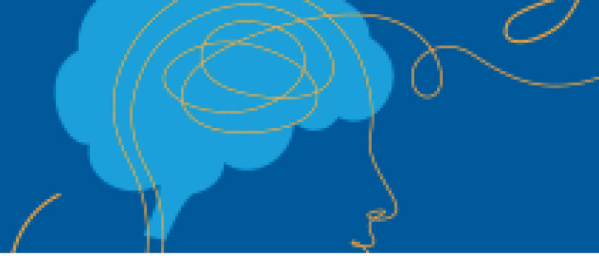
Mean ages	AE leading to discontinuation after 48 weeks	Mean changes from baseline in total AIMS at week 48	≥50% AIMS response at week 48
46.6 years (range 26-54) in the younger subgroup	<55 years = 9.6%	40 mg: <55 years = -4.4, ≥55 years = -6.5	40 mg: <55 years = 38%, ≥55 years = 64%
62.4 years (range 55-84) in the older subgroup	≥55 years = 18.9%	80 mg: <55 years = -7.2, ≥55 years = -9.2	80 mg: <55 years = 69%, ≥55 years = 74%

In a post-hoc analysis of a 48-week open-label study, long-term treatment with valbenazine was *well-tolerated* and associated with *sustained improvements* in AIMS score and *treatment success* in both younger and older adults

DBPC = double-blind placebo-controlled; AIMS = Abnormal Involuntary Movement Scale

Sajatovic, M, et al. International journal of geriatric psychiatry 35.1 (2020): 69-79.

Summary



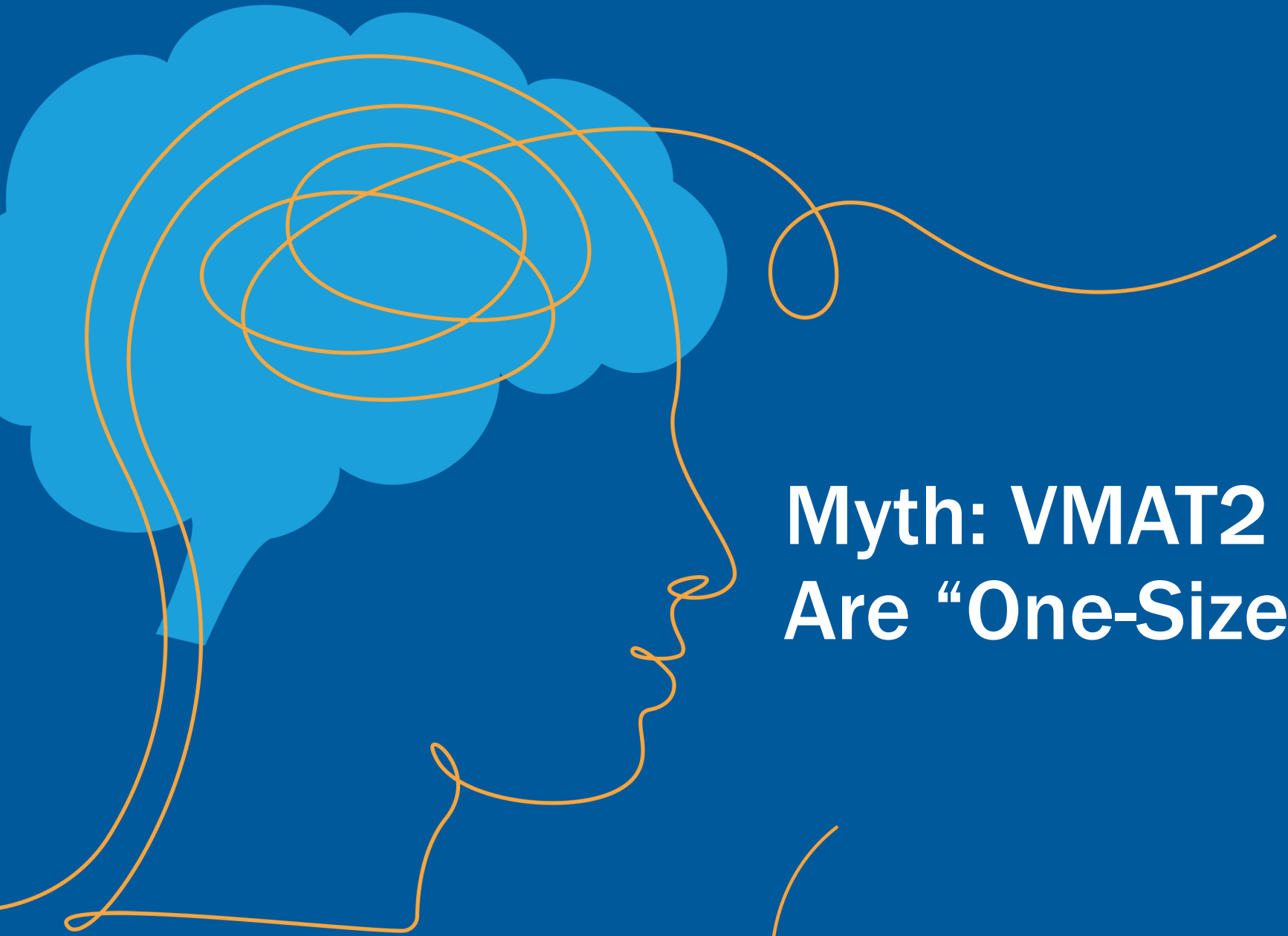
Confident diagnosis, confident treatment

There are far too few movement disorder specialists to diagnose or treat every case of TD

Psychiatry can diagnose and treat 95% of patients with TD

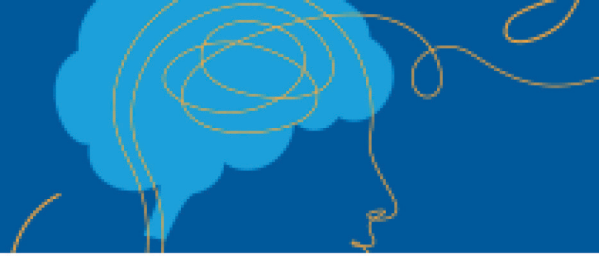
VMAT2 inhibitors are well tolerated and efficacious at therapeutic doses

You've Got This!



Myth: VMAT2 Inhibitors Are “One-Size-Fits-All”

Basic Similarities and Differences of VMAT2 Inhibitors



	Tetrabenazine	Deutetrabenazine	Valbenazine
Indications	HD Chorea; Not approved for TD	TD and HD	TD
Dosing	TID; No RCTs in TD so safe/efficacious dosing unknown	12, 15, 18, 21, and 24 mg BID	40, 60, or 80 mg once daily
Precautions	Boxed warning: Exercise caution when treating patients with a history of depression or prior suicide attempts or ideation	Max 36mg/d with strong 2D6 inhibitor; No 3A4 interactions; No clinically relevant QT prolongation at recommended doses	Max 40mg per day with strong 2D6 or 3A4 inhibitor. Not recommended with strong 3A4 inducer. No clinically relevant QT prolongation

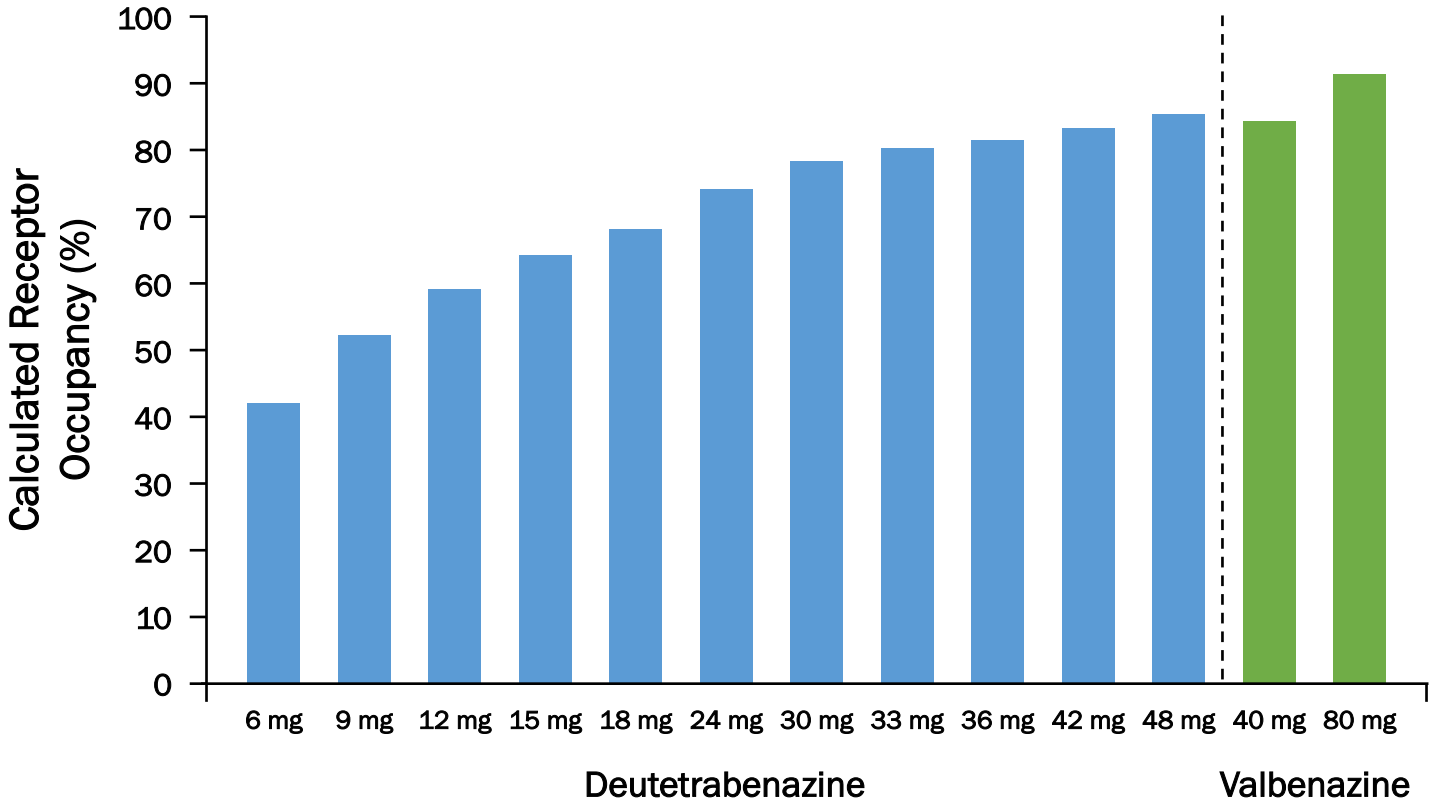
Both deutetrabenazine and valbenazine are efficacious and well-tolerated in treating TD, whatever the underlying diagnosis

Neither requires the discontinuation or change of antipsychotic therapy

Neither was shown to worsen psychiatric illness or increase suicidality in TD trials

RCT= Randomized Controlled Trial; BID = twice daily; PI = HD = Huntington's disease; TID = three times daily.
US Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

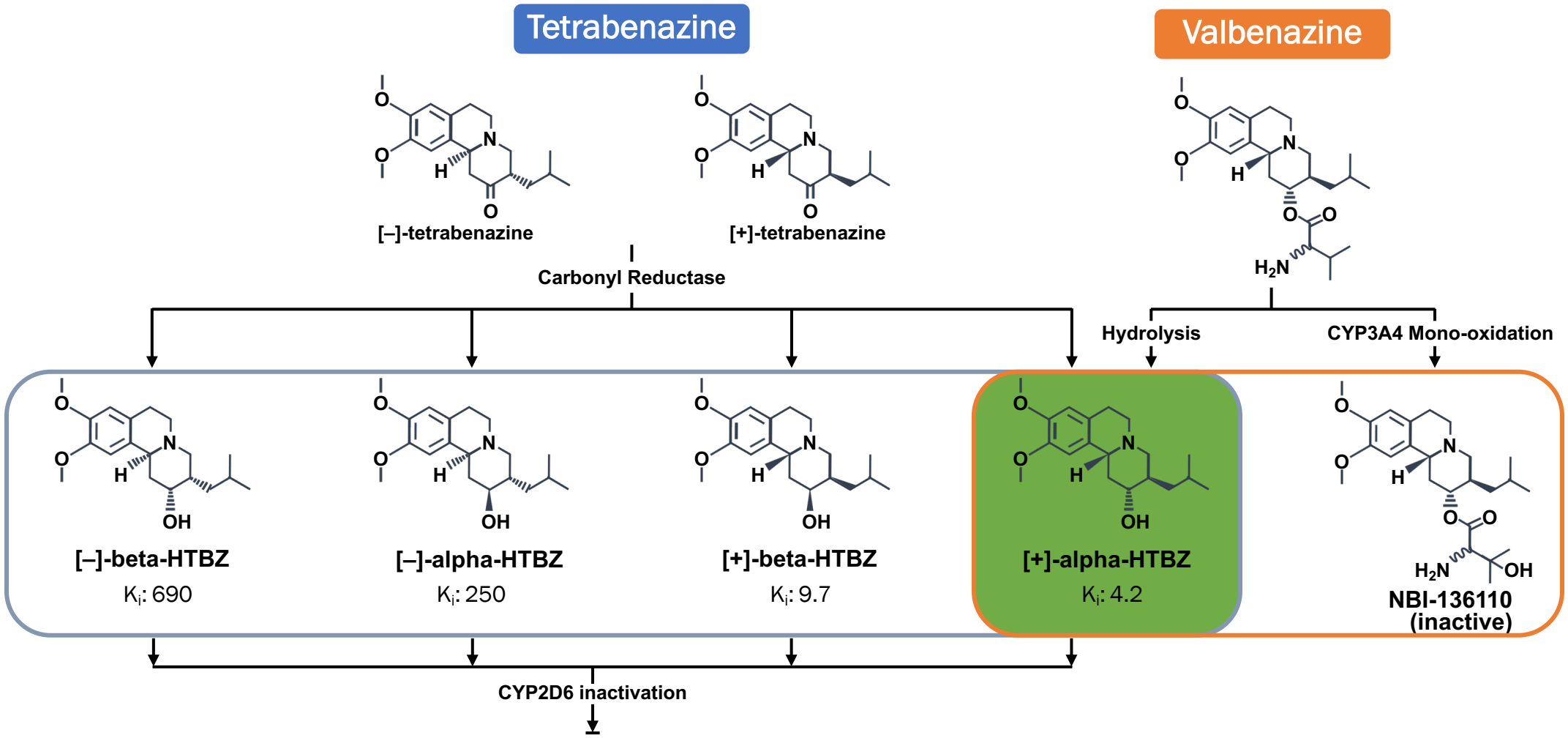
VMAT2 Receptor Occupancy of Valbenazine and Deutetrabenazine



At therapeutic doses, net occupancy of VMAT2 by the active metabolites of both compounds is comparable

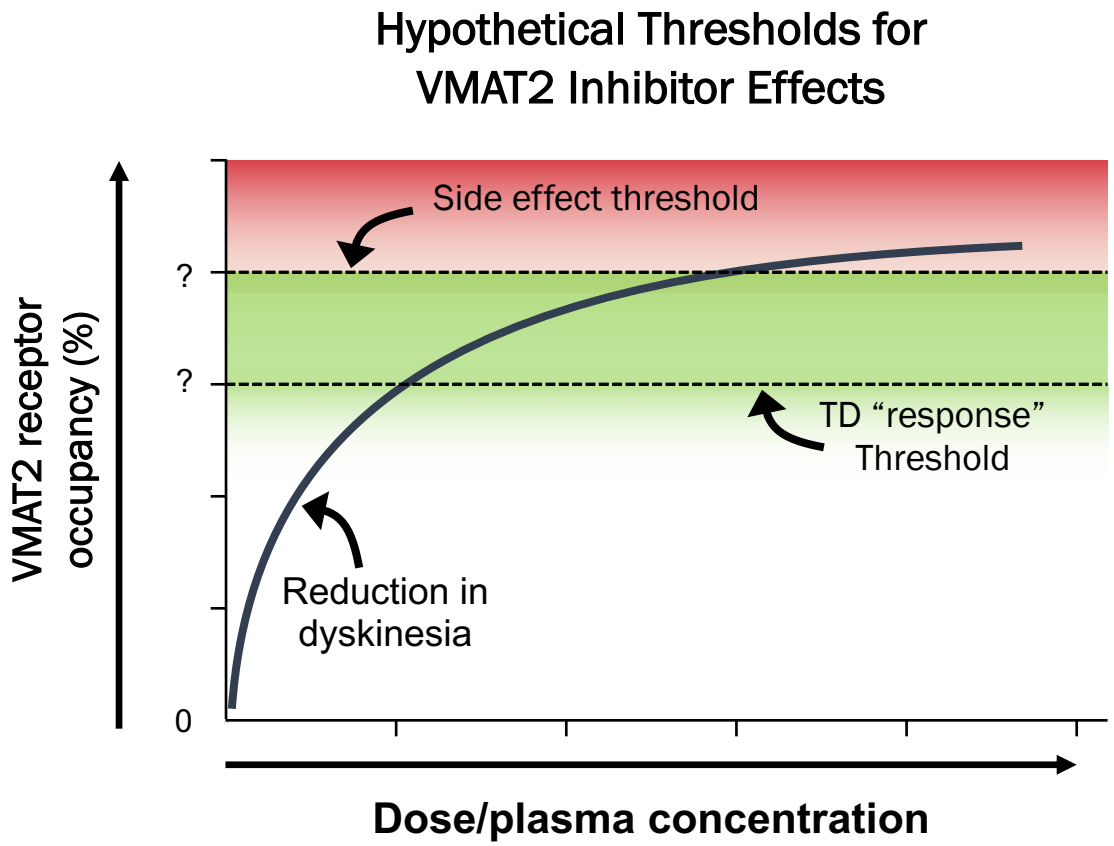
Stahl SM. *CNS Spectr*. 2018;23(4):239-247.

Differences in Metabolism of Valbenazine vs Tetrabenazine



Grigoriadis DE, et al. *J Pharmacol Exp Ther*. 2017;361(3):454-461. Skor, et al. Drugs in R&D 17.3 (2017): 449-459.

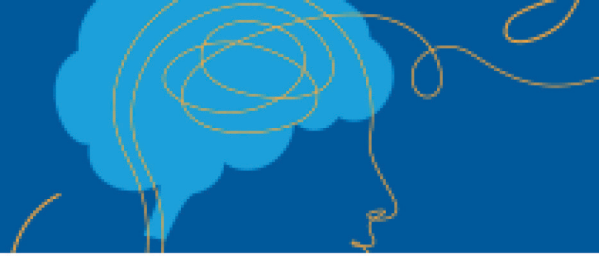
Optimizing Efficacy and Managing Side Effects of VMAT2 Inhibitors for TD



Customize the TD treatment to the individual needs of your patient!

Stahl SM. *CNS Spectr.* 2018;23(4):239-247. Chepke, C. *CureSZ Foundation Newsletter.* 2019;8:3.

Breaking Down Barriers to Using Novel VMAT2 Inhibitors



Patient Reluctance	Address concerns about potential side effects and their management	Ask specific questions about function & QoL; involve family	Motivational interviewing
Managed Care Hurdles	AIMS required (± score threshold)	Step-through benztropine requested	Step-through tetrabenazine requested
Don't give up!	Guidelines strongly recommend the novel VMAT2 inhibitors over any other treatment— or none!	**Your patients are worth fighting for!**	

Caroff SN. Neuropsychiatr Dis Treat. 2019;15:785-794. Velligan DI, et al. J Clin Psychiatry. 2009;70(Suppl 4):1-46.

Q&A