



# The Agitation in Alzheimer's Screener for Caregivers (AASC™)

*One Minute to Recognition: Development of a New Screening Tool*

This program is paid for by Otsuka  
Pharmaceutical Development &  
Commercialization, Inc. (OPDC) and  
Lundbeck, LLC.

# Objectives

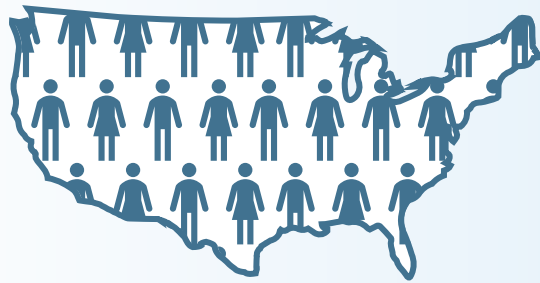
Define Agitation in Alzheimer's Dementia including symptom presentation, prevalence and burden on patients and caregivers

Identify challenges in discussing Agitation in Alzheimer's Dementia between patients, health care providers, caregivers and family members

Describe the development of the Agitation in Alzheimer's Screener for Caregivers (AASC)<sup>TM</sup>

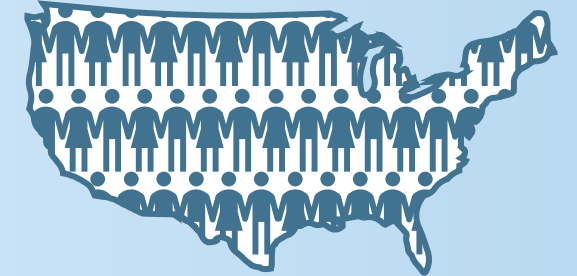
# Alzheimer's Dementia Is a Highly Prevalent Neurodegenerative Disorder<sup>1</sup>

Estimated number of US adults aged  $\geq 65$  years living with Alzheimer's dementia:



**2023**  
**~6.7**  
**MILLION**

**2050**  
**~12.7**  
**MILLION**



In 2023, ~65% of people with Alzheimer's or other forms of dementia lived in the community, receiving more care from family members and other unpaid caregivers as their disease progressed

US, United States.

1. Alzheimer's Association 2023. *Alzheimers Dement.* 2023;19(4):1598-1695.

# What Is Agitation Associated With Alzheimer's Dementia (AAD)?

Agitation is one of the most common neuropsychiatric symptoms of Alzheimer's dementia<sup>1</sup>

- Manifestations of Alzheimer's dementia are not limited to cognitive decline and functional impairment, and include a range of neuropsychiatric symptoms, such as anxiety, irritability, and agitation<sup>2-5</sup>
- Symptoms of agitation manifest as both non-aggressive and aggressive behaviors, such as<sup>6,7</sup>:

## EXCESSIVE MOTOR ACTIVITY:

Pacing, restlessness, repetitiveness, and hoarding



## VERBAL AGGRESSION:

Screaming, using profanity, and asking repetitive questions

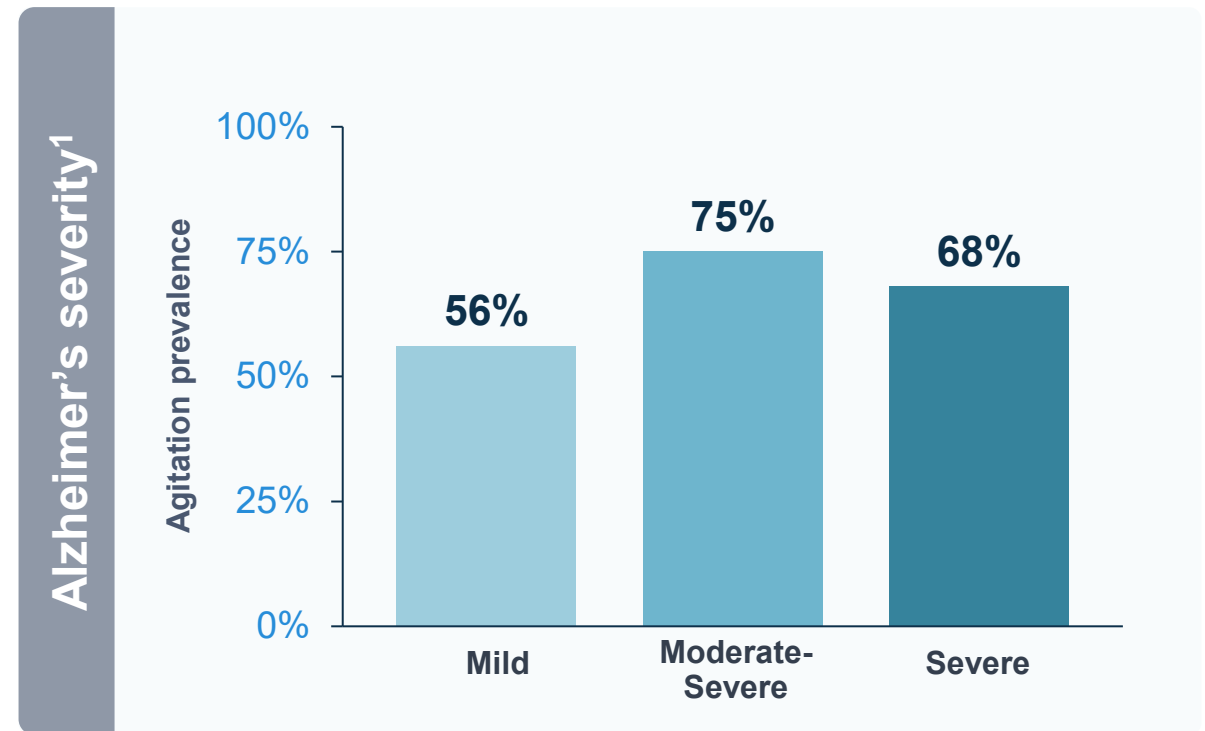
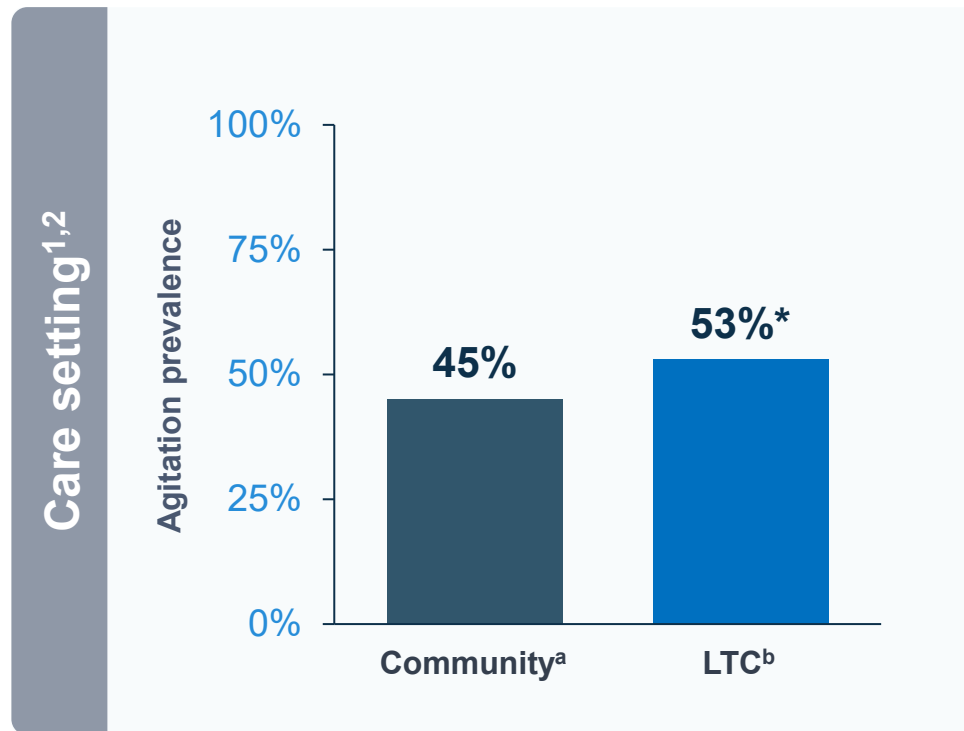
## PHYSICAL AGGRESSION:

Hitting, kicking, punching, biting, and throwing things

1. Halpern R, et al. *Int J Geriatr Psychiatry*. 2019;34(3):420-431. 2. Alzheimer's Association 2023. *Alzheimers Dement*. 2023;19(4):1598-1695. 3. Antonsdottir IM, et al. *Expert Opin Pharmacother*. 2015;16(11):1649-1656. 4. Anatchkova M, et al. *Int Psychogeriatr*. 2019;31(9):1305-1318. 5. Kales HC, et al. *BMJ*. 2015;350:h369. 6. Sano M, et al. *Int Psychogeriatr*. 2023;1-13. 7. Rabinowitz J, et al. *Am J Geriatr Psychiatry*. 2005;13(11):991-998.

# Agitation Is Highly Prevalent and Present in All Stages and Severities of Alzheimer's Dementia<sup>1</sup>

AAD is prevalent across care settings and Alzheimer's dementia severities<sup>1,2</sup>



\*Nursing home percentage reported includes those with Alzheimer's dementia and other dementias. <sup>a</sup>Residential homes. <sup>b</sup>Nursing homes/skilled nursing facilities.

AAD, agitation associated with Alzheimer's dementia. LTC, long-term care.

1. Halpern R, et al. *Int J Geriatr Psychiatry*. 2019;34(3):420-431. 2. Fillit H, et al. *Int J Geriatr Psychiatry*. 2021;36(12):1959-1969.

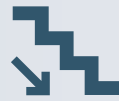
# AAD Worsens the Impact of an Already Devastating and Burdensome Disease for Patients<sup>1,2</sup>

Agitation\* in patients with Alzheimer's dementia been associated with:

Overall<sup>1-7</sup>



Accelerated disease progression



Functional decline



Decreased quality of life



Greater comorbidities



Increased use of concomitant therapies



Earlier death



Increased risk of hospitalization/institutionalization

In LTC<sup>1</sup>



Falls



Fractures



Infections



Higher medication use



Other NPS<sup>a</sup>

\*Versus no agitation.

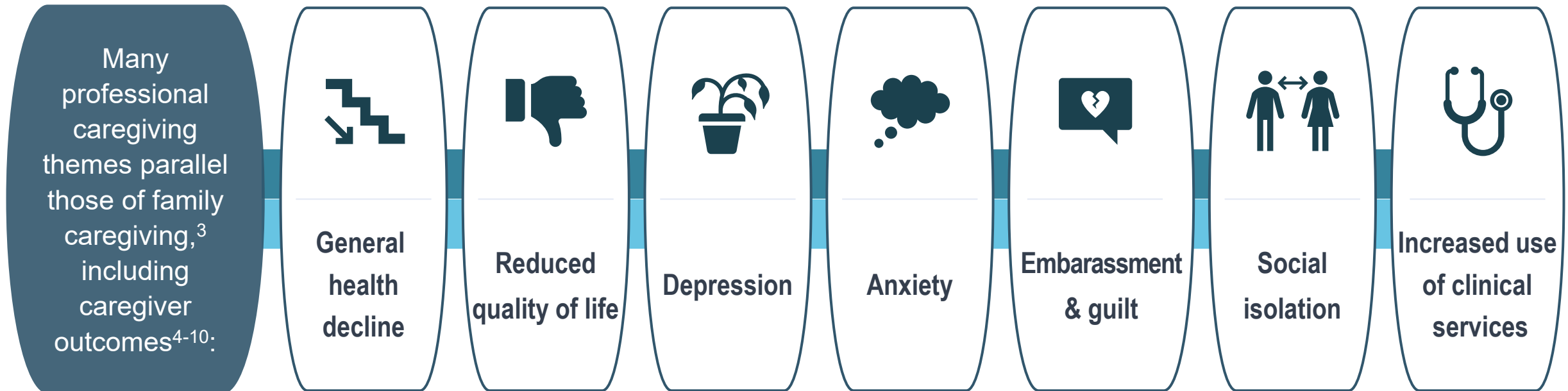
<sup>a</sup>Includes depression, anxiety, delusion, and hallucinations.

AAD, agitation associated with Alzheimer's dementia. LTC, long-term care. NPS, neuropsychiatric symptoms.

1. Fillit H, et al. *Int J Geriatr Psychiatry*. 2021;36(12):1959-1969. 2. Jones E, et al. *J Alzheimers Dis*. 2021;83(1):89-101. 3. Halpern R, et al. *Int J Geriatr Psychiatry*. 2019;34(3):420-431. 4. Koenig AM, et al. *Curr Psychiatry Rep*. 2016;18(1):3. 5. Peters ME, et al. *Am J Psychiatry*. 2015;172(5):460-465. 6. Scarmeas N, et al. *Arch Neurol*. 2007;64(12):1755-1761. 7. Banerjee S, et al. *J Neurol Neurosurg Psychiatry*. 2006;77(2):146-148.

# Agitation in Patients With Alzheimer's Dementia Has Been Associated With High Caregiver Burden Which Increases With Severity<sup>1</sup>

AAD is a risk factor for burnout, reduced workability, and generally weaker health among caregivers<sup>2</sup>



AAD, agitation associated with Alzheimer's dementia.

1. Schein J, et al. *J Alzheimers Dis.* 2022;88(2):663-677. 2. Palm R, et al. *J Alzheimers Dis.* 2018;66(4):1463-1470. 3. McCarty EF and Drebing C. *J Nurses Staff Dev.* 2002;18(5):250-257. 4. Kales HC, et al. *BMJ.* 2015;350:h369. 5. Mohamed S, et al. *Am J Geriatr Psychiatry.* 2010;18(10):917-927. 6. Isik AT, et al. *Int J Geriatr Psychiatry.* 2019;34(9):1326-1334. 7. Brodaty H and Hadzi-Pavlovic D. *Aust N Z J Psychiatry.* 1990;24(3):351-361. 8. Thomas P, et al. *Int J Geriatr Psychiatry.* 2006;21(1):50-56. 9. Patrick KS, et al. *Psychogeriatrics.* 2022;22(5):688-698. 10. Cohen-Mansfield J. *J Psychiatr Res.* 2008;43(1):64-69.



# Treatment Considerations

A primary goal of developing a comprehensive, person-centered treatment plan is symptom relief<sup>1,2</sup>



## Differential diagnosis<sup>2,3</sup>

Careful evaluation for general medical, psychiatric, environmental, or psychosocial problems that may underlie the disturbance

- Assessment for the type, frequency, severity, pattern, and timing of symptoms



## Nonpharmacologic interventions<sup>2,3</sup>

If agitation does not cause significant danger or marked distress to the patient or others, symptoms are best treated with environmental or behavioral measures including:

- Behavioral management therapy or behavioral interventions
- Emotion-oriented approaches
- Stimulation-oriented treatments (eg, recreational activity, art therapy, music therapy, and pet therapy)



## Pharmacologic interventions<sup>2,3</sup>

If nonpharmacologic measures are unsuccessful or symptoms are severe, dangerous, and/or cause significant distress, then judicious pharmacological intervention is recommended

- Antipsychotics are the pharmacological therapy recommended by the APA for agitation in dementia

**There is only one FDA-approved drug for treatment of AAD, and it is classified as an atypical antipsychotic<sup>4</sup>**



However, clinicians may prescribe other pharmacologic treatments, including<sup>3,5,6</sup>:

- ✓ Antipsychotics (typical and atypical)
- ✓ Anxiolytics or sedative-hypnotics
- ✓ Anticonvulsants
- ✓ Antidepressants
- ✓ Other medications

APA, American Psychiatric Association. AAD, agitation associated with Alzheimer's dementia.

1. Kales HC, et al *J Am Geriatr Soc*. 2014;62(4):762-769. 2. Reus IV, et al. *Am J Psychiatry*. 2016;173(5):543-546. 3. Rabins PV, et al. *Am J Psychiatry*. 2007;164(12 Suppl):5-56. 4. FDA. FDA Approves First Drug to Treat Agitation Symptoms Associated with Dementia due to Alzheimer's Disease. May 2023. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-agitation-symptoms-associated-dementia-due-alzheimers-disease>. 5. Aigbogun MS, et al. *BMC Neuro*. 2019;19(1):33. 6. Schneider LS, et al. *Am J Geriatr Psychiatry*. 2006;14(3):191-210.

# Nearly Half of People Living With Alzheimer's Dementia Will Experience Agitation, Yet HCPs and Caregivers Are Reluctant to Talk About Agitation Symptoms<sup>1-3</sup>

## Caregivers



- Are often **first to encounter** agitation behaviors<sup>3,4</sup>
- **Do not recognize** the full breadth of agitation behaviors<sup>5,6</sup>
- **Do not understand** that treatment of agitation differs from treatment of Alzheimer's dementia<sup>7</sup>
- **Do not readily talk** about agitation behaviors with HCPs<sup>2,5</sup>

## HCPs



- Generally **don't educate** families about agitation early in Alzheimer's dementia<sup>3</sup>
- Are typically **not proactive** in discussing unless symptoms are untenable for the caregiver<sup>2,8</sup>



## Early detection by caregivers with tailored tools may<sup>9</sup>:

- Improve recognition and overall management of agitation in patients with Alzheimer's dementia
- Encourage discussions with HCPs about agitation symptoms
- Assist HCPs in making a diagnosis of AAD

AAD, agitation associated with Alzheimer's dementia. HCP, healthcare provider.

1. Halpern R, et al. *Int J Geriatr Psychiatry*. 2019;34(3):420-431. 2. Richler LG, et al. *Harv Rev Psychiatry*. 2023;31(1):22-27. 3. Lindeza P, et al. *BMJ Support Palliat Care*. 2020;bmjspcare-2020-002242. 4. Gallego-Alberto L, et al. *Clin Gerontol*. 2022;45(5):1295-1303. 5. Stella F, et al. *Int J Geriatr Psychiatry*. 2015;30(12):1230-1237. 6. Sano M, et al. *Int Psychogeriatr*. 2023:1-13. 7. Gilmore-Bykovskiy A, et al. *Gerontologist*. 2020;60(5):896-904. 8. Kales HC, et al. *J Am Geriatr Soc*. 2014;62(4):762-769. 9. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.

# Current Approaches and Unmet Needs in Recognition of AAD

Caregivers are often first to experience and manage agitation behaviors and thus play a critical role in recognizing, assessing, and communicating agitation symptoms to HCPs<sup>1-4</sup>

Agitation behaviors are under-recognized, despite being among the earliest and most common NPS in Alzheimer's Dementia<sup>5</sup>



Rating scales that measure agitation are available, but they<sup>3,6-10</sup>:

- Were not designed to screen for agitation or AAD
- Are often scored differently by caregivers and HCPs
- Are not widely or easily used in clinical practice

Examples include:

- CMAI (Cohen-Mansfield Agitation Inventory)<sup>7</sup>
- NPI (Neuropsychiatric Inventory)<sup>8</sup>
- IPA (International Psychogeriatric Association) definition of agitation in cognitive disorders<sup>6</sup>

Tailored tools that help caregivers better understand symptoms of AAD can help reassure caregivers and may also improve patient outcomes and reduce caregiver burden<sup>6,11,12</sup>

AAD, association associated with Alzheimer's dementia. HCP, healthcare provider. NPS, neuropsychiatric symptoms.

1. Kales HC, et al. *BMJ*. 2015;350:h369. 2. Lindeza P, et al. *BMJ Support Palliat Care*. 2020;bmjspcare-2020-002242. 3. Stella F, et al. *Int J Geriatr Psychiatry*. 2015;30(12):1230-1237. 4. Alzheimer's Association 2023. *Alzheimers Dement*. 2023;19(4):1598-1695. 5. Lanctôt KL, et al. *Alzheimers Dement (N Y)*. 2017;3(3):440-449. 6. Sano M, et al. *Int Psychogeriatr*. 2023;1-13. 7. Cohen-Mansfield J. *Instruction Manual for the Cohen-Mansfield Agitation Inventory (CMAI)*. The Research Institute of the Hebrew Home of Greater Washington; Rockville, Maryland: 1991. 8. Cummings JL. *J Neurol*. 1997;48(5 Suppl 6):S10-6. 9. Rabinowitz J, et al. *Am J Geriatr Psychiatry*. 2005;13(11):991-998. 10. Sano M, et al. *J Prev Alzheimers Dis*. 2018;5(2):98-102. 11. Hoe J, et al. *BJPsych Open*. 2017;3(1):34-40. 12. Rodriguez K, et al. *J Alzheimers Dis Rep*. 2021;5(1):433-442.

# Agitation in Alzheimer's Screener for Caregivers (AASC™)

## Goals

1

Foster caregiver knowledge and allow for early recognition

2

Facilitate caregiver discussion of agitation symptoms with HCPs

3

Assist clinicians in making a potential diagnosis of AAD

- Operationalizes the International Psychogeriatric Association (IPA) definition of agitation in cognitive disorders
  - Includes items that screen for both presence and impact of agitation behaviors
- Pragmatic and brief
  - Includes behaviors that can be easily reported by caregivers
  - Takes <1 minute to complete
  - Involves simple scoring

AAD, agitation associated with Alzheimer's dementia. CMAI, Cohen-Mansfield Agitation Inventory. HCP, health care provider. IPA, International Psychogeriatric Association.

1. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.

# AASC™ Development Team: Multi-Disciplinary Experts

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**Jared Stroud, MD** (OhioHealth)

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**Emily Bratlee-Whitaker, PhD, RN**

**Sakshi Bhargava, PhD**

AASC™, Agitation in Alzheimer's Screener for Caregivers.

1. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.

# Development of the AASC™ Screener – Review of Existing Measures

Phase	Description
Review of existing measures	<ul style="list-style-type: none"> <li>Review of International Psychogeriatric Association (IPA) criteria and existing measures (eg, Cohen-Mansfield Agitation Inventory [CMAI] and Neuropsychiatric Inventory [NPI])<sup>1</sup></li> </ul>

## IPA Criteria Offer a Solid Foundation for Recognition of Agitation in Cognitive Disorders<sup>2</sup>

### The IPA definition of agitation in cognitive disorders includes four criteria:

1. The patient meets the criteria for cognitive impairment or dementia syndrome
2. The patient exhibit  $\geq 1$  agitation behavior(s) with emotional duress that is persistent or frequently recurrent for  $\geq 2$  weeks or the behavior represents a dramatic change from the patient's usual behavior\*
3. The behaviors are severe and associated with excess distress or produce disability beyond that due to cognitive impairment
4. The behaviors cannot be attributed to another psychiatric disorder, medical condition, including delirium, suboptimal care conditions, or the physiological effects of a substance

#### Agitation behaviors include:



#### EXCESSIVE MOTOR ACTIVITY BEHAVIORS:

- Pacing
- Rocking
- Gesturing
- Pointing fingers
- Restlessness
- Performing repetitious mannerisms



#### VERBAL AGGRESSION BEHAVIORS:

- Yelling
- Speaking in an excessively loud voice
- Using profanity
- Screaming
- Shouting



#### PHYSICAL AGGRESSION BEHAVIORS:

- Grabbing
- Shoving
- Pushing
- Resisting
- Hitting others
- Kicking objects or people
- Scratching
- Biting
- Throwing objects
- Hitting self
- Slamming doors
- Tearing things
- Destroying property

\*In special circumstances, the ability to document the behaviors over 2 weeks may not be possible and other terms of persistence and severity may be needed to capture the syndrome beyond a single episode.

AAD, agitation associated with Alzheimer's dementia. AASC™, Agitation in Alzheimer's Screener for Caregivers. IPA, International Psychogeriatric Association.

1. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.

2. Sano M, et al. *Int Psychogeriatr.* 2023;1-13. 3. Cummings J, et al. *Int Psychogeriatr.* 2015;27(1):7-17.

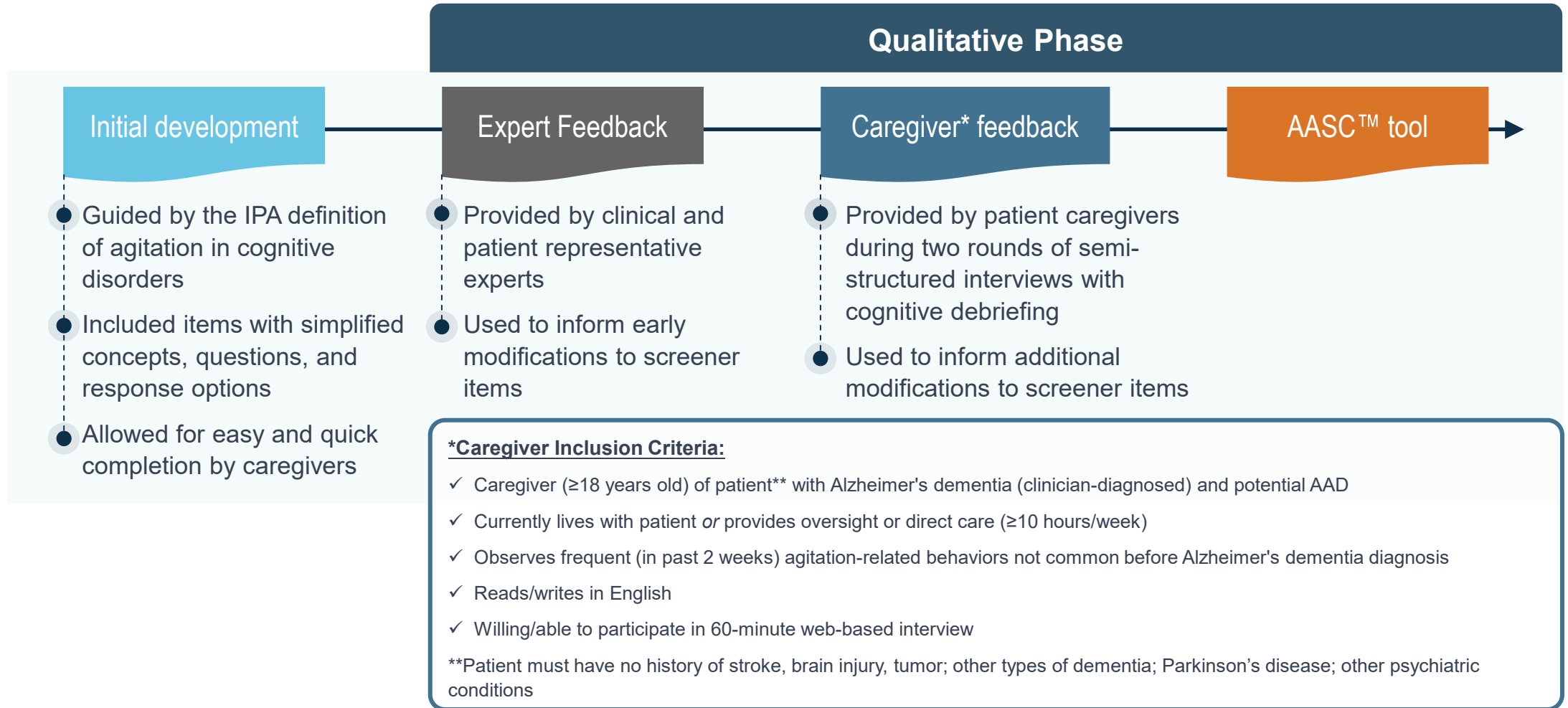
# Development of the AASC™ Screener

Phase	Description	Outcome
Review of existing measures	<ul style="list-style-type: none"> <li>Review of International Psychogeriatric Association (IPA) criteria and existing measures (eg, Cohen-Mansfield Agitation Inventory [CMAI] and Neuropsychiatric Inventory [NPI])</li> </ul>	Draft screener
Item development	<ul style="list-style-type: none"> <li>Development of draft items/concepts</li> <li>Review of draft items/concepts with multidisciplinary clinical and patient representative experts</li> </ul>	
Qualitative interviews	<ul style="list-style-type: none"> <li>Iterative cognitive debriefing with caregivers of individuals with AAD to ensure item/concept understanding and interpretation</li> <li>Item refinement with incorporation of caregiver feedback and testing of modifications</li> <li>Analysis and reporting</li> </ul>	Agitation in Alzheimer's Screener for Caregivers (AASC™)
Item refinement		

AAD, agitation associated with Alzheimer's dementia. AASC™, Agitation in Alzheimer's Screener for Caregivers.

1. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.

# Development of Qualitative Phase Included Cognitive Debriefing With Caregivers To Refine Screener Items<sup>1</sup>



AAD, agitation associated with Alzheimer's dementia. AASC™, Agitation in Alzheimer's Screener for Caregivers. CMAI, Cohen-Mansfield Agitation Inventory. IPA, International Psychogeriatric Association.

1. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.



# AASC™ Screening Tool Items<sup>1</sup>

1. Are you noticing any of the following that represent a change from the individual's usual or past behavior?
  - a. Repeating motions or behaviors (e.g., rocking, raising fist, pointing finger)
  - b. Pacing or restlessness (cannot be still)
  - c. Cursing/using profanity or lashing out verbally
  - d. Raising voice or yelling or screaming
  - e. Resisting assistance or care
  - f. Throwing or hitting or breaking things
  - g. Trying to hurt self or others (e.g., grabbing, kicking, hitting, biting)

2. Do any of these behaviors negatively affect the individual's relationships, activities, or willingness to receive care?

## AASC™ Agitation in Alzheimer's Screener for Caregivers

A person with Alzheimer's dementia may become easily upset, frustrated, or angry. These feelings may be associated with agitation, a common symptom of Alzheimer's.

The following questions ask about behaviors associated with agitation that you may have observed in the individual for whom you provide care.

Your answers to these questions can help you talk with your person's healthcare professional. Please select one response for each question.

Patient Name \_\_\_\_\_ Date \_\_\_\_\_

1. Are you noticing any of the following that represent a change from the individual's usual or past behavior?

	Yes	No
a. Repeating motions or behaviors (e.g., rocking, raising fist, pointing finger)	<input type="checkbox"/>	<input type="checkbox"/>
b. Pacing or restlessness (cannot be still)	<input type="checkbox"/>	<input type="checkbox"/>
c. Cursing/using profanity or lashing out verbally	<input type="checkbox"/>	<input type="checkbox"/>
d. Raising voice or yelling or screaming	<input type="checkbox"/>	<input type="checkbox"/>
e. Resisting assistance or care	<input type="checkbox"/>	<input type="checkbox"/>
f. Throwing or hitting or breaking things	<input type="checkbox"/>	<input type="checkbox"/>
g. Trying to hurt self or others (e.g., grabbing, kicking, hitting, biting)	<input type="checkbox"/>	<input type="checkbox"/>

2. Do any of these behaviors negatively affect the individual's relationships, activities, or willingness to receive care?
 

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

Disclaimer: Otsuka Pharmaceutical Development & Commercialization funded and contributed to the development of this screening tool. The AASC™ is a screening tool and is not a diagnostic tool.

Agitation criteria based on the International Psychogeriatric Association (IPA) definition (Sano et al., 2023).  
References: 1. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL. 2. Sano M, Cummings J, Auer S, et al. *Int Psychogeriatr*. 2023;1-13.

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The AASC™ is available for download at: <http://www.theaasc.com>

AASC™, Agitation in Alzheimer's Screener for Caregivers.

1. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.

# Summary



Agitation is highly prevalent and present in all stages and severities of Alzheimer's dementia<sup>1</sup>



AAD is associated with substantial patient and caregiver burden and long-term consequences<sup>2</sup>



Despite being among the earliest and most common symptoms of Alzheimer's dementia, agitation behaviors are largely unrecognized, worsening their negative impact on patients and caregivers<sup>3-4</sup>



In general, HCPs and caregivers do not discuss agitation behaviors until symptoms become untenable for the caregiver<sup>5,6</sup>



A new screening tool for AAD may facilitate early detection of agitation by caregivers and improve overall management of agitation in patients with Alzheimer's dementia<sup>7</sup>

AAD, agitation associated with Alzheimer's dementia. CMS, Center for Medicare and Medicaid Services. FDA, US Food and Drug Administration. LTC, long-term care.

1. Halpern R, et al. *Int J Geriatr Psychiatry*. 2019;34(3):420-431. 2. Fillit H, et al. *Int J Geriatr Psychiatry*. 2021;36(12):1959-1969. 3. Lanctôt KL, et al. *Alzheimers Dement (N Y)*. 2017;3(3):440-449. 4. Michael M. *Alzheimers Dement*. 2022;18(Suppl 11):e060656. 5. Richler LG, et al. *Harv Rev Psychiatry*. 2023;31(1):22-27. 6. Kales HC, et al. *J Am Geriatr Soc*. 2014;62(4):762-769. Clevenger C, et al. One Minute to Recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC™). The Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.