

Tool: Pain Assessment for the Dementing Elderly (PADE)
Tool developers: Villaneuva, M.R., Smith, T.L., Erickson, J.S., Lee, A.C., Singer, C.M.
Country of origin: USA
Reviewed: 04/04
Revised: 06/08

Conceptualization Panel rating: 1 Revised: 1	
Purpose	<p>The Pain Assessment for the Dementing Elderly (PADE) is an informant based tool for the assessment of pain in individuals with advanced dementia. It was developed to help caregivers assess patient behavior that may indicate pain.</p>
Conceptual basis	<p>The terms distress and pain are used interchangeably. Association between pain and agitation was noted.</p> <p>Pain assessment by observation rests upon three key assumptions:</p> <ol style="list-style-type: none"> 1. Facial characteristics, body posture and movement patterns can indicate the presence of pain. 2. Pain can interfere with activities of daily living (ADLs) such as dressing and eating. 3. Caregivers can reliably observe and rate behavior. <p>Assumptions reflect a conceptual basis for pain by observation of behaviors.</p>
Item Generation	<p>Item generation is based on:</p> <ul style="list-style-type: none"> - literature review (Kovach: facial features and ADL) - interviews with nursing staff at care facilities <p>naturalistic observation by research associate (logged 30 hours over a 2 week period in a dementia care unit).</p> <p><u>Tool items</u></p> <p>24 items in three parts:</p> <p>I Physical</p> <ul style="list-style-type: none"> - observable facial expression - breathing pattern - posture <p>II Global Assessment – proxy evaluation of pain intensity</p> <p>III Functional (ADL)</p> <ul style="list-style-type: none"> - dressing - feeding oneself - transfers from wheelchair to bed <p>Items were validated by clinical experts in three settings. Feedback was provided by staff regarding ease of use, comprehensiveness and manual instructions. Adjustments were made.</p>
Content Validity	<p>The PADE has not been subjected to content validation by independent experts in pain in elders with dementia. <i>However, subsequent studies have indicated that the tool is sensitive to pain behaviors.</i></p>
-Panel Commentary	<p>Conceptually the tool includes 5 of the 6 categories of pain indicators noted in the AGS Persistent Pain Guidelines: facial expressions, body movements,</p>

Reviewed 04/04
 Revised 06/08

	<p>verbalizations, changes in activity patterns or routines, and interpersonal interactions. However, operationalization of specific indicators is not clearly supported.</p> <p>The assumption that caregivers can reliably rate the intensity of elders' pain is not supported by current literature.</p> <p>Most items in the tool measure intensity of behaviors, not severity of pain, which may be appropriate; however, the relationship between behavior intensity and pain has not been established in this population.</p> <p>Construction of the scale is problematic in its development in several ways, based on available information:</p> <ol style="list-style-type: none"> 1. Three parts to the tool are described, yet 24 individual components are presented without clarity as to which domain of pain they are measuring. 2. Relevance of some indicators to assessment of pain is lacking (eg. Neatness of grooming). 3. Caregiver judgment of pain severity as the gold standard has not been substantiated. 4. There is inconsistency in narrative description of the tool and the tool illustration in the appendix, eg. The narrative documents Likert rating 1-4, but the tool illustrates a semi-VAS format. 5. Items 15-24 related to functional ADL are assessed retrospectively from the resident's chart. However, all other items are rated based on the resident's current situation. Differences in timing of assessment components could be problematic. 6. The relationship of the ADL section in documenting pain is unclear. However, if the tool is used regularly and consistently, it may potentially show changes over time (eg. percent of time out of bed, percent of time awake, amount of meals eaten) that could be potential indicators of pain impact. <p><i>As with any informant-based tool, the wider number of observations included increases its sensitivity but limits its specificity in that it may identify behaviors that may be due to causes other than pain.</i></p> <p>Although the tool was presented for validation by clinical experts, little information is available as to their education and clinical background. The results regarding tool comprehensiveness and ease of use are not presented. There is also no information as to whether these clinical experts were independent from those staff members involved in the development of the initial set of pain items.</p>
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<p>Subjects Panel rating: 2 Revised: 2</p>	
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<p>Subjects</p>	<p><u>Study 1: Stage 1(Villanueva et al. 2003)</u> Setting: 4 long term care facilities including 3 skilled nursing facilities and a locked dementia assisted-living facility.</p> <p>Subjects: 25 LTC residents with advanced dementia Average age: 84 years Gender: Male: 9, Females: 16 Cognitive impairment: Global Deterioration Scale, average score 5.60 (±0.71), Range 4-7.</p>
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	<p>Pain conditions: 60% suffered potentially painful medical conditions and 80% had prescribed analgesics, 55% prn and 45% scheduled dose.</p> <p>Residents were selected by the RN manager based on which caregivers were involved in the study. Most raters were certified nursing assistants or similarly trained caregivers.</p> <p><u>Study 1: Stage 2 (Villanueva et al, 2003)</u> Setting: One long term care facility in Washington state Subjects: 40 residents with similar level of dementia Average age: 81.33 years (± 7.67), Range 66-92 years Gender: Male: 8, Female: 32.</p> <p>Cognitive impairment: Global Deterioration Scale, average score: 5.28 (± 0.78), Range 4-7. Pain conditions: 25% suffered potentially painful medical conditions and 27.5% had prescribed analgesics with 9% PRN only and 91% scheduled dose.</p> <p><u>Study 2 (Cohen-Mansfield, 2006)</u> Setting: two long term care facilities Subjects: 91 residents Average age: 89 (5.78) Gender: 84% female, 16% male Cognitive impairment: mean MMSE of 7.65 (7.58) Pain: mean of 6.59 scheduled medications and 0.84 scheduled medications for pain Raters: 55 nursing staff members who had the greatest contact with the residents during the previous two weeks. During the previous 2 weeks, the staff member had worked with the resident an average of 4.78 days.</p> <p><u>Study 3 (Cohen-Mansfield, 2008)</u> Setting: 4 long term care facilities in Maryland Subjects: 121 nursing home residents with a diagnosis of dementia. 63 classified as having pain. 58 classified as not having pain Average age: 88 (59-101) Gender: female 81.8%, male 18.2% Cognitive impairment: MMSE mean of 6.3 (0-20) MDS Pain Scale: mean pain score 0.08 (0-2) Diversity: 8.3% minority Raters: nursing assistants who had the most contact with the resident.</p>
<p>-Panel Commentary</p>	<p>For all of the studies the focus on long term care setting is clearly identified. The subjects are clearly identified as having severe dementia using appropriate measurements tools. The age is appropriate. There is gender imbalance, but this reflects the distribution of older adults. Minority inclusion is only specified in the fourth study. Cognitive status and pain were assessed using standard instruments.</p> <p>In the first study the residents were selected by the RN manager based on which caregivers were involved in the study, which may result in selection bias. Also little information is available on the caregivers who participated and how they were chosen. Using 5 subjects per item as the minimum requirement for this review, a minimum sample size of 120 subjects would be needed. Thus, this sample of 25 and 40 subjects in study 1 would be insufficient for tool evaluation. In the third study, a minimum sample of 65</p>

(13 items plus global indicator x 5 subjects) would be needed. Thus, this sample of 91 subjects is sufficient for tool evaluation. In the final study a minimum sample of 70 subjects (14 items x 5 subjects) would be needed. Thus, the sample of 121 subjects is sufficient for tool evaluation. More testing is need with diverse populations and practice settings.

Administration, Scoring, Feasibility
Panel rating: 1
Revised: 2

Administration, Scoring, Feasibility

Study 1: Stage 1(Villanueva et al, 2003)
The tool has 24 items in three parts (see “Item Generation” section above).
Items 1-12, 14 and 22-24 are rated using a Likert scale. This is scored 1-4 (based upon equally spaced division on the line). Items 13 and 15-21 are multiple choices, scoring 1-4.
The method of administration is described on the tool and raters are referred to a tool manual. The instructions on the tool separate the items into two major sections. However, these do not correspond to the above mentioned three part division.
For items 1-14 the rater is instructed to observe the resident’s behavior for five minutes and then score the items by placing a vertical slash mark on a visual analogue scale. For items 8-10 the rater is instructed to mark the item “Not Applicable” if the resident is silent during the observation period. Item 13 is multiple choice.
The instructions to questions 15-24 regarding functional ADL indicate that the questions should be answered by reviewing chart documentation. Instructions ask the rater to review the Master Sheet in the manual for directions regarding how to answer the questions. Most questions are based on chart documentation from the previous 24 hours.
There is no indication in the research report or on the tool form as to how to proceed once the individual items are scored. There is no indication of a score related to each of the three main parts of the tool or total score for the assessment.
There is no guide as to how to interpret the results of the assessment.
Ratings were conducted by CNA or personnel with similar training. One hour of training was provided to raters. The PADE required 5-10 minutes to complete. An RN supervised the first two ratings to check for adherence to protocol.
Study 2 (Cohen-Mansfield, 2006)
The scoring for the PADE was altered due to the researcher’s previous experience with the tool. The visual analogs were changed to a 4-point rating scale that included the markers: none, a little, much and very much. The global question was also rated on a 4 –point scale of none, mild pain, moderate pain, and severe pain.
As with any informant-based tool, the wider number of observations included increases its sensitivity but limits its specificity in that it may identify behaviors that may be due to causes other than pain.

	<p><u>Study 3 (Cohen-Mansfield, 2008)</u> <i>The study did not evaluate questions 15-24 regarding functional ADL's that are answered by reviewing chart documentation. Rather the tool focused on items 1-4 which have been described in detail in study 1 above.</i></p>
<p>-Panel Commentary</p>	<p>Several issues are identified related to tool administration and scoring:</p> <ol style="list-style-type: none"> 1. Three parts to the tool are described, yet 24 individual components are presented without separation into parts and without clarity as to which part of the tool the individual items belong. 2. There is an expectation of finding data for some items in the patient chart. However, based on current documentation practice, accurate information may not be available. 3. Scoring procedures are very confusing due to inconsistency in narrative description of the tool and the tool representation in the appendix, eg. The narrative documents likert rating 1-4, but the tool illustrates a semi-VAS. 4. A variety of scaling approaches has been used (eg. VAS items; Likert 1-4 scales), however, all with different anchors without clear reason for inconsistent scaling approaches. This is confusing and contributes to complexity of interpretation. 5. A Score of 0 is given if an item is marked as "Not Applicable". The impact of this on the overall result and underestimation of pain is not addressed. 6. Caregiver judgment of pain severity as the gold standard is not substantiated in the literature. 7. Interpretation of tool score is unclear. <p>An instruction manual has been developed for the tool. Further explanation or clarification regarding administration and scoring of the tool may be documented. However, the instruction manual was not available for this review <i>or the updated review.</i> <i>Follow up studies focus on a revised form of the PADE with item changes and simplified scoring.</i></p> <p>It is suggested that tool administration takes 5-10 minutes. However, data to support this is not provided. The rater is asked to observe the subject for five minutes before rating. Moreover, considering the complexity of the items, the variety of scaling approaches and the expectation of finding answers in the patient record, this tool may take considerably longer to administer than the suggested 5-10 minutes. <i>Subsequent studies did not address additional supporting evidence regarding clinical utility or decrease in time requirements.</i></p> <p>Raters in the research report are primarily nursing assistants. However, there is no discussion related to nursing assistants' scope of practice. <i>Follow up studies focus on research assistant administration, thus no further data regarding use by NA's is available.</i></p>
<p>Reliability Panel rating: 1 Revised: 1</p>	
<p>Internal consistency</p>	<p><u>Study 1: Stage 1(Villanueva et al, 2003)</u> Each resident (N=25) (see sample characteristics for study 1 above) was assessed by 2 independent observers over 10 days (not consecutive). A total of 784 observations were made.</p> <p>Ratings were made by caregivers, most of whom were certified nursing assistants or similarly trained caregivers.</p>

	<p>The caregivers received a 1-hour training session. A registered nurse was chosen for onsite management and contact with the investigators. The RN observed the first two ratings to check for adherence to protocol.</p> <p>Part I: alpha 0.77 Part III: alpha 0.63</p> <p><u>Study 1: Stage 2 (Villanueva et al, 2003)</u> Each resident (N=40) (see sample characteristics for study 2 above) was simultaneously assessed by 2 independent raters at time 1 and time 2. A total of 160 observations were made. Ratings were made by caregivers, most of whom were certified nursing assistants or similarly trained caregivers. The caregivers received a 1-hour training session. A registered nurse was chosen for onsite management and contact with the investigators. The RN observed the first two ratings to check for adherence to protocol.</p> <table border="0" style="width: 100%;"> <tr> <td></td> <td style="text-align: center;"><u>Time 1</u></td> <td style="text-align: center;"><u>Time 2</u></td> </tr> <tr> <td>Part I: alpha</td> <td style="text-align: center;">0.88</td> <td style="text-align: center;">0.87</td> </tr> <tr> <td>Part III: alpha</td> <td style="text-align: center;">0.24</td> <td style="text-align: center;">0.29</td> </tr> </table>		<u>Time 1</u>	<u>Time 2</u>	Part I: alpha	0.88	0.87	Part III: alpha	0.24	0.29																		
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-Panel commentary	<p>The characteristics of the raters collecting data is not clear (age, clinical background, level of education). Supervision/monitoring of data collection by caregivers appears limited which may explain some of the variability in test results.</p>																											

	<p><u>General study I</u> Although a total of 784 observations over 10 days for 25 residents was made in study 1, the number of observations included in each of the reported results is unclear. 784/2 raters/25 residents means that each resident was observed on average 15 times, eg. more than once per day. What situation triggered the observation? With several observations per day, are the observations really independent, especially since function items are based on last 24 hours of chart documentation?</p> <p><u>Internal consistency</u> It is unclear what data were entered into analysis for items with Likert scales. In study 1, alpha measures were acceptable. In study 2, alpha measures for part I were acceptable. However, for part III the alphas were poor at both time points.</p> <p>Preliminary internal consistency of the tool is not well established for all components.</p> <p><u>Interrater reliability</u> Raters were nursing assistants. Intraclass correlations are appropriate test for data. Reliabilities are mostly strong across study 1 and 2.</p> <p><u>Test-retest reliability</u> In study 1 the time interval for the two measures included in the test-retest assessment is not reported, thus appropriateness of the procedure cannot be determined.</p> <p>In study 2 the interval was 20 days (but this interval varied slightly). No control over change in pain condition resulting from analgesic or other intervention is noted.</p> <p>The intraclass correlations for part I and III are within acceptable range in study 1 although the correlations for part I are in the lower acceptable range and the 95% confidence interval is wide suggesting variability. Intraclass correlations for part II are low.</p> <p>The intraclass correlations are acceptable for study 2 for all three parts. However, correlations for part II are in the lower acceptable range with wide confidence intervals.</p> <p><i>Study 3 and 4 did not provided additional evidence regarding the reliability of the assessment tool.</i></p>
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Validity: Criterion or construct
Panel rating: 1
Revised: 2

<p>Construct validity/ Criterion related validity</p>	<p>A description of subjects for each of the two studies is provided under <i>Subjects</i> above. A description of study procedures is provided under <i>Internal consistency</i> above.</p> <p><u>Construct/Convergent validity</u></p> <p><u>Study 1: Stage 1 (Villanueva et al, 2003)</u> The PADE was compared with Cohen-Mansfield Agitation Inventory</p>
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(CMAI). The CMAI has three subscales which assess different subtypes of agitation: verbal, physically aggressive and physically nonaggressive. It was hypothesized that the PADE would correlate with verbal but not physically aggressive agitation.

The PADE was administered at T2. The CMAI was administered at T2 and refers to the patient's behavior over the previous 3 weeks.

Results:

	CMAI Aggressive	CMAI Nonaggressive	CMAI Verbal
PADE Part I	r=.21	r=.08	r=.30
PADE Part II	r=.13	r=.18	r=.14
PADE Part III	r=.40	r=.40	r=.42

Study 2 (Cohen-Mansfield, 2006)

PADE / PAINE: $r=0.65, P<0.0001$.

PADE global question / PAINE: $r=0.42, p<0.00 (n=91)$.

Study 3 (Cohen-Mansfield, 2008)

Study completed a comparison between self-report, informant, and observational assessment tools. For the observational tools, patients with severe dementia were divided into treatment and comparison groups. An initial baseline pain assessment was taken using each tool for both the treatment and comparison groups, followed by the implementation of a pain intervention. A final pain assessment was completed and f-value provided.

Baseline and Final Results for PADE, Global PADE indicator and PAINE: baseline (final)

	Tool	Treatment	Comparison	f value
All persons with no pain at baseline	PADE	20.39(16.31)	15.57(15.84)	21.48
	Global	2.00(1.47)	1.28(1.41)	16.81
	PAINE	4.56(2.76)	2.57(2.59)	23.78
Initially in pain, but refused to continue	PADE	20.39(16.31)	15.57(15.84)	21.48
	Global	2.00(1.47)	1.28(1.41)	16.81
	PAINE	4.56(2.76)	5.51(5.29)	12.04
Subset of the Comparison group	PADE	20.39(16.31)	15.38(15.78)	15.86
	Global	2.00(1.47)	1.27(1.43)	12.33
	PAINE	4.56(2.76)	2.57(2.54)	15.73

Criterion/Discriminant Validity

Study 1: Stage 2 (Villanueva et al, 2003)

(N=40) (see sample characteristics above).

Criterion validity was assessed by comparing residents (1) with or without painful conditions (2) for whom pain was or was not a significant clinical factor, and (3) residents with or without psychoactive medications.

1) Residents with or without painful conditions

Using chart review to classify the 40 residents, 10 were judged to suffer and 30 not to suffer from painful conditions by an independent RN. There were no statistically significant differences between groups with or without painful conditions on the PADE subtests or the CMAI.

	<p>2) Residents for whom pain was or was not a significant clinical factor The sample was divided into two groups based on whether the independent RN judged pain to be an ongoing, significant clinical factor in resident's care: (n=8 pain significant factor and n=32 pain not a significant factor). Three CMAI subscales and the PADE Parts I, II and III were used to compare the groups. The pain as a significant clinical factor group had statistically significantly higher scores on the following subscales:</p> <p>CMAI Verbal z=-2.83 (p=0.01) PADE Part I z=-2.31 (p=0.01) PADE Part II z=-4.30 (p<0.001) PADE Part III z=-2.31, p<0.01)</p> <p>3) Residents with or without psychoactive medications Residents were divided into 2 groups based on whether there were presently taking psychoactive medication or not. The group on prescribed psychoactive medications had statistically significantly higher scores on the following subscales:</p> <p>CMAI Verbal z=-1.95 (p=0.05) CMAI Aggressive z=-3.34 (p=0.01) PADE Part I z=-3.19 (p<0.01) PADE Part III z=-3.25 (p<0.01)</p>
<p>-Panel commentary</p>	<p>Preliminary data may suggest those with significant pain problems may be identified through use of the tool. Although agitation and pain have been associated in elders with dementia, validation of this relationship should complement examination of other validity constructs. Although use of psychoactive medication differentiates groups, control of agitated behavior by medication could impact the behavioral presentations of pain and agitation/aggression. Use of analgesics and psychoactive medication were not controlled in relation to timing of assessments and may impact results. <i>Compared with self-report and observational measures. PADE, PAIN, and VDS were found to be the most sensitive to treatment effects and most useful in detecting pain. A decrease in levels of pain was evident with informant rating scales. Additional evaluation supports the validity of the assessment tool in measuring pain in patients with and without dementia. The informant rating scales were most effective in detecting changes in pain levels.</i></p>
<p>Summary of panel evaluation of pain assessment tool</p>	
<p>The PADE was developed to provide a simple tool for assessing pain in individuals with advanced dementia. Although 5 categories of indicators from the AGS guideline are included, operationalization of the tool shows inconsistencies in construction, presentation and lack of clarity in scoring and interpretation. The relevance of some indicators to assessment of pain is lacking. The tool assumes caregivers can judge pain severity from behavioral observation which has not been demonstrated in this population.</p> <p>Lack of control of factors that could impact the tool performance (eg. receipt of analgesics and psychotropics) limits interpretation of data.</p> <p>Because assessment activities are outside the scope of nursing assistant practice, it will be important to determine if the expectations of the tool for NA's are actually screening activity.</p> <p>Although a relationship between pain and agitation has been demonstrated, the CMAI as the only gold standard for comparison is insufficient for judgment of tool validity. The PADE requires clarification and further revision/testing.</p> <p><i>Further study of an adapted PADE with verbal descriptor rating scale and elimination of the ADL</i></p>	

component provides support for its validity and sensitivity. Additional data on clinical utility is not provided. Tool may indicate level of pain severity in a given patient, however categorizing pain severity as mild, moderate, or severe based on tool score has not been indicated.

Source of evidence

Cohen-Mansfield, J. (2006). Pain assessment in noncommunicative elderly persons-PAINE. *Clinical Journal of Pain*, 22(6), 569-75.

Cohen-Mansfield, J. & Lipson, S. (2008). The utility of pain assessment for analgesic use in persons with dementia. *Pain*, 134(1-2), p. 16-23.

Villanueva, M. R., Smith, T. L., Erickson, J. S., Lee, A. C., & Singer, C. M. (2003). Pain assessment for the dementing elderly (PADE): Reliability and validity of a new measure. *Journal of the American Medical Directors Association*, 4(1), 1-8

Key to panel rating

3= Available evidence is strong

2= Available evidence supports need for further testing

1= Available evidence is insufficient and/or tool revisions are needed

0= Evidence is absent

Contact information for tool developer

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Reviewed 04/04

Revised 06/08