

**Tool: Pain Assessment in Noncommunicative Elderly Persons (PAINE)**

**Tool developer: Cohen-Mansfield, J.**

**Country of origin: USA**

**Review Conducted: 06/08**

<b>Conceptualization</b> Panel rating: 2							
<b>Purpose</b>	PAINE is an informant-based assessment tool that was developed to assess pain in noncommunicative elders due to the limitations of self-report and observational tools for detecting pain in this population.						
<b>Conceptual basis</b>	Changes in behavior and activity level are potential indicators of pain.  Assumptions: 1. With proper education all healthcare providers are able to appropriately assess pain behaviors 2. Caregivers can reliably observe and rate pain behaviors.						
<b>Item Generation</b>	<u>Study 1 (Cohen-Mansfield &amp; Creedon, 2002)</u> <u>Stage 1</u> Although the tool was not described as a tool in 2003, the author references this earlier work as the source for item development. This stage was used to identify the behaviors and observable indicators as perceived by nurses. Nursing staff identified a total of 22 behaviors as indicative of pain. In comparing the indicators to other studies the nurses found four indicators that were unique when compared to other studies: reluctance to move, decreased participation in activities, changes in vital signs and falls. Other noted indicators were similar to those that were noted in other pain behavior instruments.  <u>Stage 2</u> A more comprehensive listing of pain indicators was generated from the items in stage 1 and a review of literature. A total of 45 behaviors were identified. The behaviors were categorized according to 4 general types: 1. Specific repetitive behaviors: squinting, rocking, rubbing, or holding an affected area of pain 2. Specific vocal repetitive behaviors: moaning, crying, or screaming 3. Visual cues: discoloration or swollen joints 4. Change from normal behavior: decreased appetite, difficulty chewing, wincing, increase in pacing, or unusual quietness.						
<b>Content Validity</b>	<u>Study 1 (Cohen-Mansfield &amp; Creedon, 2002)</u> <u>Stage 2</u> A research assistant administered a PAINE that asked the participants to rate their perceptions of the prevalence of 45 behaviors that might be related to pain and the importance of those behaviors in identifying pain. The behaviors were either selected from the literature or identified in the first pilot study as potentially useful. The prevalence of behaviors was rated on a 7-point scale that ranged from “manifested by none of the residents I worked with” (1 point) to “manifested by all of the residents I worked with” (7 points). The importance of the behaviors in identifying pain was rated on a 6-point scale ranging from “not at all important” (1 point) to “extremely important” (6-points).  <u>Most Important Indicators</u> <table><thead><tr><th></th><th><u>Means</u></th></tr></thead><tbody><tr><td>Rubbing</td><td>4.9</td></tr><tr><td>General Discoloration</td><td>4.9</td></tr></tbody></table>		<u>Means</u>	Rubbing	4.9	General Discoloration	4.9
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	<p>Swollen knuckles 5.1  Change in color of face 4.8  Tight Belly 4.7  Dislocated limbs 4.7  Heat from specific body part 4.9  Sudden impaired walking 4.9</p> <p><u>Most Prevalent Indicators</u></p> <table border="0"> <thead> <tr> <th></th> <th style="text-align: right;"><u>Means</u></th> </tr> </thead> <tbody> <tr> <td>Rubbing</td> <td style="text-align: right;">4.1</td> </tr> <tr> <td>Moaning, Grunting, whining, whimpering</td> <td style="text-align: right;">4.5</td> </tr> <tr> <td>Decrease appetite</td> <td style="text-align: right;">4.0</td> </tr> <tr> <td>Reluctant to move</td> <td style="text-align: right;">4.1</td> </tr> </tbody> </table> <p><u>Stage 3</u>  The purpose of this study was to validate the perceptions of nursing staff members concerning the applicability of the pain indicators in the previous item generation studies.</p> <p>The authors led four focus groups asking the nurses if the list of indicators was accurate and all inclusive. In the end, most of the indicators were approved by the staff to be accurate and inclusive.</p>		<u>Means</u>	Rubbing	4.1	Moaning, Grunting, whining, whimpering	4.5	Decrease appetite	4.0	Reluctant to move	4.1
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<b>-Panel Commentary</b>	<p>The conceptual assumptions are sound and the item generation uses multiple stages for tool development. The tool covers 4 of the 6 pain behavior categories that are consistent with the AGS Persistent Pain Guidelines: facial expressions, verbalizations, body movements, and changes in activity patterns or routines. More subtle behaviors in the AGS guidelines are not addressed: mental status changes and changes in interpersonal interactions. As with any informant-based tool, the wider number of observations included increases its sensitivity but limit its specificity in that it may identify behaviors that may be due to causes other than pain.</p> <p>The author refers to Cohen-Mansfield 2002 as the source for the initial development of this instrument. During this study the author conducted focus groups from 3 nursing homes and administered questionnaires to ascertain the range of indicators they used to determine the presence of pain among persons with dementia. The core indicators included specific physical repetitive movements, vocal repetitive behaviors, physical signs of pain, and changes in behavior. The author suggests that because of this methodology, PAINE utilized a more comprehensive list of symptoms than other available assessments. The author further states that the PAINE includes 22 items, all of which are based on an earlier study of nursing staff reports on the signs and symptoms they use to detect pain in persons with dementia.</p> <p>Conceptually the validation of the tool is limited to the opinions of nurses from only a few different settings. Pain behaviors identified by nursing staff represent one institution and convenience samples and may not be generalizable to other settings. No evidence is provided how the sample nursing staff, made up of mostly NAs and LPNs with few RNs in supervisory roles are experts at recognition of pain in dementia patients.</p> <p>In subsequent validation studies there is no further description of the final tool development.</p>										
<b>Subjects</b> <b>Panel rating: 2</b>											
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	<p><u>Stage 1</u>  The description of subjects reported in this study refers to the subjects who are part of the tool development.</p> <p>Setting: A large 558-bed nonprofit nursing home  Sample: 29 nursing staff members (7 nurse managers, 7 charge nurses, and 15 nursing assistants. Among the charge nurses and managers were 8 registered nurses and 6 licensed practical nurses.  Mean number of years of post-secondary education: 3.0 years for charge nurses and 1.2 for nursing assistants.  Gender: female 26 (90%), male 3 (10%)  Diversity: black 19, white 8, Hispanic 2  Mean years of employment: nurse managers 4.9, charge nurses 4.4, CNAs 5.8</p> <p><u>Stage 2</u>  Setting: Large 558-bed nonprofit nursing home  Sample: 15 nurse caregivers not involved in the previous study were surveyed (BSN 1, RN 2, LPN 3, NA 9)  Gender: female 19, male 1  Diversity: Black 9, White 3, Asian 2, Hispanic 1  Average range of employment: 64 months</p> <p><u>Stage 3</u>  Setting: four focus groups were conducted in 3 nursing homes; 2 were conducted in the original nursing home and 1 in each of the 2 smaller nursing homes.  Sample: between 4 and 11 staff members participated in each of the focus groups. Staff members included RNs, LPNs and NAs. Three of the 4 focus groups consisted exclusively of nursing staff members and in 1 focus group members of the activities and social work departments were represented in addition to a majority of staff members from nursing.</p> <p><u>Study 2 (Cohen-Mansfield, 2006)</u>  <u>Stage 1</u>  Setting: large suburban nursing home  Sample: 80 residents with a diagnosis of dementia.  Average age: 87 (SD 7.2)  Gender: female 84 %, male 16%  Cognitive Status: MMSE of 7.17 ± 8.05  Pain: Mean of 0.51 scheduled medication for pain.  Staff: The first PAINE was administered by a research assistant to the NA most familiar with the resident, while the second PAINE was administered to a nurse who was not necessarily familiar with the resident.</p> <p><u>Stage 2</u>  Setting: 2 long term care facilities  Sample: 91 residents from 2 nursing homes.  Average age: 89 (SD = 5.78)  Gender: female 84%, male 16%  Cognitive Status: MMSE of 7.65 (SD = 7.58)  Pain: Mean of 0.84 scheduled pain medications.  Staff: PAINE administered by the research assistants to the nursing staff member who had the most contact with the patient.</p>
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	<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 Status: MMSE mean of 6.3 (0-20)  Ethnicity: 8.3% minority  MDS Pain Scale: mean pain score 0.08 (0-2)  Staff: Assessments conducted by the research assistants with the help of the CNA who had the most contact with the resident.</p>
<b>-Panel Commentary</b>	<p>The focus on long term care is clearly identified. For study 1, a convenience sample of mostly non-white nursing staff was used. For studies 2 and 3, age and gender distribution of the resident samples are appropriate for this population. Study 2 does not provide information on minority inclusion of nursing home residents. Using 5 subjects per tool item as a minimum requirement for this review, a minimum sample size of 110 subjects (22 items x 5 subjects) would be needed. Thus the sample sizes used in study 2 (80 and 91) are insufficient. Sample size in study 3 (121) is inadequate when divided into 3 study groups as well.</p>
<b>Administration, Scoring, Feasibility</b>	
<b>Panel rating: 1</b>	
<b>Administration, Scoring, Feasibility</b>	<p><u>Scoring</u>  The tool uses a 6-point rating scale to measure the frequency of occurrence of pain behaviors. The scoring ranges from 1 (never) to 7 (several times an hour). There is no further information regarding scoring or interpretation of scores provided.</p> <p><u>Study 3 (Cohen-Mansfield, 2008)</u>  The tool has clinical utility to recognize patients who would benefit from pain medication: The PAINE was able to show a treatment effect compared to a comparison group not in pain (F=23.78), a comparison group that refused treatment (F=12.04), and a type of attention control group (F=15.73).</p>
<b>-Panel Commentary</b>	<p>The tool has only been administered through research assistants and has not been studied for feasibility in the clinical setting. There is no discussion about time or skill level needed for administration.</p>
<b>Reliability</b>	
<b>Panel rating: 2</b>	
<b>Internal consistency</b>	<p><u>Study 2 (Cohen-Mansfield, 2006)</u>  <u>Stage 1</u>  Internal consistency: Cronbach alpha 0.78</p> <p><u>Stage 2</u>  Internal consistency: Cronbach's alpha 0.75</p>
<b>Interrater reliability</b>	<p><u>Study 2 (Cohen-Mansfield, 2006)</u>  <u>Stage 1</u>  Interrater reliability was assessed in 2 ways. For the first measure, 2 research assistants independently and simultaneously completed the PAINE. For the second measure, research assistants independently administered PAINEs to two nursing staff members (NAs) the first of which was more familiar with the resident than the second.</p> <p>Interrater reliability between the 2 RA's <math>r = 0.999</math>, <math>p &lt; 0.001</math>.  Interrater reliability between the 2 different nursing assistants was <math>r = 0.711</math>, <math>p &lt; 0.001</math>.</p>

<b>Test-retest reliability</b>	<u>Study 2 (Cohen-Mansfield, 2006)</u> <u>Stage 1</u> PAINE completed by nursing staff initially and one week later. Test-retest: $r = 0.783$ , $p < 0.001$
<b>-Panel commentary</b>	PAINE has preliminary good internal consistency. Reliability testing shows good interrater reliability even between staff members of variable familiarity with the patient. This is important in employment conditions with high staff turnover rates. Assuming stable pain-states among subjects, there was sufficient test-retest reliability.
<b>Validity: Criterion or construct</b> <b>Panel rating: 1</b>	
<b>Construct validity/ Criterion related validity</b>	<p><u>Study 2 (Cohen-Mansfield, 2006)</u> <u>Stage 1</u> Each participant was assessed by a nursing staff member, a geriatrician, a relative and via self-reports using the Global Pain Assessment (GPA). A nursing staff member familiar with the resident administered the PAINE and also rated the global level of the resident's physical pain during the previous 2 weeks on the 6-point scale.</p> <p>ROC analyses were used to compare different diagnostic procedures using values ranging from 0 to 1, with higher numbers indicating better sensitivity and specificity of 1 diagnostic procedure with the other as a criterion. In a previous study, ROC validity showed that the caregiver and physician reported reasonable levels of consistency in assessment of persons with mild dementia, but there were questionable reports in persons with severe dementia. Analysis was therefore limited to mild dementia patients.</p> <p>ROC analyses had the following results: Physician ratings identified true pain 2 out of 3 times (AUC 0.67), patient self report (AUC 0.78) and nurses (AUC 0.83) did so approximately 4 out of 5 times while family members (AUC 0.99) recognized true pain in most all instances.</p> <p><u>Stage 2</u> The PAINE was compared to PPI and GPA (two self-report assessment tools), the PADE (another informant based assessment tool), and the PAINAD and CNPI (two observational assessment tools). Trained research assistants administered all tools to nursing staff members and residents.</p> <p>Pearson correlations were calculated between PAINE and the different assessments.</p> <p>Correlation between PADE and PAINE: <math>r=0.65</math>, <math>p &lt; 0.001</math>  PAINE and 6-point scale (geriatrician): <math>r=0.54</math>, <math>p &lt; 0.001</math>  PADE global question and PAINE: <math>r = 0.42</math>, <math>p &lt; 0.001</math>  PAINE and PAINAD: <math>r=0.23</math>, <math>p = 0.014</math>  PAINE and CNPI: <math>r =0.22</math>, <math>p &lt; 0.05</math></p> <p>Only 53 of the participants were able to provide a self report.  PAINE and GPA (self-report): <math>r=0.24</math>, <math>p &lt; 0.05</math>  PAINE and PPI: <math>r=0.15</math>, <math>p = 0.014</math></p> <p><u>Study 3 (Cohen-Mansfield, 2008)</u>  Study 3 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</p>

	<p>treatment and comparison groups, followed by the implementation of a pain intervention in the treatment group. A final pain assessment was completed in each group and f-value provided.</p> <p>Baseline and Final Results for PADE, Global PADE indicator and PAINE:</p> <table border="1" data-bbox="560 373 1388 835"> <thead> <tr> <th></th> <th>Tool</th> <th>Treatment</th> <th>Comparison</th> <th>f value</th> </tr> </thead> <tbody> <tr> <td rowspan="3">All persons with no pain at baseline</td> <td>PADE</td> <td>20.39 (16.31)</td> <td>15.57 (15.84)</td> <td>21.48***</td> </tr> <tr> <td>Global</td> <td>2.00 (1.47)</td> <td>1.28 (1.41)</td> <td>16.81***</td> </tr> <tr> <td>PAINE</td> <td>4.56 (2.76)</td> <td>2.57 (2.59)</td> <td>23.78***</td> </tr> <tr> <td rowspan="3">Initially in pain, but refused to continue (this group compares to a no-treatment control group)</td> <td>PADE</td> <td>20.39 (16.31)</td> <td>24.59 (24.30)</td> <td>7.60**</td> </tr> <tr> <td>Global</td> <td>2.00 (1.47)</td> <td>2.30 (2.00)</td> <td>1.31</td> </tr> <tr> <td>PAINE</td> <td>4.56 (2.76)</td> <td>5.51(5.29)</td> <td>12.04***</td> </tr> <tr> <td rowspan="3">Subset of the Comparison group with no pain. (This group compares to an attention control group)</td> <td>PADE</td> <td>20.39 (16.31)</td> <td>15.38 (15.78)</td> <td>15.86***</td> </tr> <tr> <td>Global</td> <td>2.00 (1.47)</td> <td>1.27 (1.43)</td> <td>12.33***</td> </tr> <tr> <td>PAINE</td> <td>4.56 (2.76)</td> <td>2.57 (2.54)</td> <td>15.73 ***</td> </tr> </tbody> </table> <p>*Baseline (final). *p ≤ 0.05, **p ≤ 0.01, ***p ≤ 0.001</p> <p>The PAINE was able to detect changes from baseline to after treatment. There were significant differences between the experimental groups and the control groups from baseline to final based on PAINE evaluations.</p>		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 (this group compares to a no-treatment control group)	PADE	20.39 (16.31)	24.59 (24.30)	7.60**	Global	2.00 (1.47)	2.30 (2.00)	1.31	PAINE	4.56 (2.76)	5.51(5.29)	12.04***	Subset of the Comparison group with no pain. (This group compares to an attention control 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 ***
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<p><b>-Panel commentary</b></p>	<p>Although the procedures are unclear and difficult to follow there appears to be preliminary construct validity and good correlation with other tools in studies testing the PAINE's responsiveness to intervention. Evaluation of the PAINE shows preliminary criterion validity as well. The procedures for study 2 are not clear, for example, it is unknown which tools were assessed in the ROC analysis. There is a good correlation between PAINE and another informant based rating tool. However, PAINE is weakly correlated with observational and self-report assessment tools. Given that the literature consistently shows a correlation of approximately .30 between self-report and other assessment tools, the low correlations of .15 between the PAINE and the PPI raises concern. When compared with self-report and observational measures, PADE, PAINE, and VDS were found to be the most sensitive to treatment effects and most useful in detecting pain. It should be noted in study 3 that it appears the PAINE and PADE were used to determine whether a patient had pain or not, thus it would be logical that there were high correlation values. The good correlation among categories of tools (informant with informant, observation with observation and self-report with self report) confirms the idea that informant tools may over-identify, while self-report and observation tools under-identify pain in dementia patients.</p>																																												
<p><b>Summary of panel evaluation of pain assessment tool</b></p>																																													
<p>The PAINE is conceptually supported and the method for item generation while limited in scope is appropriate. Studies testing psychometrics employ sound and creative methodology and yield promising reliability and validity but are under-powered. More testing in larger and more diverse samples of patients is recommended. The low correlation between the PAINE and self-report instruments raises concern. Additional data for interrater reliability when PAINE is actually by nursing assistants themselves is desirable.</p>																																													

**Sources of evidence**

- Cohen-Mansfield, J. & Creedon, M. (2002). Nursing staff members perceptions of pain indicators in persons with severe dementia. *Clinical Journal of Pain*, 18(1), 64-73.
- 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.

**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:****Jiska Cohen-Mansfield, PhD**

Hebrew Home of Greater Washington  
Research Institute on Aging  
6121 Montrose Road  
Rockville, MD 20852  
Email: [cohen-mansfield@hebrew-home.org](mailto:cohen-mansfield@hebrew-home.org)

**Evaluation completed by:**

K. Herr, S. Decker, K. Bjoro, University of Iowa.  
Contact information: [keela-herr@uiowa.edu](mailto:keela-herr@uiowa.edu)