**Tool:** **The Assessment in Advanced Dementia (PAINAD)**
**Tool developer:** **Warden V., Hurley, A.C., Volicer, L.**
**Country of origin:** USA
**Reviewed:** **04/04**
*Revised:* *06/08*

| Conceptualization<br>Panel rating: 1<br>*Revised: 2* | |
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| **Purpose** | The Pain Assessment in Advanced Dementia (PAINAD) Scale was developed to provide a clinically relevant and easy to use observational pain assessment tool for individuals with advanced dementia.<br>The aim of the tool developers was to "develop a tool for measuring pain in non-communicative individuals that would be simple to administer and had a score from 0 to 10." |
| **Conceptual basis** | Pain is the concept being measured.<br>The tool attempts to measure pain severity. |
| **Item Generation** | Tool items<br>• Breathing<br>• Negative vocalization<br>• Facial expression<br>• Body language<br>• Consolability<br>Each item is leveled on a three point scale for severity using behavioral descriptors.<br><br>Item generation<br>PAINAD is based on selected items from the DS-DAT and the FLACC. The FLACC was developed for measuring postoperative pain in young children. The article provides a review of literature and existing pain tools. However, little information on item generation is available. |
| **Content Validity** | The content validity of the PAINAD was not established by independent content experts. *However, subsequent evaluation studies have demonstrated that the tool measures pain behavior.* |
| *-Panel Commentary* | The measurement of pain severity has not been substantiated in the research on pain in elders with dementia. Although establishing a 0-10 point scale to represent pain severity may be clinically desirable, the validity of determining level of pain severity in a population of non-verbal elders with diverse presentations of possible pain related behaviors has not been established.<br><br>The tool covers 3 of 6 categories of non-verbal pain behaviors in the AGS Persistent Pain Guidelines: Facial expression, verbalizations/vocalizations and body language. Three items not addressed are: Changes in activity patterns or routines, Mental status changes, Changes in interpersonal interactions.<br><br>The FLACC indicators have not been demonstrated appropriate for elders with dementia and the tool item generation is narrow in focus. With only 5 items used to assess pain, the most salient indicators should be included to ensure greatest likelihood of detecting pain. Of the five pain-related behavior categories in the PAINAD, two are not most salient (breathing and consolability), potentially minimizing the likelihood of detecting pain. *However, subsequent studies have demonstrated that the tool can detect* |

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| | *presence of pain.*<br><br>Scoring of the breathing indicator seems unrelated to pain severity. Breathing does not seem to be a key indicator of pain. However, the tool developers argue that one of the known areas believed to cause negative feelings for persons with dementia is the aversive symptoms associated with intercurrent respiratory infections and that pneumonia is a the proximal cause of death for many demented persons. Thus, they included the breathing item.<br><br>We perceive consolablity as a response to an intervention, not a behavioral manifestation of pain. However, the relationship between consolability and pain may be an area for future research in this population.<br><br>The validity for the scoring of items according to pain severity or separation of behaviors within each major category is not established, (eg. Breathing is scored: Normal=0, Occasional labored breathing/Short period of hyperventilation =1, Noisy labored breathing/Long period of hyperventilation/Cheyne-Stokes respirations=2). *However the tool appears to identify higher and lower levels of pain in an individual.*<br><br>*Although the* PAINAD does not adequately sample the content area of behavioral indicators for pain in elders with dementia who are unable to communicate, *studies have demonstrated that the tool measures pain. It may not detect pain in patients that demonstrate pain with behaviors other than those included in the tool*. |
| **Subjects**<br>**Panel rating: 1**<br>*Revised: 3* | |
| **Subjects** | Study 1 *(Warden et al., 2003)*<br>Long term care VA Dementia Special Care Unit (96 patient unit).<br>Subjects: 19 veterans, all Caucasian<br>Average age: 78.1 years (±5), Range 66-85 years<br>Gender: Female: 0, Male: 100%<br>The subjects had dementia for 8.7 years on average (±4.7), Range 1-20.<br>Length of time in residence: 16.5 months average (±13.5), Range 1-50 months.<br>MMSE: 2.8 ±4.5, Range 0-16.<br>Bedford Alzheimer Nursing Severity Subscale: average 16.4 ±4.4, Range 9-23.<br><br>Study 2 *Lane et al., 2003)*<br>QI study – charts of 25 patients were used.<br>No demographic data or disease characteristics are available for these subjects.<br><br>*Study 3 (Costardi et al., 2006)*<br>*Geriatric Evaluation and Rehabilitation Unit, Northern Italy (n=1)*<br>*Subjects: 20 with chronic pain and dementia*<br>*Average age: 82 (SD=5.9) years; Range: 73-93 years*<br>*Gender: Female 80% Male: 20%*<br>*MMSE: 16.4 + 3.8, range 10-22*<br><br>*Study 4 (Hutchison et al., 2006)*<br>*Acute care hospital, US (n=1)*<br>*Subjects: 53 control and 27 PAINAD with acute postop pain* |

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| | *Average Age: 85.2 control and 88 PAINAD*<br>*Gender: 85% female in control and 78% female in PAINAD*<br>*MMSE: control: 0% with less than 25 in control and 100% diagnosed*<br>*dementia*<br>*PAINAD group: 23.6% with MMSE less than 25 and 76.4% diagnosed*<br>*dementia*<br><br>*Study 5 (Leong et al., 2006)*<br>*Nursing Home in Singapore (n=1)*<br>*Subjects: 88 with moderate and severe dementia*<br>*Average Age: 79.6 (SD=8.3)*<br>*Gender: 61.4% female; 38.6% male*<br>*MMSE: Not reported*<br><br>*Study 6 (van Iersel et al., 2006)*<br>*Palliative care patients in NH setting (n=17)*<br>*Patients who could not express pain*<br>*Subjects: 157 patients*<br>*Average Age: 85 years; range 22-100*<br>*Gender: 78% female; 22% male*<br>*MMSE: Not reported*<br><br>*Study 7 (Zwakhalen et al., 2006)*<br>*Nursing Homes in Netherlands (n=3)*<br>*Subjects: 128 patients with dementia; both acute and chronic pain*<br>*Average Age: 82.4 (SD=6.8) years; range 60-96*<br>*Gender: 78.1% female; 21.9% male*<br>*MMSE: Not reported; Cognitive Performance Scale: 21.9% mild, 28.1%*<br>*moderate, 47.7% severe*<br><br>*Study 8 (Schuler et al., 2007)*<br>*Nursing Homes in Germany (n=8)*<br>*Subjects: 99 residents with dementia*<br>*Average Age: 84.9 (SD=7.5)*<br>*Gender: 80% female; 20% male*<br>*MMSE: Mean 12.1 (SD=9.7)*<br><br>*Study 9 (Cohen-Mansfield & Lipson, 2008)*<br>*Nursing homes in US (n=4)*<br>*Subjects: 121 with dementia*<br>*Average Age: 88 (range 59-101)*<br>*Gender: 81.8% female*<br>*MMSE: Mean 6.3 (range 0-20)*<br><br>*Study 10 (DeWaters et al., 2008)*<br>*Orthopedic unit in US hospital (n=1)*<br>*Subjects: 25 verbal older persons, includes 13 cognitively intact and 12*<br>*cognitively impaired persons*<br>*Average age: 81.24 (range 65-95)*<br>*Gender: 84% female*<br>*MMSE: 20.52 (range 9-30) plus diagnosis of dementia or confusion* |
| *-Panel Commentary* | *The PAINAD has received considerable attention internationally and 7*<br>*additional studies have been conducted that provide additional psychometric*<br>*data on this tool. The PAINAD was translated and tested in Singapore,*<br>*Belgium, Italy, Netherlands, and Germany, as well as two studies in the US.*<br>*The majority of additional study has been conducted in NHs, however testing* |

| | has also occurred in acute care hospitals and geriatric rehabilitation center. These studies have added data with female subjects, a gap in the development studies. There is still limited data on individuals from different races, although cultural variation has been tested across countries. All studies have included individuals with dementia. Age of subjects across studies is appropriate with mean age of samples ranging from 78 to 88 years. |
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| **Administration, Scoring, Feasibility** **Panel rating: 2** *Revised: 3* | |
| **Administration, Scoring, Feasibility** | In the pilot test, subjects were observed for 5 minutes prior to scoring. Definitions for each item are provided. The scoring system is based on a 3 point scale: 0, 1, 2. Total scores range from 0 to 10 points, a maximum of 2 points per category. The tool developers report that because they wanted the 10 point scale, they determined that there would be a 3 point rating option for each item, and that in general, 0=none, 1=small or some or occasionally, and 2=large or a more intense negative behavior making that item operational. Specific definitions for each behavior are provided. No interpretation of the score is provided. A two hour training program was developed including video training tapes.<br><br>*Study 3 (Costardi et al., 2006)* *Comment easily administered with appropriate training*<br><br>*Study 4 (Hutchison et al., 2006)* *Raters received 15 minute in-service instruction. Clinicians reported easy to administer, requiring less than 1 minute of time.*<br><br>*Study 5 (Leong et al., 2006)* *No comments provided.*<br><br>*Study 6 (van Iersel et al., 2006)* *Care providers (n=17): 80% agreed or had no opinion (20% disagreed) that the PAINAD was a good measure to judge pain and 76% agreed or had no opinion that PAINAD was easy to use (28% disagreed). Breathing and consolability indicators were less good indicators (<60%)*<br><br>*Study 7 (Zwakhalen et al., 2006)* *On scale of 0-10 for clinical usefulness, nurses (12 nurses in 3 NHs) rated the PAINAD 5.89 (SD 1.7). 75% preferred the PACSLAC. The PAINAD was considered user-friendly and not time-consuming by participating nurses requiring a few minutes to assess.*<br><br>*Study 8 (Schuler et al., 2007)* *Used a 2 minute period to observe routine nursing activities and complete rating. No comments regarding nurse perceptions/rating of usability.*<br><br>*Study 9 (Cohen-Mansfield & Lipson, 2008)* *Used a 5 minute observation period. No comments regarding nurse perceptions/ratings of usability.*<br><br>*Study 10 (DeWaters et al., 2008)* *No comments re. clinical feasibility* |
| *-Panel Commentary* | Method of administration is described and a guide with definitions of items is provided. |

| | Scoring procedures are clearly described. |
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| | No guide to interpretation of tool score is provided. The tool developers argue that clinicians are familiar with a 0-10 scale and that it is assumed that 0 means no observed pain and 10 means a high level of observed pain that should be treated. |
| | However, this assumes that judging severity of pain represented by behavioral presentation in non-verbal elders is valid—which has not been substantiated in the literature. |
| | *Subsequent studies have demonstrated strong clinical utility with administration possible within 1-3 minutes, limited training required (minimum of 15 minutes to 2 hours), and reported ease of use by raters.* |

**Reliability**
**Panel rating: 1**
*Revised: 3*

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| **Internal consistency** | Study 1 & 2 (Warden et al, 2003; Lane et al., 2003) |
| | Internal consistency was evaluated based on data from a sample of 19 veterans and QI data from 25 residents. (For sample characteristics see subjects above). |
| | Raters were 4 professional nurses with experience on dementia special care units and a master's level social work intern. Three observations of subjects for 5 minutes were made under different conditions as indicated below. To achieve 10 participants per item, the research and QI data were pooled and examined for internal consistency. |
| | Observation 1: During rest or no activity: Cronbach's alpha=.50 |
| | Observation 2: Pleasant activity: movement could lead to pain: Cronbach's alpha=.59, .63 |
| | Observation 3: Potentially unpleasant caregiving activity (eg. Transfers, bathing, toileting) Cronbach's alpha=.50, .67. |
| | *Additional data on internal consistency has been reported by 3 studies.* |
| | *Study 3 (Costardi et al., 2006)* |
| | *Internal consistency=0.74* |
| | *Study 7 (Zwakhalen et al., 2006)* |
| | *Cronbach's alpha 0.69-0.74; Breathing scored consistently low -.51 to .12* |
| | *Study 8 (Schuler et al., 2007)* |
| | *Cronbach's alpha= 0.85* |
| | *Study 10 (DeWaters et al., 2008)* |
| | *Cronbach's alpha for combined group 0.852* |
| | *Cronbach's alpha for cognitively intact group =0.846* |
| | *Cronbach's alpha for cognitively impaired group =0.847* |
| **Interrater reliability** | Study 1 (Warden et al., 2003) |
| | Interrater reliability is reported for 19 subjects by pairs of simultaneous observations by two independent raters. |
| | Pearson's correlation coefficient: |
| | • During pleasant activity     r=.97 |
| | • During unpleasant activity  r=.82. |
| | *Additional data on inter-rater reliability has been reported by 4 studies* |
| | *Study 3 (Costardi et al., 2006)* |
| | *Two raters same day=0.87  (p=.001)* |

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| | *Study 7 (Zwakhalen et al., 2006)*<br>*Inter-rater reliabilities reported: 0.75 (rest), 0.85 (after flu vaccine) and 0.81*<br>*(patient-specific moment of potential pain). Agreement less strong at rest than*<br>*during potential painful activity.*<br><br>*Study 8 (Schuler et al., 2007)*<br>*Two nurses morning and evening assessments: reliability= 0.80 (p=.001)*<br><br>*Study 9 (Cohen-Mansfield & Lipson, 2008)*<br>*Inter-rater agreement across three RAs:  ICC=0.92*<br><br>*Study 10 (DeWaters et al., 2008)*<br>*Interrater reliability between 2 master's prepared nurse RAs for ten video*<br>*vignette ratings:  ICC= 0.98* |
| **Test-retest reliability** | No test-retest reliability is reported.<br>*Data on test-retest and/or intra-rater reliability reported in 3 studies.*<br><br>*Study 3 (Costardi et al., 2006)*<br>*One expert rater at baseline and after 15 days=0.88 (p=.045)*<br><br>*Study 7 (Zwakhalen et al., 2006)*<br>*Intra-rater reliability=0.89; comparing rating in person with rating on video*<br><br>*Study 8 (Schuler et al., 2007)*<br>*One  nurses morning and evening assessments; r=0.90 (p<.001)* |
| *-Panel commentary* | Internal consistency<br>*Follow-up studies have demonstrated good internal consistency with*<br>*correlations ranging from 0.69 to 0.85. However, the item of breathing is low.*<br><br>Interrater reliability<br>*Interrater reliability reports across 5 studies indicate strong reliability.*<br>*Pearson's r ranges from 0.75 to 0.97 with most reports over 0.80 and strong*<br>*ICCs.*<br><br>Test-retest reliability<br>*Three studies report strong test-retest reliability with r's ranging from 0.88 to*<br>*0.90.* |

**Validity: Criterion or construct**
**Panel rating: 2**
*Revised:  2*

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| **Construct validity/**<br>**Criterion related validity** | Construct validity<br>Factor structure analysis for combined PAINAD data for study 1 and study 2<br>1 factor = 50.1% variance (eigenvalue 2.51), 1 minor factor (breathing alone)<br>explained another 20.6% (eigenvalue 1.03).<br>QI data: one factor solution: 61% variance (eigenvalue 3.05).<br><br>Concurrent validity<br>The PAINAD was compared to the DS-DAT with VAS components included.<br>Concurrent validity was reported based on associations from observations of<br>pain and discomfort at rest.<br><br>PAINAD & Pain VAS:  r=.75, p<.001<br>PAINAD & DS-DAT:  r=.76, p<.001<br>PAINAD & DS-VAS:   r=.76, p<.001 |

Concurrent validity was reported based on associations from observations of pain during 1) presumed pleasant conditions for 18 veterans and 2) presumed unpleasant conditions for 19 veterans (p=.001 for all correlations).

1) Presumed pleasant conditions (n=18)
PAINAD (1) & Pain-VAS (1)   r=.92
PAINAD (1) & Pain-VAS (2)   r=.89
Pain-VAS (1) & PAINAD (2)   r=.93
PAINAD (2) & Pain-VAS (2)   r=.95

2) Presumed unpleasant conditions (n=19)
PAINAD (1) & Pain VAS (1)   r=.82
PAINAD (1) & Pain VAS (2)   r=.90
Pain-VAS (1) & PAINAD (2)   r=.90
PAINAD (2) & Pain-VAS (2)   r=.91

Discriminant validity
Study 1
(For sample characteristics see subjects above.)
Subjects (n=19) were observed 3 times to establish expected pain with significant outcomes ($F_{1,17}$ = 10.93, P<0.001)

| | Mean score |
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| 1. During rest or time of no activity: | $1.3\pm1.3$ |
| 2. During a pleasant activity: | $1.0\pm1.3$ |
| 3. During caregiving that might be unpleasant: | $3.1\pm1.7$ |

Study 2
(For sample characteristics see subjects above.)
Change in PAINAD before and after administration of prn medications was reported based on quality improvement data from chart audit of 25 DAT residents. The PAINAD was administered prior to prn medication and 30 minutes after pain medication with significant results (T(24)=9.6, p<.001):

| Prior to prn medication | 30 minutes after medication |
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| $6.7\pm 1.8$ | $1.8 \pm 2.2$ |

*Study 3 (Costardi et al., 2006)*
*Concurrent:  PAINAD compared with VDS (0.65, p=0.008)*

*Study 4 (Hutchison et al., 2006)*
*Predictive:  Compared PME in PAINAD assessed group and control group. Significantly higher PME in PAINAD group (11.25mg) compared to control group ( 5.75mg) (p<.01).  Total of unknown pain intensity lower in PAINAD group (15%)  versus control group (68%)  (p<0.01)*

*Study 5 (Leong et al., 2006)*
*Concurrent:  PAINAD compared with Nurses Report r=0.842 (p<.001)*
*PAINAD compared with Patient Self-Report r=0.304 (p<.005)*
*Discriminant:  PAINAD and Cornell Depression r=0.292 (P<.005)*
*PAINAD and Abbreviated Mental Test r=-0.198*
*Few residents had severe pain; strongest relationship with nurse reported pain. Weak relationship between patients report and PAINAD. Demonstrated ordinal nature of PAINAD categorizing 0-1 as no pain; 2-3 as mild pain; 4 > as moderate and severe pain.  The categorization correlated strongly with Nurses Rating of Pain (kappa 0.85, p=.001).  However, because nurses made both judgments, potential for  bias exists.   Good discriminant validity.*

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| | *Study 6 (van Iersel et al., 2006)*<br>*Construct: 185 care providers report on perceptions of measure of pain. 80% agreed that three indicators were most valuable in measuring pain: facial expression, vocalization and body language. Breathing and consolability less good indicators (<60% agreement).*<br><br>*Study 7 (Zwakhalen et al., 2006)*<br>*Predictivet: Pain versus non-pain groups. Evaluated at rest (T1)1, after flu vaccination (T2) and after potentially painful activity (T3). Consistent upward trend of mean total score on PAINAD during three times as expected.*<br>*Concurrent: PAINAD compared with VAS rater=0.89*<br>*PAINAD compared with VAS nurse=0.81*<br>*PAINAD compared with VRS (patient)=0.81*<br>*PAINAD compared with PACSLAC=0.85*<br><br>*Study 8 (Schuler et al., 2007)*<br>*Construct: Demonstrated one factor structure accounting for 63.5% variance in morning assessment and 62.4% in evening assessment*<br>*Predictive: Compared ratings for patients judged to have pain compared to those judged to be free of pain. All categories of scale (except consolability) rated higher in residents with pain than without. Pain intensity rated by nurses did not correlate with the occurrence of pain behaviors. PAINAD-G did not allow prediction of pain intensity.*<br>*Discriminant: No significant correlations between PAINAD-G and observational measures aimed at nonpain behaviors (apathy, neuropsychiatric)*<br><br>*Study 9 (Cohen-Mansfield & Lipson, 2008)*<br>*Sensitivity: Compared ability of PAINAD (and other tools) to detect pain and change in pain resulting from treatment intervention. In treatment group of 63, 36 completed treatment to achieve no pain, 27 refused treatment by family or physician. A comparison group of 58 without pain used*<br>*Determination of pain compared across tools noting that this was made by PAINAD in only 5%. Higher rates found in informant based tools (e.g. PADE, PAINE). PAINAD was not strong in detecting treatment effects.*<br><br>*Study 10 (DeWaters et al., 2008)*<br>*Concurrent validity/Pearson's r of PAINAD with NRS*<br>    *For all observations (50): 0.834 (p= .01)*<br>    *Unlikely pain (at rest) (25): 0.639 (p= .01)*<br>    *Likely pain (with movement) (25): 0.764 (p=.01)*<br>    *Cognitively intact (26): 0.735 (p<.001)*<br>    *Cognitively impaired (24): 0.915 (p<.001)*<br>*Discriminant validity/Wilcoxon signed rank test between likely and unlikely pain events*<br>*For all observations: z=4.086* |
| *-Panel commentary* | <u>Construct validity</u><br>Data from studies 1 and 2 were combined to conduct the factor analysis. Although a single factor was isolated contributing a moderate amount of variance, the pain scores were not normally distributed with many scores clustering around 0, especially during a pleasant condition or 30 minutes after pain medication.<br>This limits evaluation of scale effectiveness in those with higher levels of pain-related behaviors.<br>*Further study of the PAINAD provides support for construct validity. A single factor was again isolated with greater distribution of pain. However, the* |

| | *number of patients with behaviors reflecting the high end of the scale scoring is still small.* |
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| | Concurrent validity<br>Correlations among the pain tools are strong. However, lack of independent raters for scoring of the pain tools and the associated VAS's potentially impacts the level of associations.<br>*Further study of the PAINAD provides support for good concurrent validity with across tool correlations ranging from 0.65 to 095 with the exception of comparison of the PAINAD to self report of pain (0.30).*<br><br>Discriminant validity<br>Study 1 results show differences in expected outcome, although scores are compressed at the lower end of the scale and further study is needed.<br><br>The results of study 2 (QI study) appear to capture pain and change in pain. However, limited information on subjects, variability of raters/assessors, control over chart audit data limits conclusions that can be reached for initial tool development and suggest the need for more controlled study.<br>*Further study of the PAINAD provides some support for construct, predictive, concurrent and discriminant validity. The most recent study that examines tool sensitivity in detecting change from treatment raises questions regarding the tools ability to do so with persons with severe dementia. Further study is needed.*<br><br>*Although studies have raised concern regarding the items of breathing and consolability, authors urge maintaining the current items structure to allow international comparisons. Because removal of items did not demonstrate improved internal consistency, this recommendation seems supportable.* |

## Summary of panel evaluation of pain assessment tool

The PAINAD was developed as a shorter, easier observation tool for assessing pain in nonverbal elders. The tool items included are not comprehensive, *but subsequent studies have provided data suggesting the tool does detect pain and changing levels of behavior (not pain) intensity. Because of the small number of items that are used to detect pain*, the ability of the PAINAD to detect pain *in those with less obvious changes in behavior (e.g. mental status changes, aggressive behavior, changes in activities) may still be compromised.*

Although clinicians desire to have a tool that provides a 1-10 score similar to the 1-10 NRS commonly used as the gold standard in verbal patients, the soundness of establishing a rating scale with pain severity scoring of behaviors has not been substantiated in the literature. *Completed studies suggest the tool could be used to show higher and lower levels of pain, but there is no data to attach level of pain severity to the number obtained with the tool.*

Tool reliability is good for interrater reliability, but internal consistency is only moderate and stability has not been demonstrated. *Tool has good reliability in all areas.*

Some conceptual and methodological issues have been identified with the development and testing of the PAINAD. However, the positive findings in detection of changes in pain behavior following intervention in the QI study reported suggests additional study in controlled circumstances is warranted. *Follow-up studies have continued to document ability to detect pain and differentiate pain and no pain groups. Follow-up studies must be differentiated according to degree of dementia in the sample population, whether they study acute or chronic pain and the setting of care. Further study of tool sensitivity to detect change in behavior in response to treatment is needed.*

## Source of evidence

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## 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 address for tool developer:
**Victoria Warden, RN**
GRECC (182B)
E. N. Rogers Memorial Veterans Hospital, 200 Springs Road, Bedford, MA 01730.

E-mail: Victoria.Warden@med.va.gov.

## Evaluation completed by:
K. Herr, S. Decker, K. Bjoro, University of Iowa.

Reviewed 04/04                    10
Revised 06/08