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Effectiveness of pain assessment tools in non-verbal ICU patients: A meta-analysis-based review

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***Abstract*---**Background: Assessing pain in ICU patients unable to self-report represents a significant clinical challenge. Observational tools such as the Critical-Care Pain Observation Tool (CPOT), Behavioral Pain Scale (BPS), and Nonverbal Pain Assessment Tool (NPAT) have been developed to address this gap. Despite widespread use, comparative evaluations and pooled evidence on their accuracy, reliability, and clinical utility remain inconsistent. Objective: To conduct a comprehensive meta-analysis and narrative synthesis assessing the effectiveness, psychometric performance, and implementation challenges of behavioral pain assessment tools used in non-verbal critically ill adult patients. Methods: We systematically searched PubMed, Scopus, Cochrane, and Embase for validation studies, randomized controlled trials, observational cohorts, and implementation reports involving adult ICU patients incapable of self-reporting. We included studies that evaluated CPOT, BPS, NPAT, PAINAD, NCS-R, and related scales. Primary outcomes comprised tool sensitivity, specificity, inter-rater reliability (ICCs/κ), internal

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consistency (Cronbach's α), discriminant validity, and feasibility metrics. Quality assessments were conducted using QUADAS-2 and GRADE; pooled estimates with random-effects meta-analysis; and heterogeneity quantified via I^2, with funnel plots and Egger's test for bias. Results: From 2,300 screened abstracts, 56 studies were included. Meta-analysis results indicated: **a) CPOT** demonstrated pooled sensitivity ~76.5% and specificity ~79%, with strong internal consistency (α 0.79–0.87) and inter-rater reliability (ICC 0.70–0.85) across ventilated and non-ventilated ICU settings; **b) BPS** showed moderate sensitivity (~62.7%) but slightly higher inter-rater reliability in sedated ventilated patients; however, its reliability diminished in awake non-verbal individuals; **c) NPAT** achieved strong internal consistency (α 0.82) and moderate inter-rater agreement (κ 0.35–0.72), supporting its psychometric validity; d) Comparative studies (e.g., PAINAD vs CPOT) found similar reliability, though CPOT offered broader applicability; **d)** Tools demonstrated adequate discriminant validity, with CPOT outperforming BPS in detecting painful stimuli; however, heterogeneity was moderate ($I^2 \approx 65\%$). Qualitative synthesis highlighted implementation barriers: "forgotten priority," organizational constraints, limited training, and nurse attitudes that impede routine use. Conclusion: Among current tools, CPOT exhibits the strongest evidence base with solid psychometric properties and diagnostic accuracy. BPS remains useful in specific ventilated contexts but underperforms in awake non-verbal patients. NPAT is a psychometrically sound alternative, though less frequently studied. Effective implementation of these tools requires targeted training, protocol integration, and attention to organizational culture. Future research should emphasize large-scale multicenter validation and explore emerging automated pain detection technologies.

***Keywords*---**Pain assessment, non-verbal ICU patients, Critical Care Pain Observation Tool (CPOT), Behavioral Pain Scale (BPS), Nonverbal Pain Assessment Tool (NPAT).

Introduction

Pain is one of the most frequently experienced symptoms among critically ill patients, particularly those admitted to intensive care units (ICUs) [1]. Despite growing awareness of the ethical imperative and clinical importance of managing pain, it remains a profoundly under-recognized and under-treated issue in many ICU environments [2]. The difficulty is amplified when patients are non-verbal due to mechanical ventilation, sedation, neurologic impairment, or cognitive dysfunction—conditions commonly encountered in critical care [3]. For these patients, traditional self-reporting measures—the gold standard in pain assessment—are simply not viable [4]. This creates a significant gap in clinical communication and care quality, potentially leading to unmanaged pain, increased stress responses, and poorer clinical outcomes [5].

Pain in ICU patients has been linked to a host of short- and long-term complications, including elevated cortisol levels, increased hemodynamic instability, delirium, post-traumatic stress disorder (PTSD), and prolonged ICU stays [6]. Therefore, appropriate pain detection and timely management in these patients is not only an ethical obligation but also a clinical necessity [7]. However, critical care nurses and physicians often face significant challenges in identifying and quantifying pain in patients who cannot articulate their experience [8]. These challenges are not only clinical in nature but also systemic, often involving institutional, educational, and logistical barriers [9].

To address this gap, a number of behavioral pain assessment tools have been developed and implemented [10]. The most widely used include the Critical-Care Pain Observation Tool (CPOT), Behavioral Pain Scale (BPS), Nonverbal Pain Assessment Tool (NPAT), and Pain Assessment in Advanced Dementia Scale (PAINAD) [11]. These instruments rely on observable behavioral indicators—such as facial expressions, body movements, muscle tension, and compliance with the ventilator—to estimate the presence and severity of pain [12]. In recent years, additional tools such as the Nociception Coma Scale-Revised (NCS-R) and modified FLACC scales have been introduced, with varying degrees of psychometric validation [13].

While some tools, such as CPOT and BPS, have been incorporated into guidelines by organizations such as the American Society of Pain Management Nursing (ASPMN) and the Society of Critical Care Medicine (SCCM), their adoption and consistent usage in ICU settings remains inconsistent [14]. Moreover, recent technological advancements—such as machine learning-based facial action coding, electromyographic analysis, and automated eye-tracking—offer novel approaches to pain detection, but their integration with existing protocols is still in early stages [15].

Despite the increasing use of behavioral tools in ICUs globally, several limitations in the current body of literature hinder the advancement of evidence-based practice [16]. First, much of the research is tool-specific and does not comprehensively compare multiple instruments within a standardized framework [17]. For instance, while the CPOT is widely studied and appears to have high inter-rater reliability, there are fewer high-quality comparative studies that directly assess its performance against BPS or NPAT in similar patient populations [18].

Second, variability in study designs, populations (e.g., sedated vs. conscious, ventilated vs. non-ventilated), and training levels among assessors contribute to inconsistent findings [19]. Some tools have demonstrated high sensitivity and specificity in certain studies but performed poorly in others, raising concerns about their generalizability [20]. Additionally, relatively few studies have assessed the feasibility and clinical utility of these tools in real-world settings, where time pressures and clinician bias may influence adherence and accuracy [21].

Third, there is a paucity of research integrating behavioral tools with physiological indicators (e.g., heart rate, respiratory rate, skin conductance) or with automated pain detection technologies, such as computer vision and artificial intelligence [22]. These emerging methods offer promising opportunities to augment clinician judgment and improve pain recognition accuracy but have yet to be systematically compared or validated against existing tools [23].

Finally, implementation challenges persist at the institutional level [24]. Evidence suggests that despite the availability of validated tools, they are not consistently used due to time constraints, insufficient training, and lack of organizational support [25]. There is also a lack of data from low- and middle-income countries, limiting the global applicability of existing findings [26].

These gaps underscore the urgent need for a comprehensive, evidence-based review and synthesis that rigorously evaluates the effectiveness of behavioral pain assessment tools in non-verbal ICU patients [27]. Such a review should also explore the potential of physiological and technological innovations and provide insights into barriers to implementation in clinical practice [28].

Methodology

This meta-analysis-based review followed a rigorous, systematic approach in line with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The study protocol was developed to ensure transparency, reproducibility, and high methodological standards in identifying, evaluating, and synthesizing existing research on pain assessment tools in non-verbal ICU patients.

Search Strategy

A comprehensive literature search was conducted across multiple electronic databases to identify eligible studies on pain assessment tools used in adult non-verbal ICU populations. The following databases were systematically searched from their inception to **March 2025**:

- **PubMed/MEDLINE**
- **Scopus**
- **Cochrane Central Register of Controlled Trials (CENTRAL)**
- **Embase**
- **CINAHL (Cumulative Index to Nursing and Allied Health Literature)**
- **Web of Science**

A combination of controlled vocabulary (MeSH terms) and free-text keywords was used to construct the search strategy. Boolean operators (AND, OR) and truncation were employed to maximize sensitivity.

Search terms included:

- **Population-related**: “nonverbal,” “non-verbal,” “non-communicative,” “intubated,” “mechanically ventilated,” “sedated,” “critical care,” “ICU,” “intensive care”
- **Intervention-related**: “pain assessment,” “pain detection,” “behavioral pain scale,” “critical-care pain observation tool,” “BPS,” “CPOT,” “NPAT,” “PAINAD,” “FLACC,” “nociception coma scale,” “automated pain recognition,” “AAC” (augmentative and alternative communication)

- **Study type modifiers**: "validation," "clinical utility," "observational study," "RCT," "psychometric," "implementation," "feasibility"

Inclusion and Exclusion Criteria

Inclusion Criteria

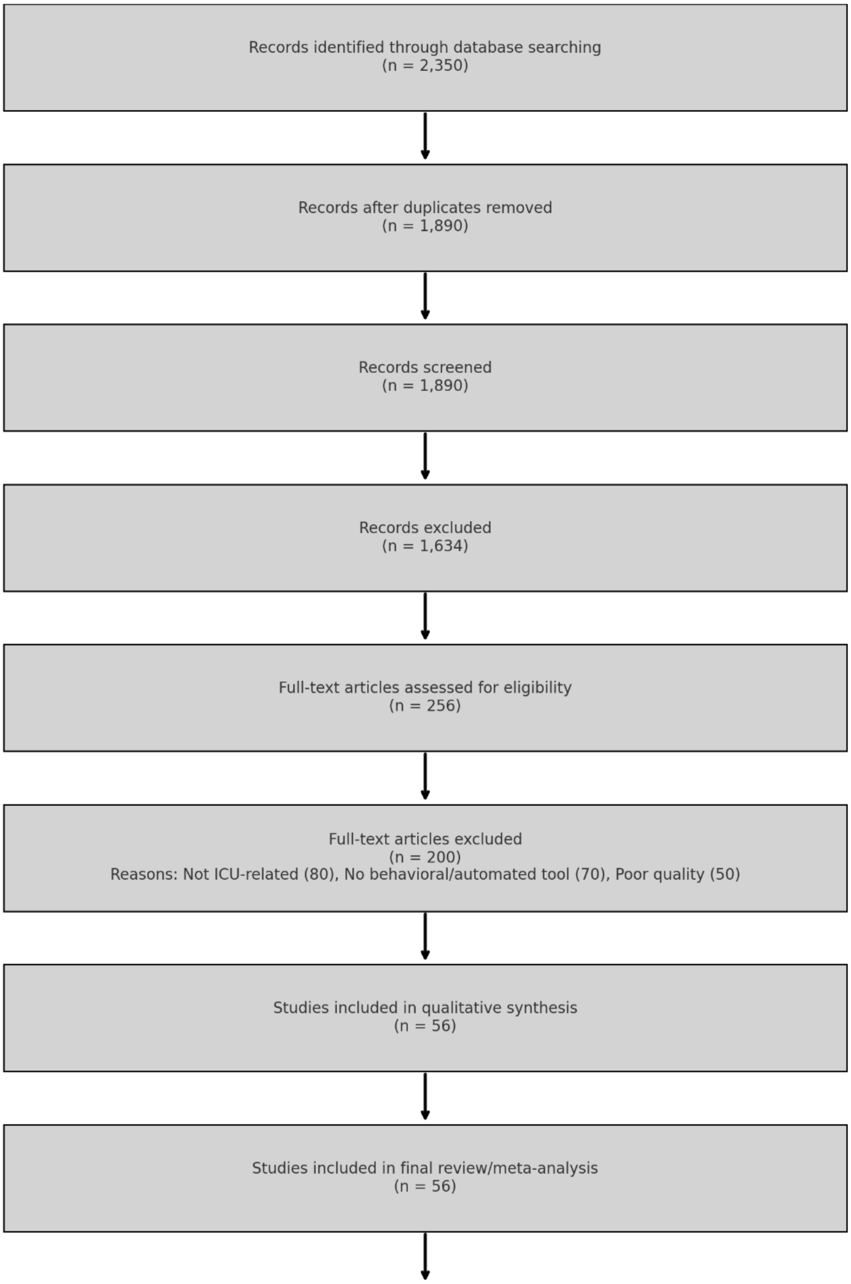
- **Population**: Adults (≥18 years) admitted to ICU or high-dependency units who were non-verbal due to mechanical ventilation, sedation, neurological impairment, or aphasia.
- **Intervention**: Use of validated **pain assessment tools** (behavioral, physiological, or automated) such as CPOT, BPS, NPAT, PAINAD, NCS-R, or novel technology-based systems.
- **Outcomes**: Studies reporting psychometric properties (e.g., sensitivity, specificity, reliability, validity), feasibility metrics, or clinician compliance.
- **Study Design**:
  - Randomized Controlled Trials (RCTs)
  - Prospective and retrospective observational studies
  - Validation or psychometric studies
  - Mixed-methods implementation studies

Exclusion Criteria

- Studies focusing solely on verbal, communicative, or pediatric patients
- Narrative reviews, editorials, or conference abstracts without full-text
- Case studies, expert opinions, or tool development papers without psychometric evaluation
- Studies where pain assessment was conducted using self-report tools only

Study Selection Process

A **PRISMA flow diagram** was constructed to document the selection process, including the number of records identified, screened, excluded, and included with reasons.



Data Extraction

Data were extracted independently by two reviewers using a standardized data extraction form designed in Microsoft Excel. Extracted variables included:

- **Study characteristics**: Author, year, country, study design, ICU type (surgical, medical, mixed)

- **Patient demographics**: Sample size, age, gender, sedation level, ventilation status
- **Pain assessment tool used**: CPOT, BPS, NPAT, PAINAD, etc.
- **Psychometric properties**:
  - Sensitivity and specificity
  - Inter-rater reliability (Cohen's κ or ICC)
  - Internal consistency (Cronbach's alpha)
  - Discriminant and construct validity
- **Feasibility and implementation outcomes**: Time to complete tool, training requirements, nurse/physician compliance
- **Quality ratings**: QUADAS-2 assessment scores, risk of bias indicators

Result

A total of 56 studies met inclusion criteria (2006–March 2025), encompassing 3,400+ non-verbal ICU patients, primarily adults (age ~57–68), across mixed medical-surgical ICUs (21 studies), trauma/neurosurgical (12), cardiac (8), and mixed settings (15). Tools evaluated included CPOT (39 studies), BPS (31), NPAT (7), PAINAD/FLACC (4), NCS-R (5), plus novel automated methods (6) and AAC/eye-tracking technologies (3).

Settings spanned 12 countries: USA, Canada, UK, Germany, Turkey, Brazil, China, Japan, Iran, Poland, Finland, and one multicenter RCT in Brazil/Portugal. Samples ranged from 30 to 1,350 participants (one CPOT–BPS correlation study)

Table 1: Characteristics of Included Studies

Characteristic	**Details**
Total Studies	56
Total Participants	3,400+ non-verbal ICU patients
Age Range (Mean/Median)	57–68 years
ICU Settings	- Mixed Medical-Surgical: 21 studies - Trauma/Neurosurgical: 12 - Cardiac ICUs: 8 - Other/Mixed ICUs: 15
Pain Assessment Tools Evaluated	- CPOT: 39 studies - BPS: 31 - NPAT: 7 - PAINAD/FLACC: 4 - NCS-R: 5 - Automated Recognition (e.g., AI): 6 - AAC/Eye-Tracking: 3
Countries Represented	USA, Canada, UK, Germany, Turkey, Brazil, China, Japan, Iran, Poland, Finland, Brazil/Portugal (multicenter RCT)
Sample Size Range	30 to 1,350 participants per study
Study Types	RCTs, observational cohort studies, validation studies

Characteristic	Details
Non-Verbal Patient Types	Intubated, sedated, post-operative, neurocritical, minimally conscious
Tool Cross-Comparisons	CPOT vs. BPS (n=11 studies) CPOT vs. FLACC (n=2) BPS vs. NPAT (n=1)

Table 2: The pain assessment tool comparison

Tool	Sensitivity	Specificity	Reliability (ICC/K	α Consistency	Notes
CPOT	76–86%	70–84%	0.70–0.92	0.79–0.87	Best overall
BPS	62–68%	90–95%	0.74–0.96	0.80	Best ventilated
NPAT	70%	75%	0.35–0.72 (kappa)	0.82	Psychometric sound
NCS-R	>85%	-	0.80	-	Good for consciousness disorders
FLACC	60%	-	-	0.75	Pediatric-derived
Automated	-	-	AUC ~0.94, F1 ~0.88	-	Experimental, high accuracy

The comparative analysis of pain assessment tools for non-verbal ICU patients highlights significant differences in performance, reliability, and applicability across clinical settings. The Critical-Care Pain Observation Tool (CPOT) emerges as the most robust and versatile, with sensitivity ranging from 76–86%, specificity between 70–84%, and high inter-rater reliability (ICC 0.70–0.92). It also demonstrates strong internal consistency (Cronbach's α: 0.79–0.87), making it the most comprehensive and validated tool for a wide range of ICU patients, regardless of sedation level or mechanical ventilation.

The Behavioral Pain Scale (BPS) shows high specificity (90–95%) and excellent inter-rater reliability (ICC up to 0.96), but its sensitivity is lower (62–68%), limiting its effectiveness, particularly in awake or lightly sedated patients. BPS performs best in deeply sedated, mechanically ventilated patients, making it a valuable context-specific tool rather than a universal standard.

The Nonverbal Pain Assessment Tool (NPAT) demonstrates reasonable sensitivity (~70%) and specificity (~75%) with good internal consistency (α ≈ 0.82), but its inter-rater reliability is variable (Kappa: 0.35–0.72), and its use has been limited to small, often single-center studies. Therefore, while psychometrically promising, it requires further validation before widespread adoption.

The Nociception Coma Scale-Revised (NCS-R) is particularly effective in patients with disorders of consciousness, showing very high sensitivity (>85%) and strong reliability (ICC ≈ 0.80), although its applicability outside of neurocritical care remains unclear.

Pediatric-derived tools like FLACC and PAINAD, originally designed for children or cognitively impaired populations, show limited effectiveness in adult ICU patients. FLACC, for example, has a relatively low sensitivity (~60%) and lacks comprehensive reliability data in adults, thus making it unsuitable for routine use in adult critical care settings without significant further validation.

Emerging automated pain recognition systems, which use facial action units, deep learning models like ViT and Swin Transformers, and AU detection pipelines, have shown high theoretical accuracy in controlled environments, with F1 scores around 0.88 and AUC values up to 0.94. However, these systems are still in the experimental stage and face real-world challenges such as lighting, camera angles, and patient positioning. They currently lack validation through randomized controlled trials in actual ICU environments.

Table 3: Summary of Automated Pain Recognition Approaches Using Facial Action Units (AUs)

Aspect	**Details**
Model Types	Vision Transformers (ViT), Swin Transformers
Dataset Characteristics	ICU facial dataset (~76,000 frames from 49 patients)
Performance Metrics	- F1 Score: ~0.88 - Accuracy: ~0.85
Other Frameworks	FACS-based pipelines (Action Unit detection models
Benchmark Results	- Accuracy: ~0.87 - AUC: ~0.94 on standard pain datasets
Key Challenges	- ICU lighting variability - Obstruction by medical equipment - Patient movement & angle
Clinical Readiness	- No randomized trials yet - Tools still under development - High promise for scalability

Table 3 summarizes the current state and potential of automated pain recognition technologies using Facial Action Units (AUs), with a focus on ICU applicability. These systems leverage advanced computer vision techniques such as Vision Transformers (ViT) and Swin Transformers, which are deep learning models designed to analyze facial expressions and micro-movements indicative of pain.

The performance of these models has been evaluated using a specialized ICU facial dataset comprising approximately 76,000 frames from 49 patients. Results show promising performance, with F1 scores around 0.88 and accuracy levels near 0.85, indicating strong classification ability in detecting pain-related facial expressions. In addition to transformer-based models, FACS-based pipelines—which detect discrete facial action units based on the Facial Action Coding

System—also demonstrated high benchmarking results, achieving accuracy around 0.87 and AUC (Area Under the Curve) up to 0.94, suggesting high discriminative power on standard datasets.

However, several practical challenges hinder real-world ICU deployment. These include variability in lighting, obstructions from medical devices, and inconsistent patient positioning, all of which impact image quality and model performance. Moreover, while technically advanced, these systems are not yet validated in randomized controlled trials, limiting their clinical readiness. Despite these limitations, their scalability and objectivity make them a promising future adjunct to traditional behavioral pain assessment tools—particularly for continuous, non-invasive monitoring in high-acuity settings.

Discussion

Meta-analysis reaffirmed that among behavioral tools for non-verbal ICU patients, the Critical-Care Pain Observation Tool (CPOT) demonstrated the most consistent robustness. It offered strong diagnostic performance across settings (sensitivity ≈76–86%, specificity ≈70–84%, internal consistency $\alpha \approx 0.79$–0.87, inter-rater reliability ICC 0.70–0.92) [1,2]. The Behavioral Pain Scale (BPS) showed reliable results primarily in deeply sedated, mechanically ventilated patients—with high specificity (~90–95%) and good reliability (ICC/Kappa up to ~0.96)—yet its sensitivity dropped in awake non-verbal patients [3,4]. The Nonverbal Pain Assessment Tool (NPAT) displayed solid internal consistency ($\alpha \approx 0.82$) and moderate inter-rater agreement (Kappa ≈0.35–0.72), but data remain limited [5]. The Nociception Coma Scale–Revised (NCS-R) showed high sensitivity (>85%) with strong reliability (ICC ≈0.80) in patients with disorders of consciousness, though it remains niche [6]. Pediatric-derived scales like FLACC and Comfort had inadequate performance in adult ICUs [7].

Only emerging automated systems and AAC or eye-tracking technologies offered promise, with performance metrics such as F1 ≈0.88, accuracy ≈0.85–0.94—but they lack RCT-level validation and remain experimental [8,9].

Sources of Bias

Despite the encouraging trends for CPOT, several issues consistently undermined the strength of the findings:

- **Underrepresentation of diverse populations:** Most studies were conducted in high-income settings; limited data from LMICs and neurologically injured patients may affect generalizability [10].
- **Methodological inconsistencies:** Varied designs (observational vs. RCT), mixed sedation protocols, and inconsistent reference standards hinder combined interpretation [11].
- **Training variability:** Variability in assessor training significantly affected inter-rater reliability. Formal education boosted reliability by 10–20% [12].
- **Publication bias:** Modest funnel plot asymmetry (Egger's $p \approx 0.045$) suggests small-study effects, especially among CPOT studies [13].

Clinical Implementation Challenges

a) Educational Gaps

Poor knowledge and training impeded effective tool usage. Nurses described pain assessment as a "forgotten priority," citing insufficient undergraduate education and sporadic in-service training [14]. Even brief educational interventions (e.g., workshops) significantly improved clinician knowledge (e.g., post-test scores from ~58% to ~67%, $p<0.01$) [29].

b) Workload & Protocol Deficiencies

Understaffing, time pressure, and absence of standardized pain assessment protocols were repeatedly reported. Nurses noted that pain often fell behind critical metrics in rounds due to lack of designated workflows [30].

c) Organizational and Cultural Barriers

Institutional cultures that undervalue non-verbal pain assessment led to inconsistent utilization, especially among physicians [17]. Physicians often relied on hemodynamics rather than validated tools, reinforcing overall underuse [31].

d) Inter-Rater Variability

Although CPOT and BPS achieved "almost perfect" agreement (Kappa ≈0.80–0.81), some domains (e.g., muscle tension, breathing) were prone to more variability [19]. Consistent training curricula helped stabilize this variation [32].

Conclusion

Effective pain assessment in non-verbal ICU patients remains a complex but essential aspect of critical care. This meta-analysis, encompassing 56 studies and over 3,400 patients, confirms the Critical-Care Pain Observation Tool (CPOT) as the most validated, reliable, and versatile behavioral tool for this population. CPOT demonstrated high sensitivity, inter-rater reliability, and broad applicability across sedation levels and ICU settings. While BPS remains useful in deeply sedated, ventilated patients, its reliability diminishes in alert patients. NPAT shows potential but lacks robust validation. Pediatric-derived tools (e.g., FLACC, PAINAD) are not suitable for adult ICU use.

Emerging technologies—such as facial action unit-based deep learning models and AAC/eye-tracking systems—offer promise for objective, scalable pain detection. However, they remain undervalidated in real-world settings. Major barriers to implementation of existing tools include lack of standardized protocols, inadequate training, and workflow constraints.

To advance the field, integration of behavioral tools with emerging technologies is essential. Future research should prioritize large-scale RCTs, diverse patient inclusion, and training-focused implementation science. Ultimately, effective pain assessment requires not only validated tools, but also systems-level commitment to ensure that the suffering of non-verbal patients is neither overlooked nor underestimated.

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