Core Outcome Set Measurement Selection for Recurrent Acute and Chronic Pancreatitis

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Article

Core Outcome Set Measurement Selection for Recurrent Acute and Chronic Pancreatitis

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Abstract

Core outcome set (COS) was previously established for recurrent acute and chronic pancreatitis, identifying pain severity, ability to participate in social roles and activities, and pancreatitis-related hospitalizations or acute attacks as mandatory domains for clinical trials. This study aimed to identify and evaluate candidate patient-reported outcome measures (PROMs) for core outcome domains in recurrent acute and chronic pancreatitis by assessing their psychometric properties, with the goal of informing outcome selection for clinical trials. Available psychometric evidence was used to inform evaluation of candidate PROMs across core outcome domains including the COMPAT-SF, Brief Pain Inventory (BPI/BPI-SF), PROMIS Pain Interference (PROMIS-PI), PEI-Q, and PROMIS Social Roles and Activities (SRA) Short Form. PROMs were assessed for psychometric properties including validity, reliability, and responsiveness using established psychometric principles. Findings were integrated to support evidence-informed recommendations for PROMs selection in RAP and CP clinical trials. COMPAT-SF and BPI/BPI-SF are recommended for pain assessment, PEI-Q for exocrine insufficiency, and PROMIS SRA for social role participation. The Patient Global Impression of Change (PGIC) has been broadly accepted and frequently used in clinical trials to support meaningful within-patient change. Adoption of these validated instruments will enhance consistency, patient-centeredness, and the quality of outcomes in future research and therapeutic development for RAP and CP.

Keywords: core outcome sets; recurrent acute pancreatitis; chronic pancreatitis

Introduction:

Recurrent acute pancreatitis (RAP) and chronic pancreatitis (CP) are progressive, debilitating conditions associated with impaired quality of life, and high healthcare utilization.[1–3] A proportion of individuals with RAP will eventually progress to CP, a chronic disease marked by persistent pancreatic inflammation, irreversible fibrosis, and loss of both exocrine and endocrine function. The clinical manifestations of RAP and CP are diverse and include recurrent episodes of abdominal pain, diabetes mellitus, exocrine pancreatic insufficiency (EPI), osteopathy, and an increased risk of pancreatic cancer. [4–6] These conditions affect both children and adults, contributing to significant reductions in health-related quality of life and substantial healthcare costs. In the United States, the combined economic burden of acute pancreatitis (AP), RAP, and CP exceeds $2 billion annually. [2,3]

Despite this significant disease burden, progress in therapeutic development for RAP and CP has been limited by a lack of standardized, patient-centered outcome measures suitable for use in clinical trials. To address this unmet need, we established a Core Outcome Set (COS) for RAP and CP clinical trials[7]. Through a structured, stakeholder-driven process and collaboration with patients, parents, and healthcare providers, pain severity, ability to participate in social roles and activities, and pancreatitis-related hospitalizations or acute attacks were identified as mandatory outcome domains for future research.

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The goal of this study is to identify and assess core outcome assessments for the mandatory domains identified by examining the measurement properties of available instruments, including their validity, reliability, responsiveness, and interpretability. This approach allows for comparison of health measurement tools to determine their suitability for use in both research and clinical settings. This study assesses patient-reported outcome measures (PROMs), including COMPAT, BPI/BPI-SF, PROMIS Pain Interference Short Form, and PEI-Q.

Methods:

Having reached a consensus on the relevant domains, the next step involved identifying specific instruments for those domains. The objective was to evaluate the measurement performance of candidate instruments to support informed outcome selection for clinical trials.

An evidence-informed approach was used to identify published psychometric evaluations of PROMs relevant to the core outcome domains.

Candidate instruments were selected based on clinical relevance to RAP and CP, prior use in pancreatitis or chronic pain populations. Constructs of interest included pain severity and interference, exocrine pancreatic insufficiency, and ability to participate in social roles and activities. The PROMs were vetted by domain experts. The constructs for pediatric-specific pain PROMs were excluded from reassessment, as these instruments had been previously reviewed[8], and their recommendations were incorporated from existing expert consensus.

The PROMs evaluated in this study included the COMPAT-SF, Brief Pain Inventory (BPI/BPI-SF), and the PROMIS Pain Interference Short Form for pain; the PROMIS Social Roles and Activities Short Form for participation in social roles and activities; and the PEI-Q for exocrine pancreatic insufficiency (Table 1). Key psychometric characteristics assessed for each PROM included content validity, structural validity, internal consistency, reliability, cross-cultural validity, criterion validity, hypothesis testing (construct validity), and responsiveness.

Table 1. PROMs evaluated for psychometric Properties.

Mandatory Domain	PROMs/Measurements
Pain intensity, other (adults)	COMPAT/COMAPT-SF
Pain intensity and interference (adults)	Brief Pain Inventory (BPI)
Pain interference (adults)	PROMIS Bank v1.1 – Pain Interference
Social roles/activities	PROMIS Short Form v2.0 – social roles and activities
Nutrition/EPI	PEI-Q

The methodological quality of each included study was assessed by rating the measurement property as “very good,” “adequate,” “doubtful,” or “inadequate.” Subsequently, the results for each property were classified as sufficient (+), insufficient (–), or indeterminate (?). An overall level of confidence in the evidence (high, moderate, low, or very low) was then determined for each measurement property of each PROM using an evidence-grading approach that accounts for study quality, consistency, and precision. Findings were integrated with expert judgment to formulate recommendations regarding suitability of each PROM for use in RAP and CP clinical trials.

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Results:

Overview of Evidence Informing PROM Evaluation:

A targeted review of the psychometric literature was undertaken to support evaluation of candidate PROMs relevant to the mandatory core outcome domains for recurrent acute and chronic pancreatitis. Published studies reporting measurement properties of the instruments were identified through a literature search. Across the available literature, 22 studies were identified that provided psychometric evidence for 6 PROMs: COMPAT/COMPAT-SF, BPI-SF, PROMIS Pain Interference (PROMIS-PI), PEI-Q, and PROMIS Social Roles and Activities (PROMIS-SRA). Figure 1 provides an overview of the evidence identification process.

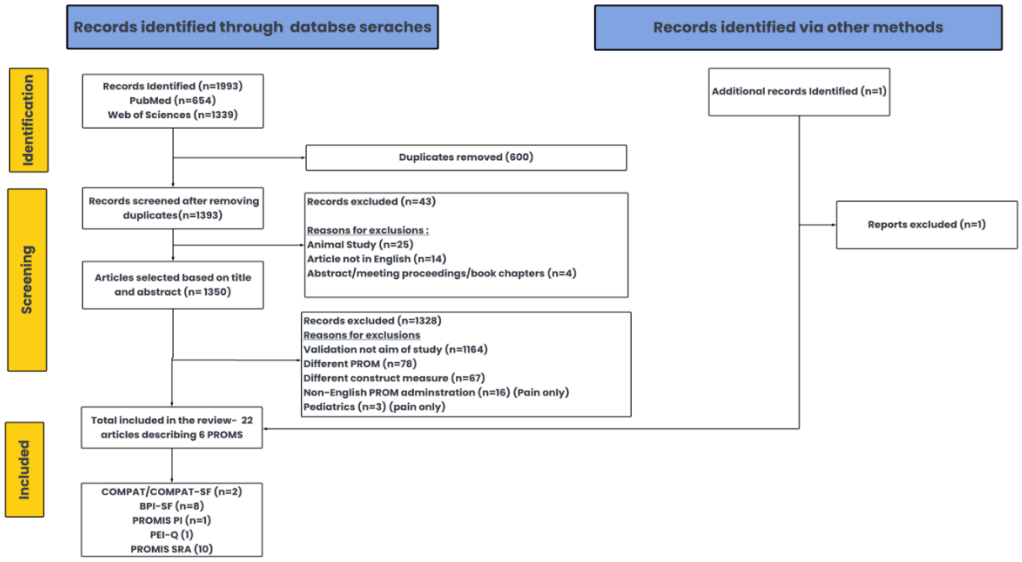

Figure 1.

Pain:

COMPAT/COMPAT-SF were the only measures specifically developed for use in RAP/CP, while the Brief Pain Inventory (BPI) and the PROMIS- pain interference short form were widely evaluated across chronic pain conditions.

COMPAT/COMPAT-SF demonstrated supportive evidence for construct validity, internal consistency, and responsiveness (Table 2 & 3). Evidence for structural validity and reliability was limited or inconsistent, and measurement error and criterion validity were not adequately supported by the available literature. Nevertheless, the quality of evidence supporting internal consistency was high despite the overall limited volume of data. Overall, this tool received an "A" recommendation, indicating strong support for use based on sufficient psychometric properties in relevant populations (Table 4).

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Table 2. Overall Rating and Quality of Evidence.

Summary of Findings Table			
	Summary or pooled results	Overall rating	Quality of evidence ()
Content Validity			
COMPAT	Sufficient relevance, sufficent comprehensivess, sufficent comprehensibility	+	high
BPI			
PROMIS-PI			
PEI-Q			
PROMIS SRA			
Structrual Validity			
COMPAT-SF	Insufficient structural validity	-	Low, only one study of doubtful quality
BPI	Heterogenous chronic pain patients: Sufficient structural validity	+	High, one good quality study
PROMIS-PI	Not available		
PEI-Q	Indeterminate	?	Moderate, one adequate study
PROMIS SRA	Sufficent (CFA >0.9)	+	High, one good quality study
Internal consistency			
COMPAT-SF	Sufficient internal consistency	+	Low, only one study of doubtful quality
BPI	Sufficient internal consistency	+	High, Multiple very good quality studies
PROMIS-PI	Not available		
PEI-Q	Sufficient - Cronbach's alpha, 0.90 (+)	+	High, one good quality study
PROMIS SRA	Sufficent	+	High, one good quality study
Reliability			
COMPAT-SF	Insufficient reliability	-	High, one good quality study
BPI	Sufficient reliability	+	High, Multiple very good quality studies
PROMIS-PI	NR		
PEI-Q	Sufficent -ICC >= 0.7 (+)	+	High, one good quality study
PROMIS SRA	Sufficient - ICC >= 0.7 (+)	+	High, one good quality study
Measurement error			
COMPAT-SF	Insufficient measurement error	-	High, one good quality study
BPI	NR		
PROMIS-PI	NR		
PEI-Q	NR		
PROMIS SRA	NR		
Criterion validity			
COMPAT-SF	Insufficient criterion validity	-	High, one very good quality study
BPI	Sufficient criterion validity	+	High, Multiple very good quality studies
PROMIS-PI	Sufficient criterion validity	+	High, one very good quality study
PEI-Q	PEI-Q compared to GIQLI scores, the PEI-Q symptom domains and total score correlated moderately with the GIQLI symptom domain (range: 0.64-0.77). Similarly, the PEI-Q impact score correlated moderately with the GIQLI impact domain (range: 0.61-0.67).	-	High, one good quality study
PROMIS SRA	Sufficient Correlation to SF36 and FACT- GP	+	High, one good quality study
Hypothesis testing			
COMPAT-SF	NR		
BPI	Sufficient	+	High multiple good quality studies. Only one study showing insufficiency
PROMIS-PI	NR		
PEI-Q	Indeterminate	-	High, one good quality study
PROMIS SRA	Sufficient for chronic condition, insufficient for after surgery		
Responsiveness			
COMPAT-SF	Sufficient	+	High, one good quality study
BPI	Insufficient	-	High, Multiple very good quality studies
PROMIS-PI	NR		
PEI-Q	NR		
PROMIS SRA	Insufficient	-	High

The Brief Pain Inventory (BPI/BPI-SF) showed strong psychometric performance across domains. Structural validity was supported by one good quality study in heterogeneous chronic pain populations (Table 2). Internal consistency was consistently high across multiple high-quality studies, with Cronbach's alpha values ranging from 0.76 to 0.96. Test-retest reliability was also robust (ICC > 0.76), and criterion validity and hypothesis testing were supported by high-quality evidence. Responsiveness was rated sufficient, with multiple studies confirming expected change over time (Table 2 &3). Overall, the BPI received an "A*" rating, indicating strong evidence for use with caveats Table 4).

PROMIS Pain Interference (PROMIS-PI) demonstrated mixed evidence. Criterion validity was supported by high-quality evidence, but the instrument demonstrated insufficient reliability in one high-quality study (Table 2 &3). Other domains including measurement error and responsiveness were not reported. Based on available evidence, PROMIS-PI was assigned a "B" recommendation for use, indicating that the instrument shows promise but that further validation or evidence is needed before widespread adoption (Table 4).

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Table 3. Summary of Findings.

PROM	Findings
COMPAT/COMPAT-SF	Sufficient for construct validity, internal consistency and responsiveness.
BPI/BPI-SF	Sufficient internal consistency (Cronbach's alpha values ,0.76-0.96), reliability (ICC> 0.76), criterion validity, responsiveness.
PROMIS pain interference SF	Reported insufficient reliability but sufficient criterion validity
PEI-Q	The quality of methods was "very good" for most of the measures while the results/ratings were positive for internal consistency, reliability, and criterion validity.
PROMIS Social Roles and Activity SF	• Sufficient structural validity, internal consistency (2/10 studies), reliability, criterion validity, and responsiveness • Structural validity was reported in one study with positive results (CFA >0.9), • Reliability results were reported in one study with positive results (ICC= 0.77), • 5/10 reported on responsiveness with only one reporting accordance with hypothesis.

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Table 4. Recommendation for Use.

PROM	Construct	Recommendation for use
COMPAT/COMPAT-SF (Adults)	Pain severity, other CP specific	A
BPI (Adults)	Pain severity and interference	A*
PROMIS-PI (Adults)	Pain interference	B
PEI-Q (Adults, adolescents)	Pancreatic enzyme Insufficiency	A
PROMIS ability to participate in social roles and activities (adults)	Ability to participant in social roles and activities	A

Pediatric pain PROMs were previously evaluated, & recommendations were made (Li et al) *BPI demonstrated better measurement across all properties evaluated likely due to more studies evaluating this instrument. **PROMs categorized as 'A'** can be recommended for use and results obtained with these PROMs can be trusted. **PROMs categorized as 'B'** have potential to be recommended for use, but they require further research to assess the quality of these PROMs. **PROMs categorized as 'C'** should not be recommended for use.

Pancreatic Enzyme Insufficiency:

The PEI-Q, used to assess outcomes related to pancreatic exocrine insufficiency, demonstrated generally strong psychometric performance (Table 2 & 3). Evidence supported high internal consistency (Cronbach's alpha > 0.90), adequate reliability (ICC > 0.7), and moderate correlations with reference measures like the GIQLI and FACT-GP across symptom and impact domains (range: 0.61–0.67). Structural validity was indeterminate based on moderate quality evidence from a single study, and no data were reported on measurement error or responsiveness (Table 2). Based on the available evidence, PEI-Q was assigned an "A" recommendation, supporting its use in adults and adolescents with PEI (Table 4).

Social Roles and Activities:

The PROMIS Social Roles and Activity Short Form was evaluated across 10 studies. Supportive evidence was identified for sufficient structural validity, internal consistency (in 2 out of 10 studies), reliability, criterion validity, and responsiveness (Table 2). Structural validity was reported positively in one study, with a confirmatory factor analysis (CFA) score greater than 0.9 and internal consistency was sufficient in two studies. Reliability was positively reported in one study, with an intraclass correlation coefficient (ICC) of 0.77. Criterion validity was supported by strong correlations with SF-36 and FACT-GP. Out of 10 studies, 5 reported on responsiveness, but only one study showed results consistent with the hypothesis (Table 2 &3). Measurement error and internal consistency were not uniformly reported. PROMIS SRA was assigned an "A" recommendation overall (Table 4)

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Evidence based Recommendations:

Based on the available psychometric evidence and expert input, several PROMs are recommended for use in clinical trials in RAP and CP. For assessing pain severity in adults, both the COMPAT-SF and the Brief Pain Inventory (BPI/BPI-SF) are recommended. The COMPAT-SF, which was specifically developed for use in RAP and CP, demonstrated strong content validity and responsiveness, earning a grade A recommendation (Table 4). The BPI/BPI-SF also performed well across multiple psychometric domains and is widely used in chronic pain research; it received a grade A* recommendation, indicating strong support with some caveats.

For evaluating the ability to participate in social roles and activities, the PROMIS Social Roles and Activities Short Form (PROMIS SRA) is recommended. This instrument showed sufficient structural validity, internal consistency, and responsiveness, supporting its use in both clinical research and practice. (Table 3 and 4). For measuring exocrine pancreatic insufficiency (EPI), the PEI-Q is recommended (Table 3 & 4). It demonstrated high internal consistency and reliability and is appropriate for use in both adults and adolescents.

In contrast, the PROMIS Pain Interference (PROMIS-PI) instrument showed promising results for criterion validity but demonstrated insufficient reliability and lacked evidence for responsiveness. As a result, it received a grade B recommendation, indicating that further validation is needed before it can be widely adopted in RAP and CP trials.

Together, these evidence-based recommendations support the use of validated, patient-centered instruments for assessing core outcomes in RAP and CP, thereby improving the consistency, relevance, and quality of clinical research in these conditions.

Additional Recommendations and Considerations:

Pain treatment satisfaction was identified as a "mandatory in certain circumstances" outcome domain in the core outcome set for RAP and CP [7], highlighting its relevance in specific trial contexts. Although the psychometric properties were not assessed in this study, the Patient Global Impression of Change (PGIC) is a widely used single-item measure that captures a patient's overall perception of improvement or worsening over time. Its simplicity and direct relevance to patient experience make effective for assessing clinically meaningful change. For example, PGIC has been used in studies of chronic low back pain, fibromyalgia, and neuropathic pain, where it often serves as a reference for validating changes in other outcome measures, including the Brief Pain Inventory and PROMIS tools.[9–12] Studies have evaluated the psychometric properties of PGIC including validity, test-retest reliability in various conditions.[10,13,14] Given its broad acceptance and validity, PGIC can serve as a valuable tool in RAP and CP clinical trials, offering a key measure of patient satisfaction and perceived benefit when used alongside multi-item PROMs.

Acute Pancreatitis Flares:

Acute pancreatitis flares were identified as a mandatory outcome domain for clinical trials in recurrent RAP and CP. [7] In prior clinical trials, a range of endpoints have been used to capture the clinical impact of AP flares, though standardization remains limited. Since December 2024, the FDA has accepted "flare" events as clinical trial endpoints in conditions involving pancreatitis. Inebilizumab (Uplizna), approved on April 3, 2025, for the treatment of IgG4-related disease, evaluated time to disease flare adjudicated using organ-specific criteria that included pancreatic involvement as the primary endpoint.[15] Olezarsen (Tryngolza) was approved in December 2024 for Familial Chylomicronemia Syndrome, used adjudicated acute pancreatitis events as a secondary endpoint based on the Revised Atlanta Classification.[16,17] A similar approach is being used in ongoing trials of plozasiran (ARO-APOC3). [18]

Final recommendations for PROM selection, mapped to COS constructs and supported by psychometric evidence, are summarized in Table 5

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Table 5. Summary of Adult and pediatric PROMS.

Construct	Adult PROM	Pediatric PROM
Pain Severity	COMPAT/COMPAT-SF, BPI	Numerical Rating Scale (0-10 NRS)
Pain interference with daily living	BPI	Functional Disability Inventory (FDI)
Ability to participate in social roles and activities	PROMIS ability to participate in social roles and activities SF	Functional Disability Inventory (FDI)
Pancreatic enzyme Insufficiency	PEI-Q	PEI-Q
Pain Treatment Satisfaction	PGIC (patient global impression of change)	PGIC (patient global impression of change)
Disease Sequela	None	None
ER visits/hospitalization	None	None
AP attacks	None	None

Discussion:

Core outcome domains in RAP and CP were previously established through a consensus process involving patients, caregivers, clinicians, and researchers. This process identified pain severity, ability to participate in social roles and activities, and pancreatitis-related hospitalizations, and acute flares as mandatory outcomes in all trials.[7] To support measurement of these domains, we undertook an evidence-informed evaluation of patient-reported outcome measures (PROMs) to identify instruments with strong measurement performance and clinical relevance for RAP and CP research.

Using available psychometric evidence and expert input, this evaluation supports the use of several PROMs as core outcome assessments in RAP and CP trials. For pain severity, the Brief Pain Inventory (BPI/BPI-SF) and the COMPAT-SF emerged as appropriate instruments. The BPI showed consistently strong measurement performance across key psychometric domains, with an "A*" recommendation for use in pain assessment. The COMPAT-SF, a tool specifically developed for RAP and CP, showed high content validity and responsiveness but had limited evidence for structural validity and test-retest reliability. Still, it was awarded an "A" recommendation based on its relevance and performance in pancreatitis-specific populations. The PROMIS Pain Interference Short Form demonstrated acceptable criterion validity but insufficient evidence for reliability and responsiveness in pancreatitis populations, indicating that additional research is needed before it can be routinely adopted in RAP and CP trials.

For evaluating exocrine pancreatic insufficiency (EPI), the PEI-Q showed favorable measurement properties, including high internal consistency ($\alpha > 0.90$) and moderate correlations with reference instruments, resulting in an "A" recommendation. The PROMIS Social Roles and Activities Short Form (SRA SF) was recommended for measuring the impact of disease on participation in daily life, with evidence supporting its structural validity, internal consistency, and responsiveness across multiple studies.

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The Patient Global Impression of Change (PGIC), although not assessed here, may serve as a valuable adjunct tool for capturing patient satisfaction with pain treatment. PGIC has been widely used in trials for chronic pain, fibromyalgia, and neuropathic pain, where it serves both as a treatment anchor and a reference for meaningful change. Its relevance is further supported by the designation of pain treatment satisfaction as a "mandatory in certain circumstances" domain in the COS. In the context of RAP and CP, PGIC may help assess perceived benefit following interventions targeting acute pain episodes or flare-related hospitalization, offering a global, patient-centered measure of improvement.

Importantly, acute pancreatitis flares were identified as a mandatory outcome domain in the core set[7], yet definitions and measurement strategies for flares vary widely across trials. Many studies rely on clinical endpoints such as hospitalization, duration of symptoms, or use of opioids to define flares, but these fail to capture the full impact on the patient. Incorporating PROMs to characterize flare frequency, severity, and disruption to daily life particularly from the patient's perspective is essential for more meaningful trial outcomes. Harmonizing these endpoints will enhance both trial comparability and clinical relevance.

Since December 2024, the FDA has accepted pancreatitis "flare" events as trial endpoints, as demonstrated by approvals such as inebilizumab for IgG4-related disease[15] and olezarsen for familial chylomicronemia syndrome[16], both using adjudicated AP flares in their efficacy evaluations. This regulatory precedent is also informing ongoing trials, including plozasiran studies, which similarly incorporate adjudicated flare events. [18]

This study provides evidence-based recommendations to guide the selection of outcome measures for RAP and CP trials. Adoption of these validated tools tailored to RAP and CP (Table 5) can improve the consistency and relevance of clinical research, ensuring outcomes reflect the lived experience of patients. Continued research will be essential to refine these tools, expand their applicability, and support patient-centered therapeutic development.

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