MEASUREMENT INSTRUMENTS FOR A CORE OUTCOME SET IN PEDIATRIC RECURRENT ACUTE AND CHRONIC PANCREATITIS

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BACKGROUND & OBJECTIVE

- Pediatric recurrent acute pancreatitis (RAP) and chronic pancreatitis (CP) trials lack consistent outcome measurement, limiting comparability across studies.
- In prior work, a Delphi poll and multi-stakeholder consensus process produced a Core Outcome Set (COS)[1] within the OMERACT framework,[2] identifying mandatory and optional domains.
- A COS defines WHAT to measure — it does not specify HOW to measure it.
- Objective: The pediatric working group aimed to identify feasible, valid measurement instruments for each PROM-based domain.

METHODS

- A structured review was conducted by the pediatric working group.
- Candidate PROMs were identified through a systematic scan of validated instruments for each PROM-based domain.
- Data were extracted on psychometric properties, age ranges, availability of proxy-report versions, and translation status.
- Recommendations were reached through structured consensus.

PEDIATRIC WORKING GROUP

Pediatric gastroenterologists · Pediatric pain psychologist · Patient / parent representative · Nonprofit stakeholders

RESULTS

Across the mandatory and optional core outcome domains, the group recommended 15 pediatric instruments spanning the full age range (0–18 years).

15 instruments recommended

0–18 years of age covered

Self + proxy reporting options

Table 1 Mandatory domains

Domain	Recommended instrument	Ages	Reporter
Pain severity	0–10 Numerical Rating Scale (NRS)[3]	8–18	Self
	Abdominal Pain Index (API) – Child[4]	8–18	Self
	Faces Pain Scale – Revised (FPS-R)[5]	4–16	Self
	FLACC[6]	0–7	Observer
Pain interference with daily living	Functional Disability Inventory (FDI)[7, 19]	8–18	Self
	Child's Activity Limitations Interview (CALI-9)[8]	8–18	Self or proxy
	PROMIS Pediatric Pain Interference SF 8a[9,14]	8–17	Self; proxy 5–17
Ability to participate in social roles and activities	PedsQL 4.0[10]	5–18	Self; proxy 2–18
Pancreatic enzyme insufficiency	PEI-Q[11]	≥12	Self
Pain treatment satisfaction	Patient Global Impression of Change (PGIC)† [12, 18]	12–17	Self; proxy <12

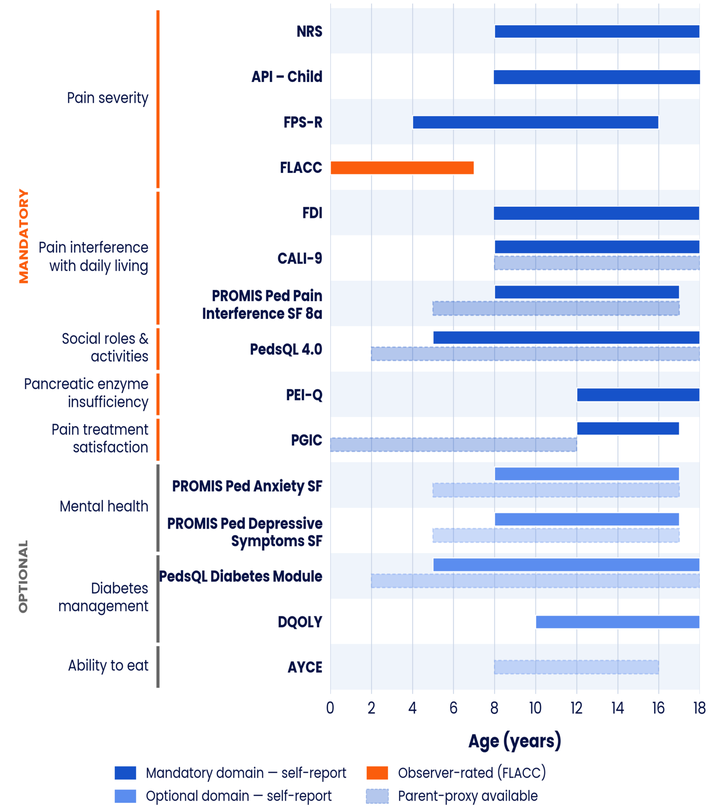
Table 2 Important but optional domains

Domain	Recommended instrument	Ages	Reporter
Mental health	PROMIS Pediatric Anxiety SF[13,14]	8–17	Self; proxy 5–17
	PROMIS Pediatric Depressive Symptoms SF[13,14]	8–17	Self; proxy 5–17
Diabetes management	PedsQL Diabetes Module[15]	5–18	Self; proxy 2–18
	Diabetes Quality of Life for Youth (DQOLY)[16]	10–18	Self
Ability to eat	About Your Child's Eating (AYCE)[17]	8–16	Parent-proxy

† PGIC age ranges reflect the pediatric working group's consensus, consistent with common pediatric trial practice (self-report ≥12; caregiver-report for younger children). No PGIC is yet formally validated in pediatric chronic pain [ref: Ceniza-Bordallo 2026]; the original PGIC was validated in adults [ref: Hurst 2004].

Abbreviations: AYCE, About Your Child's Eating; API, Abdominal Pain Index; CALI-9, Child's Activity Limitations Interview; COS, core outcome set; CP, chronic pancreatitis; DQOLY, Diabetes Quality of Life for Youth; FDI, Functional Disability Inventory; FLACC, Face, Legs, Activity, Cry, Consolability; FPS-R, Faces Pain Scale – Revised; NRS, Numerical Rating Scale; OMERACT, Outcome Measures in Rheumatology; PEI-Q, Pancreatic Exocrine Insufficiency Questionnaire; PGIC, Patient Global Impression of Change; PROM, patient-reported outcome measure; PROMIS, Patient-Reported Outcomes Measurement Information System; RAP, recurrent acute pancreatitis; SF, short form.

Figure 1 Age coverage of recommended instruments



Solid bars indicate the age range for self-report (or observer-rated, for FLACC); dashed bars indicate an available parent-proxy version. PEI-Q is recommended for ages ≥12; PGIC parent-proxy is used for ages <12.

WHY MULTIPLE INSTRUMENTS PER DOMAIN?

Within a domain, instruments are complementary — together they span the full 0–18 age range and offer self- and proxy-report options. Where age ranges overlap, the measures differ in construct, response format, or scoring metric:

Pain severity: NRS (numeric) and FPS-R (faces) capture momentary intensity at different developmental levels; FLACC is observer-rated for pre-verbal children; API is abdominal-pain-specific and composite (frequency × duration × intensity).

Pain interference: FDI measures general functional disability; CALI-9 is pain-specific and separates Active vs Routine activities; PROMIS is an item-bank/CAT on a T-score metric with proxy from age 5.

CONCLUSION

- The pediatric working group produced a practical, age-anchored measurement toolkit aligned with the established COS for pediatric RAP/CP trials.
- Standardizing use of these instruments will improve comparability across studies, facilitate meta-analysis, and accelerate generation of patient-centered evidence for emerging therapies.
- Next steps: operationalize the toolkit in prospective pediatric cohorts and trials, evaluate feasibility and respondent burden, and align with regulatory endpoint development for pancreatitis.

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