

Patient-Reported Outcomes

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Outline

- Review outcome domains and measures recommended in chronic pain clinical trials
- Highlight innovations in patient-reported outcome assessment that could be applied to pancreatic pain
 - sensors, electronic diaries, ecological momentary assessment

Patient Reported Outcomes (PROs)

- PROs provide unique information on the impact of a medical condition and its treatment from the patient's perspective
- Assessment of disease symptoms or treatment side effects, such as pain, fatigue, or anxiety
- Assessment of functional outcomes such as physical, social, role, emotional, or cognitive functioning
- Can include multidimensional constructs such as health-related quality of life (HRQOL) or health utility

IMMPACT Recommendations: Chronic Pain

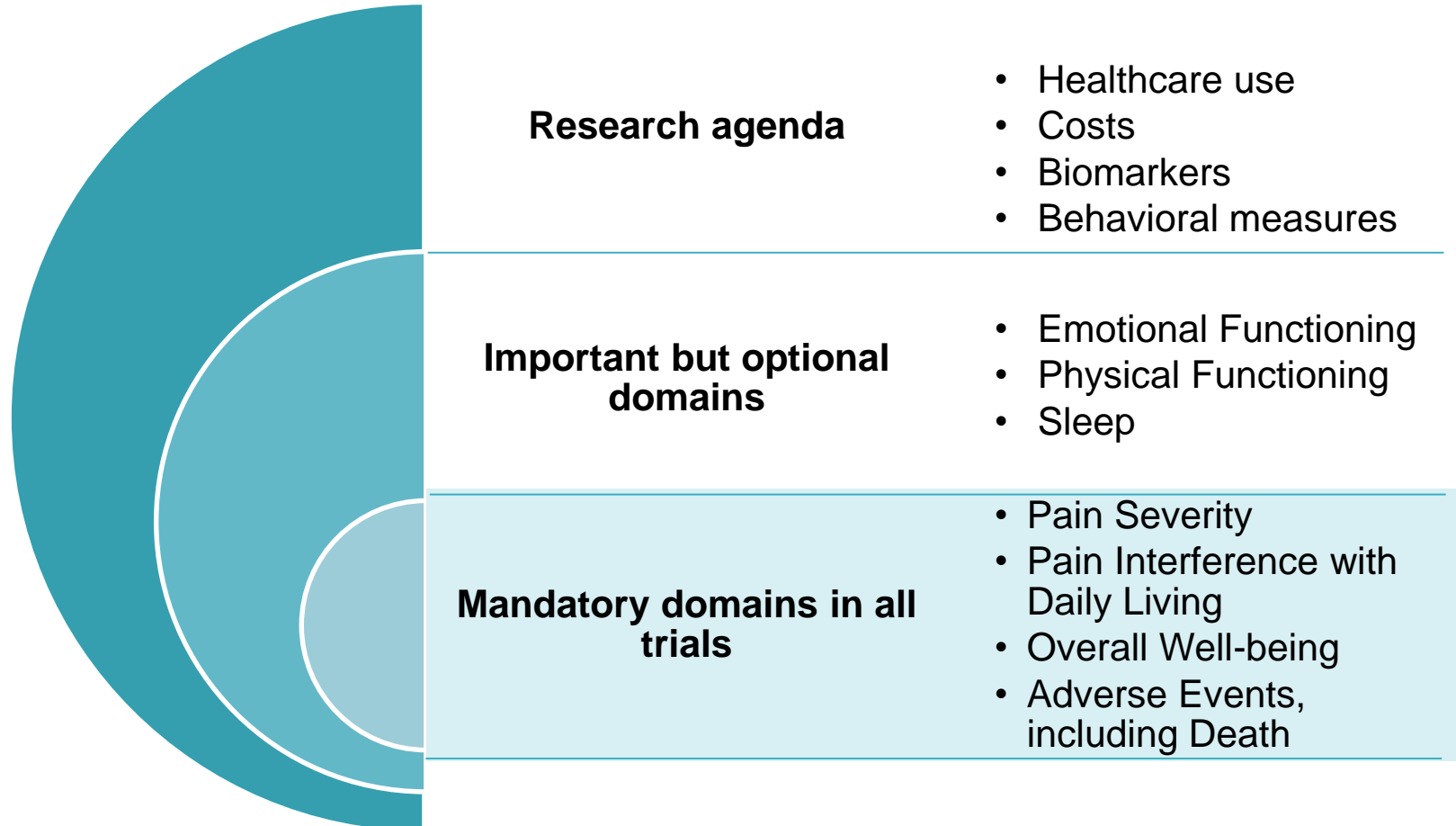
Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)

(2003 adult,
2008 pediatric),
consensus
based

IMMPACT domains:

- pain intensity
- physical functioning
- emotional functioning
- participant ratings of improvement and satisfaction with treatment
- symptoms and adverse events
- participant disposition (e.g. adherence to the treatment regimen and reasons for premature withdrawal from the trial)

Pediatric Core Outcome Set for Chronic Pain Trials



Palermo, et al., 2021, PAIN

NIH HEAL Pain ERN (Effectiveness Research Network) Common Data Elements

- Adult Chronic Pain (Number of total CDE Questions - 30 questions)*

Pain Intensity	Pain Interference	Physical Functioning/ QOL	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with Treatment	Substance Use Screener
PEG (Pain, Enjoyment, General Activity)		PROMIS Physical Functioning Short Form 6b	PROMIS Sleep Disturbance 6a + Sleep Duration Question	Pain Catastrophizing Scale – Short Form 6	PHQ-2	GAD-2	PGIC	TAPS 1
3		6	6	6	2	2	1	4

*monitor opioids (including dosage) by appropriate PRO, EHR, or other measure.

Pancreatitis Pain

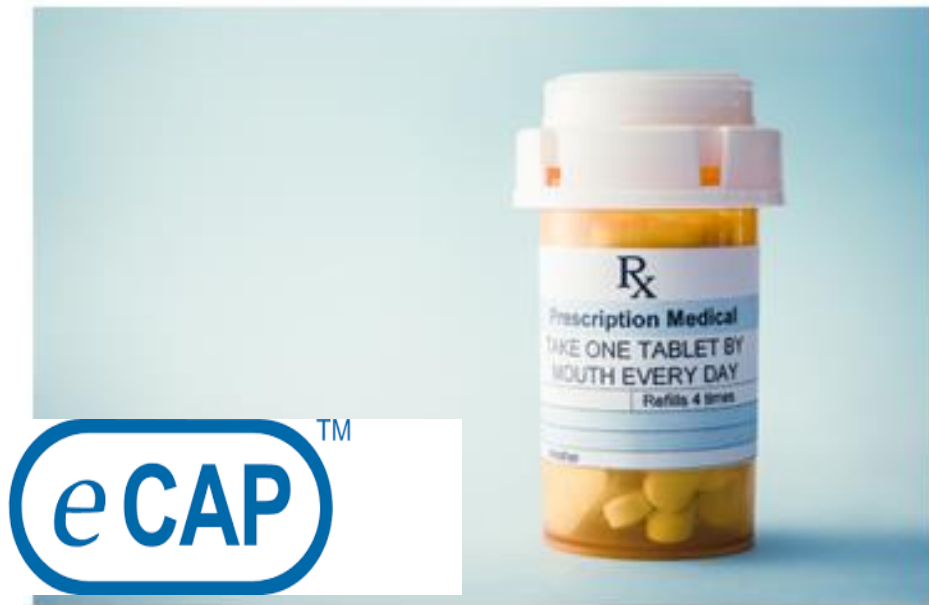
- Disease specific measures
 - Pain measures (COMPAT)
 - Health related quality of life (PANQOLI)
- General measures
 - PROMIS measures
 - Legacy pain measures
- Remain gaps in measurement of some domains and overreliance on pain as single retrospective measure

Innovations in Measurement

- Objective measures/sensors
 - Actigraphy
- Daily diaries
- Ecological momentary assessment

Electronic Capture of Medication Use

- Real time capture of medication use by vial opening
- Passive recording of time/date
- Can be used to examine temporal patterns or to convert to percent adherence as an overall adherence measure

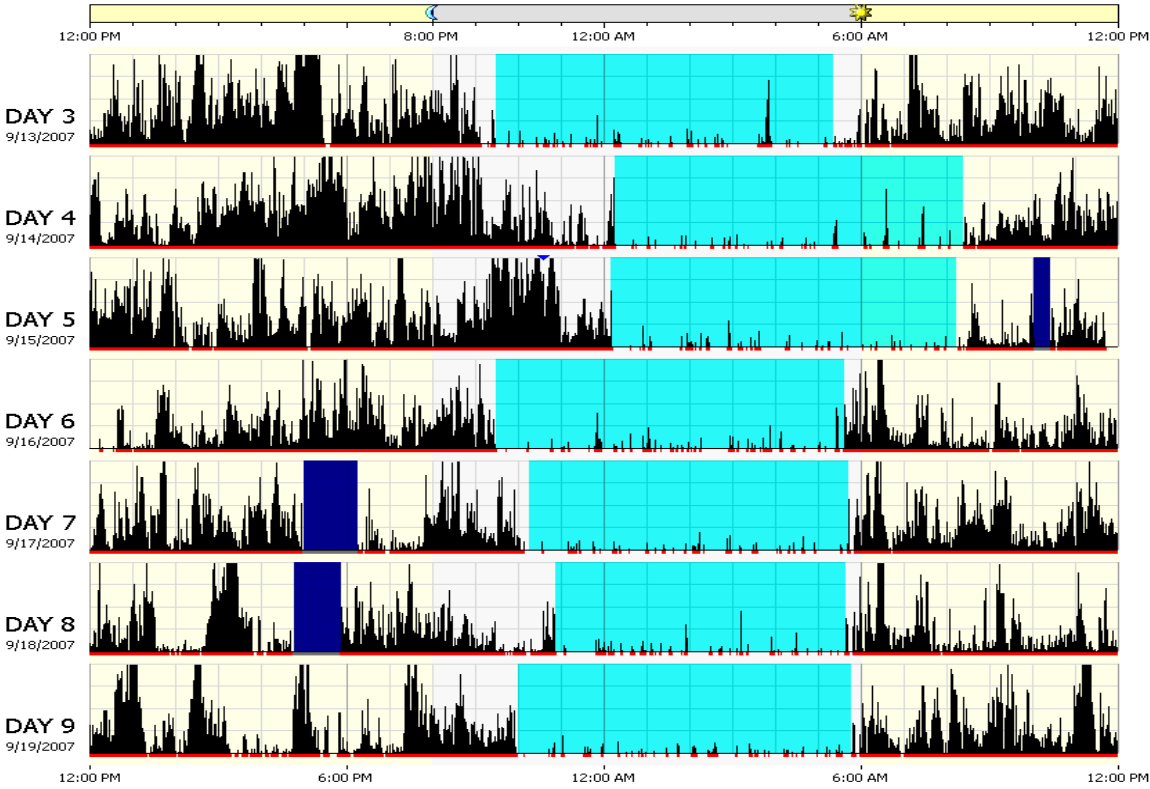


Objective Assessment Tools

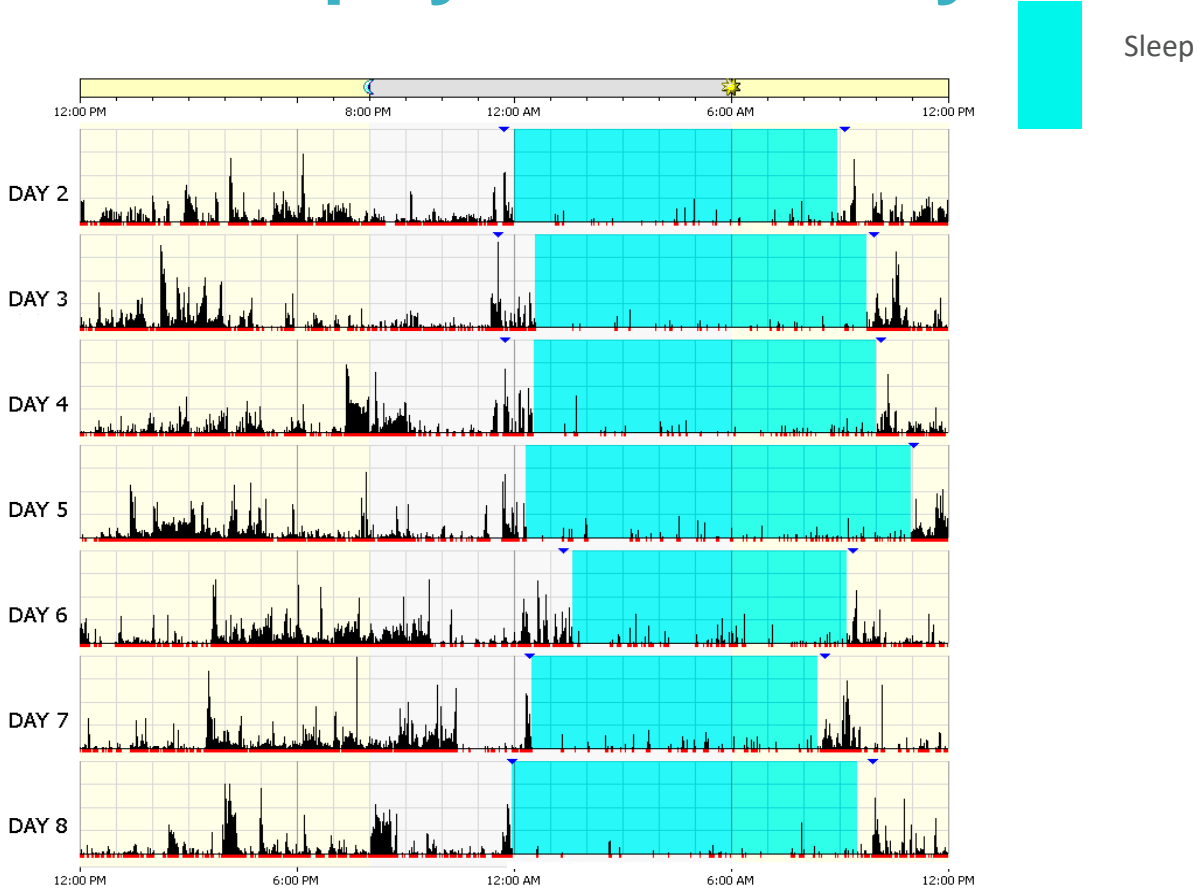


- Ambulatory actigraphy can be used to assess sleep and activity patterns
- Research vs commercial grade (Fitbit, etc)?
- Relatively unobtrusive, embedded in day-to-day life
- Minute by minute (or more frequent) time stamped data

High physical activity

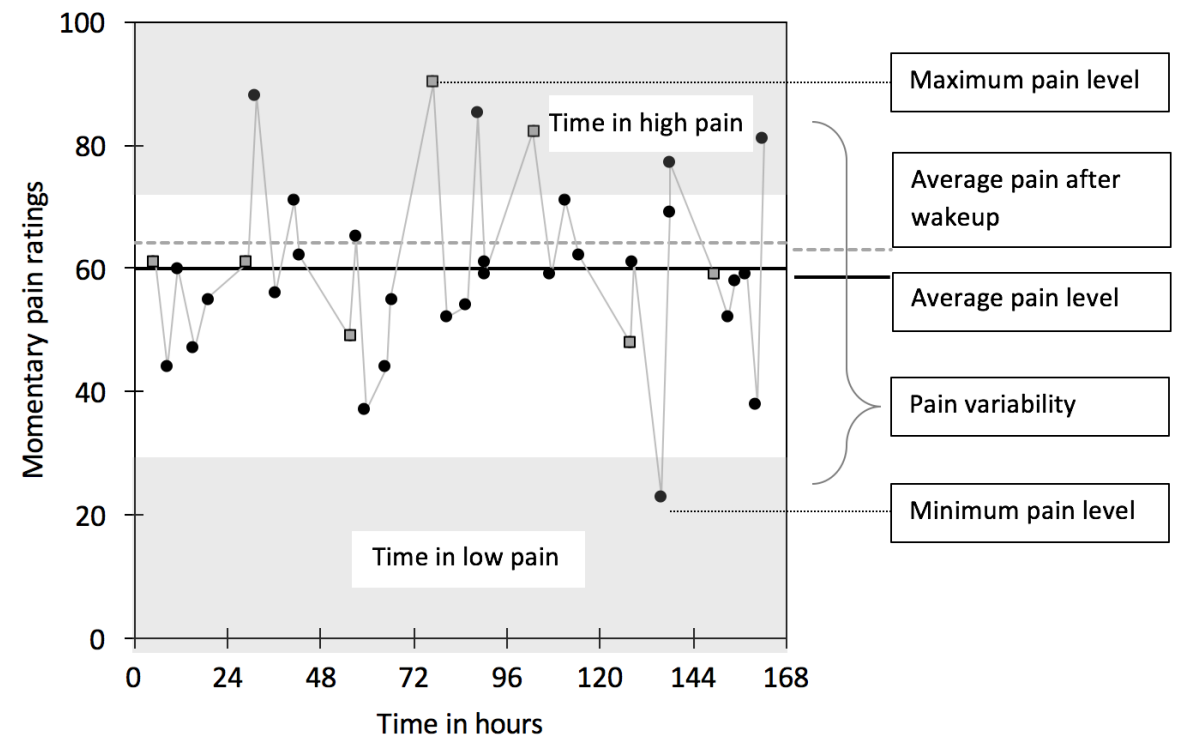


Low physical activity



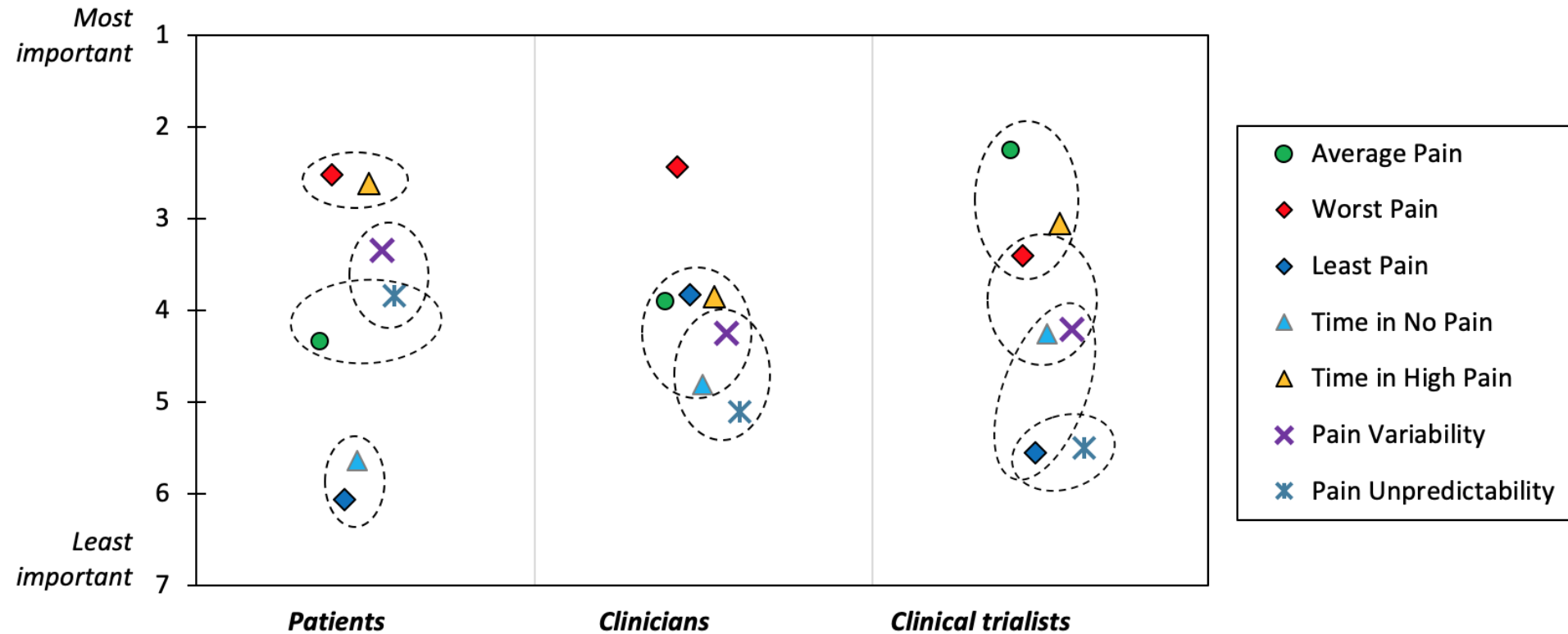
Patient-Reported Outcome Diaries

- Prospective daily diary can provide information on patterns over time
- Real time assessment
- Reduces recall bias, ability to determine dynamic changes in domains of interest
- Can examine group-based or individual trajectories



See series of papers in J Pain 2021 April: [Stefan Schneider](#),¹ [Doerte U. Junghaenel](#),¹ [Masakatsu Ono](#),¹ [Joan E. Broderick](#),¹ and [Arthur A. Stone](#)^{1,2}

Importance Ratings by Stakeholders



E-diaries in Clinical Trials: REDCap and Customized

End of day diary

Pain characteristics

Activity limitations (e.g., school, sports, social activities)

Can get very high compliance in protocols from 7-30 days long

WebMAP

Check-in

What was your level of pain today?

0 1 2 3 4 5 6 7 8 9 10
no pain worst pain

How difficult was schoolwork?

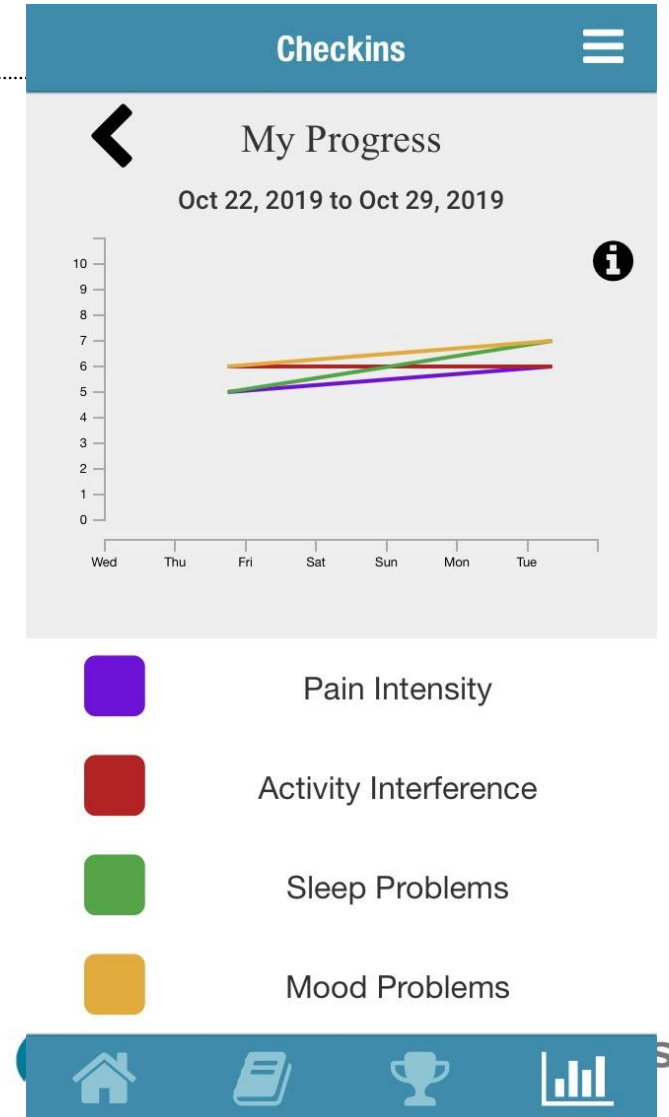
0 1 2 3 4 5 6 7 8 9 10
Not very Somewhat Extremely

How difficult was it to fall or stay asleep last night?

0 1 2 3 4 5 6 7 8 9 10
Not very Somewhat Extremely

Did you feel down, depressed, or hopeless today?

0 1 2 3 4 5 6 7 8 9 10
Not very Somewhat Extremely



Summary and Conclusions

- Outcome assessment is a critically important component of identifying effective treatments
- There are some gaps in measurement of pancreatitis pain in certain domains and in prospective measurement of pain
- Innovations in use of sensors/devices and daily measurements using electronic methods may enhance symptom capture in pancreatitis studies



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