Aligning Research / Clinical EHR-based Assessment: Facilitators, barriers, and opportunities

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Supported by NIH: UH2/UH3NS088731 (NINDS-PPACT), UG3/UH3AT010739 (HEAL / NCCIH - BackInAction), UG3/UH3AG067493 (HEAL / NIA – RESOLVE), UF1MH121949 (HEAL / NIMH – MICARE)

The Case for ReThinking our Approach to Patient Reported Outcomes in Pragmatic / Implementation Trials

- **Full HEAL Common Data Elements core allows broader data sharing and comparability, yet are there potential unanticipated costs?…**
  - ~ 100 items in HEAL CDE core set (before any study tailored assessment additions) many of which not routinely used in many clinical care settings
  - Lower assessment response rates to be expected among those with lower health literacy / higher social determinants of health needs than with more parsimonious set of PROs and strategic use of EHR extracted data
  - Resource and time to develop parallel research processes expensive
  - Forfeiting the opportunity to help encourage and support working key pain-relevant assessments into routine clinical care and seen as relevant to patients and clinicians (Biggest "cost"?)

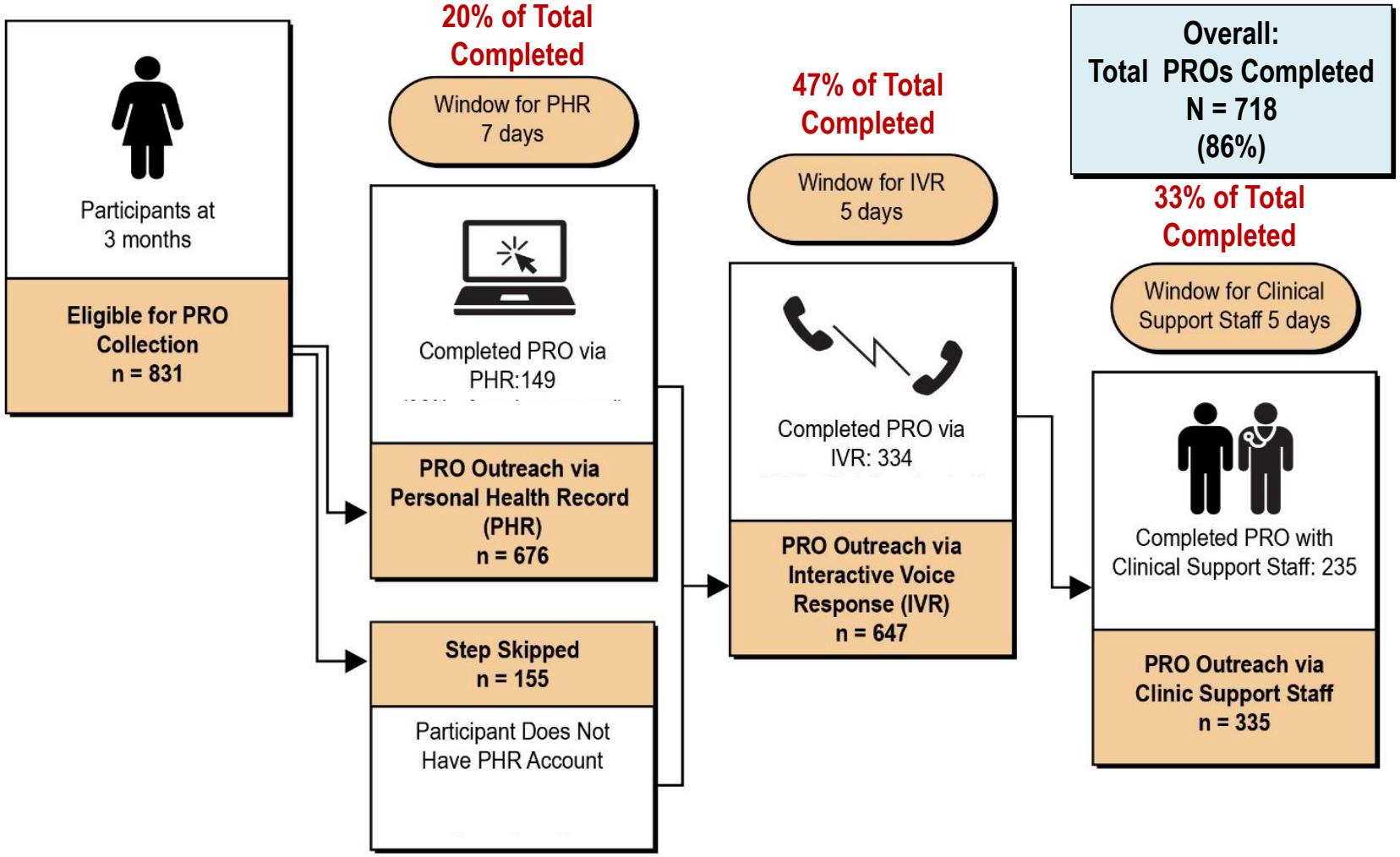
A Tale of 4 Pragmatic Pain-related Trials… (3 HEAL PCTs / 1 earlier Collaboratory PCT)

	PPACT	RESOLVE (HEAL)	BackInAction (HEAL)	MICARE (HEAL)
Target population	Any chronic pain and on long-term opioid treatment (N = 805)	High impact musculoskeletal pain; 45% in rural or medically underserved regions (N = 2,333)	Older adults (≥ 65) with chronic low back pain; Integrated care delivery, FFS, and FQHC settings (N = 800)	Opioid use disorder + depression symptoms; non treatment seeking (N = 804)
Intervention	Primary care-based integrated pain management	Telehealth delivered cognitive behavioral therapy	Acupuncture needling (community & primary care-based LAcs)	Primary care based collaborative care (Meds + NPT)
Assessment battery	29 items baseline / 27 items follow-up (EHR augmentation)	98 items baseline / 76 items follow-up (CORE HEAL CDE only)	98 items baseline / 76 items follow-up (CORE HEAL CDE only)	No primary data collection Zelen / encouragement design)
Follow-up data missingness	84-88% (w/o incentives)	70-82% (~10% lower in rural nonKP site and for online CBT arm)	83-94% (~10% lower in diverse urban FQHC site and for usual care arm)	Secondary data – depends on EHR and state PMP capture
Implications	N/A	Pattern Mixture Imputation (>15% missingness) + inverse weighting for those with no follow-up time points ***greatly complicating analysis & interpretation***	Pattern Mixture Imputation (>15% missingness) + inverse weighting for those with no follow-up time points ***greatly complicating analysis & interpretation***	Need to be able to combine state PMP data and adequate PHQ clinical assessment – mirrors what available for clinician decisions but bumpy

A Different Path for Pragmatic / Implementation Trials (and to better leverage health services research)?

- **Early NIH Collaboratory model / expectation for pragmatic trial data collection.** Ambitious use of clinically derived / aligned research quality data
- **Asking applicants to be resourceful and creative in aligning clinical trials data with clinical care could result in big gains for pragmatic / implementation trials** (requires building assessments into clinical workflow and attending to panel support tool [e.g., Epic workbench])
- **What could be the broader payoffs for richer, research quality clinical assessment data?**
  - Ability to utilize research designs (Zelen / Encouragement) with more generalizable findings and enhanced patient engagement
  - Better grasp of patient pain/functioning (although variation in individual patient data density -> need for methodological rigor)
  - Learn from cases of positive deviancy?

What it <u>really</u> takes to collect PRO data in routine clinical care:



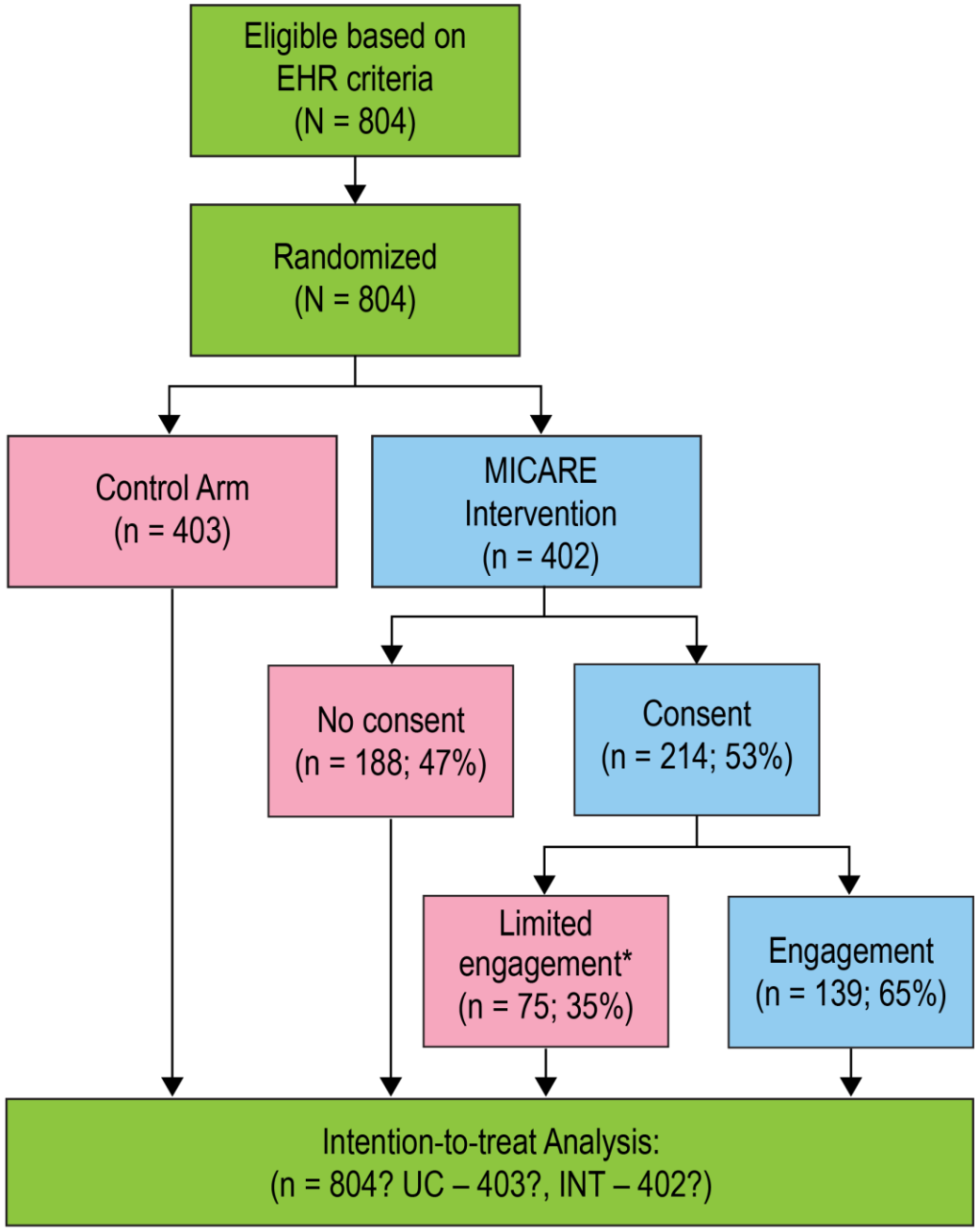
Owen-Smith A, et al. *J Gen Intern Med*. 2018 May;33(Suppl 1):31-37.

Encouragement Trial (Zelen Design)

Rationale/Benefits:

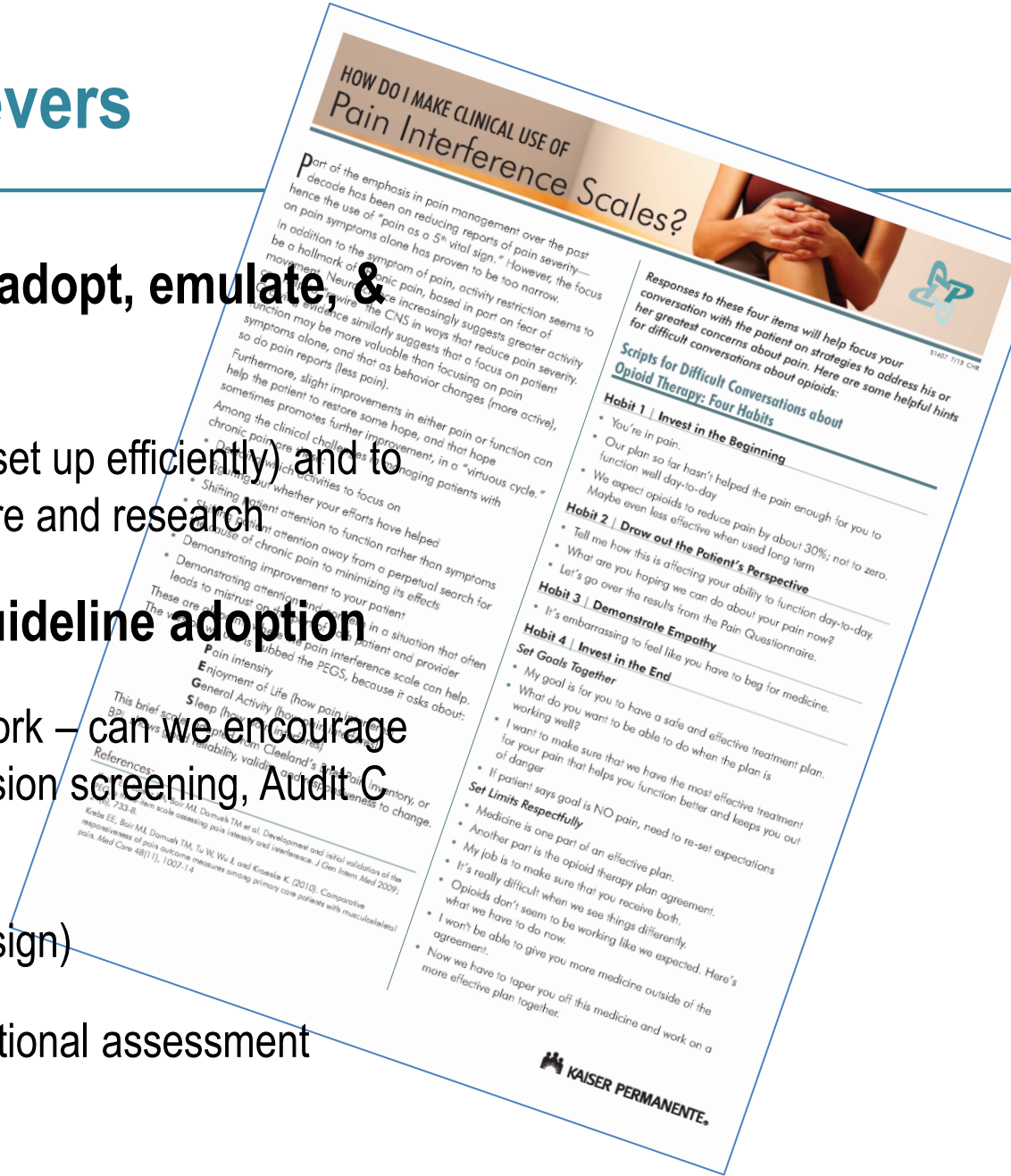
- Increased generalizability (especially for stigmatized conditions)
- Real-world samples
- True “usual care” controls (never contacted)
- Evaluates population benefits
- Prepares for later implementation
- ***Entirely dependent on secondary data***

*Limited engagement – fewer than 3 post-consent intervention visits



Overall Conclusion and Possible Levers

- **Reduce research externalities wherever possible and adopt, emulate, & align with frontline clinical care processes & tools**
  - Much more likely to get buy in of frontline clinicians and patients (if set up efficiently) and to be able to optimize sustainability and wider integration of clinical care and research
- **Consider / encourage chronic pain-relevant clinical guideline adoption**
  - Healthcare systems often driven by HEDIS ratings /NCQA driven work – can we encourage adoption of chronic pain-related HEDIS metric (e.g., PHQ-9 depression screening, Audit C heavy alcohol use screening)?
  - For chronic pain, focus on functioning (travails of pain as a 5th vital sign)
  - Opioid prescribing guidelines at least previous catalyst for pain/functional assessment
  - Other levers?


HOW DO I MAKE CLINICAL USE OF
Pain Interference Scales?

Responses to these four items will help focus your conversation with the patient on strategies to address his or her greatest concerns about pain. Here are some helpful hints for difficult conversations about opioids:

Scripts for Difficult Conversations about Opioid Therapy: Four Habits

Habit 1 | Invest in the Beginning
- You're in pain.
- Our plan so far hasn't helped the pain enough for you to function well day-to-day.
- We expect opioids to reduce pain by about 30%; not to zero. Maybe even less effective when used long term

Habit 2 | Draw out the Patient's Perspective
- Tell me how this is affecting your ability to function day-to-day.
- What are you hoping we can do about your pain now?
- Let's go over the results from the Pain Questionnaire.

Habit 3 | Demonstrate Empathy
- It's embarrassing to feel like you have to beg for medicine.

Habit 4 | Invest in the End

Set Goals Together
- My goal is for you to have a safe and effective treatment plan.
- What do you want to be able to do when the plan is working well?
- I want to make sure that we have the most effective treatment for your pain that helps you function better and keeps you out of danger
- If patient says goal is NO pain, need to re-set expectations

Set Limits Respectfully
- Medicine is one part of an effective plan.
- Another part is the opioid therapy plan agreement.
- My job is to make sure that you receive both.
- It's really difficult when we see things differently.
- Opioids don't seem to be working like we expected. Here's what we have to do now.
- Opioids don't seem to be working like we expected. Here's what we have to do now.
- I won't be able to give you more medicine outside of the agreement.
- Now we have to taper you off this medicine and work on a more effective plan together.

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QUESTIONS?....DISCUSSION?