Coordinated Care Pain Management Technology Implementation (CARNATION)

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Study Background and Rationale

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Response to HEAL NOFO (Key Features)

Coordinated pain care approaches centered in primary care involving multiple disciplines aimed to improve pain management based on biopsychosocial model of pain

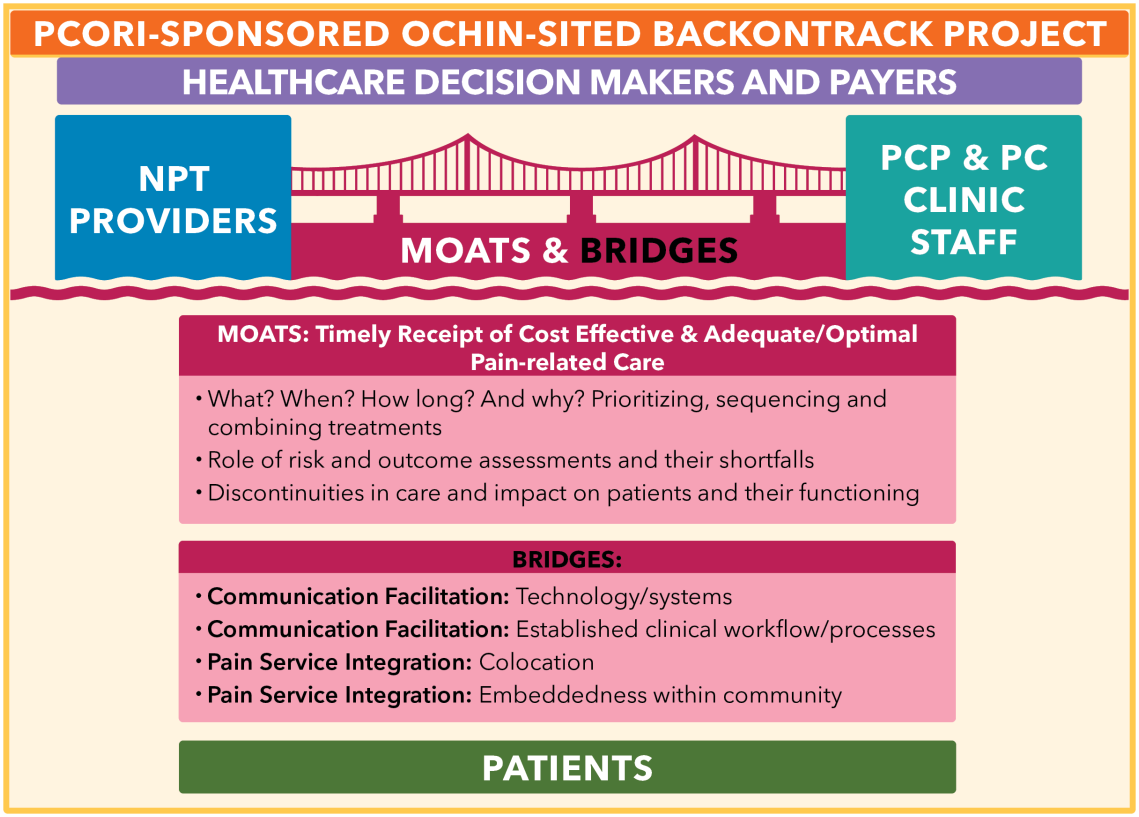
- Required: medication management program, psychological approaches, and physical interventions
- Optional: procedures and complementary interventions

Emphasis on reaching populations of greatest need in healthcare systems that do not have infrastructure to provide quality coordinated pain care

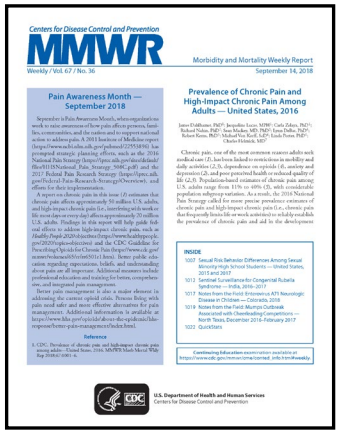
- Targeting populations who experience health disparities and greater barriers to quality pain care than in general population

Restricted to implementation research aiming to consider behavior of practitioners, support staff, patients, payers, and policy makers as key influencers on the adoption, implementation, and sustainability of the evidence-based health interventions proposed in the study

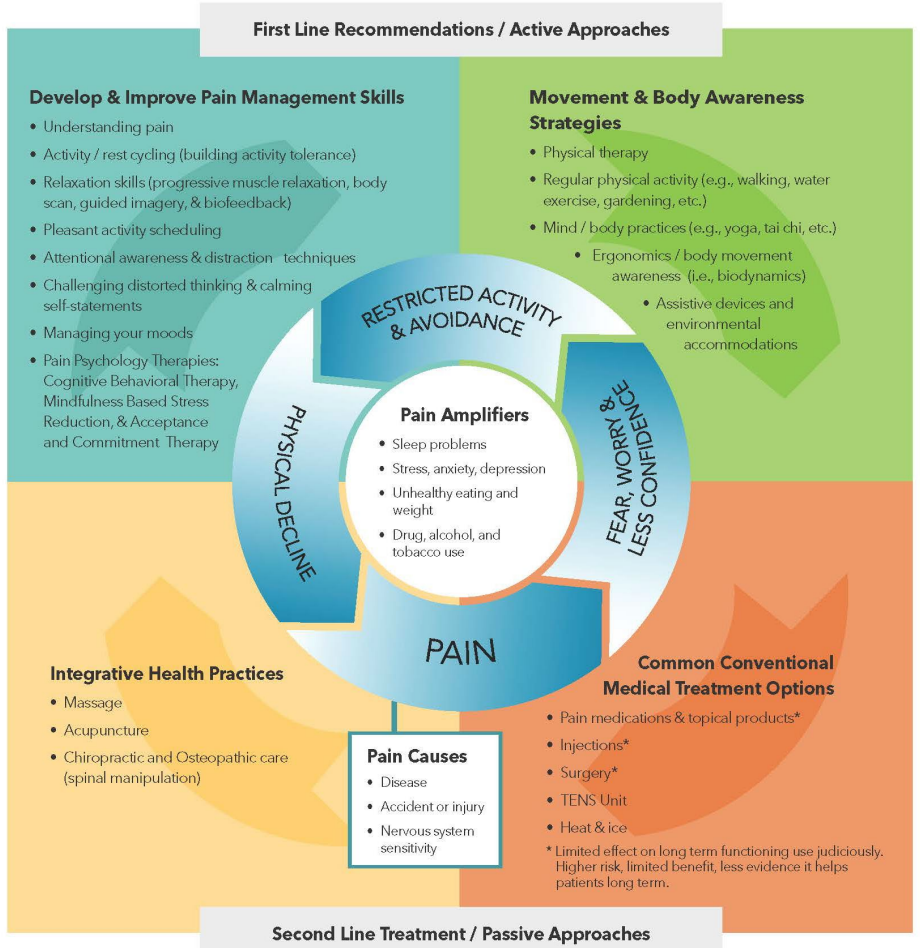
Building on Our Prior Research…



- High impact chronic pain (HICP) most prevalent among adults: living in poverty, with less than a high school education, and on public health insurance
- Rural communities hit harder (more HICP with complicating comorbidities)



- ***Moats*** (barriers to) and ***bridges*** (factors supporting) Integrated Pain Management (IPM) in OCHIN Community Health Centers (CHCs) – *PCORI Back on Track Study*
- IPM includes elements of biopsychosocial-based pain management strategies from each quadrant – *NIH PPACT and RESOLVE Pragmatic Clinical Trials*



Study Design Overview

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UG3: Specific Aim 1

Engage key advisors (clinical, policy, and medical informatics experts; CHC clinicians and staff with interest/expertise in IPM) and identify participating CHCs

- Tailor health information technology (HIT) infrastructure / EHR tools to optimize facilitation of IPM-congruent care delivery
- Ensure adequate EHR/HIT infrastructure and data quality to conduct UH3 trial
- Refine process and outcome measures and related clinical workflow processes when relevant
- Finalize study approach (e.g., refined power analysis) and develop related documentation (protocol, SAP)
- Partner with clinicians, healthcare system leaders, and patients to ensure the implementation support strategies to be tested reflect their priorities and with the NIH Pragmatic Trials Collaboratory to ensure a feasible and rigorous final study design

UH3: Specific Aims 2 & 3

Aim 2: Use a hybrid type 3 implementation effectiveness clinic-cluster randomized trial to test the impact of the implementation support intervention package on CHCs' use of the tailored HIT tools for the delivery of coordinated multidisciplinary pain care among CHC patients with chronic musculoskeletal pain

Hypothesis 2a: Providing multi-component implementation support will significantly increase use of core IPM components: medication management, psychological approaches, and physical interventions (primary [implementation] outcome)

Hypothesis 2b: Eligible patients in CHCs randomized to the early implementation support arm will demonstrate significant reductions in pain-related functional impairment within six months of initiating coordinated pain care management (secondary [effectiveness] outcome)

Aim 3: Conduct formative evaluation and budget impact analyses to understand and explain implementation Reach, Effectiveness, Adoption, Implementation (both arms), to enhance those elements (delayed implementation/control arm)and understand Maintenance (early implementation arm)

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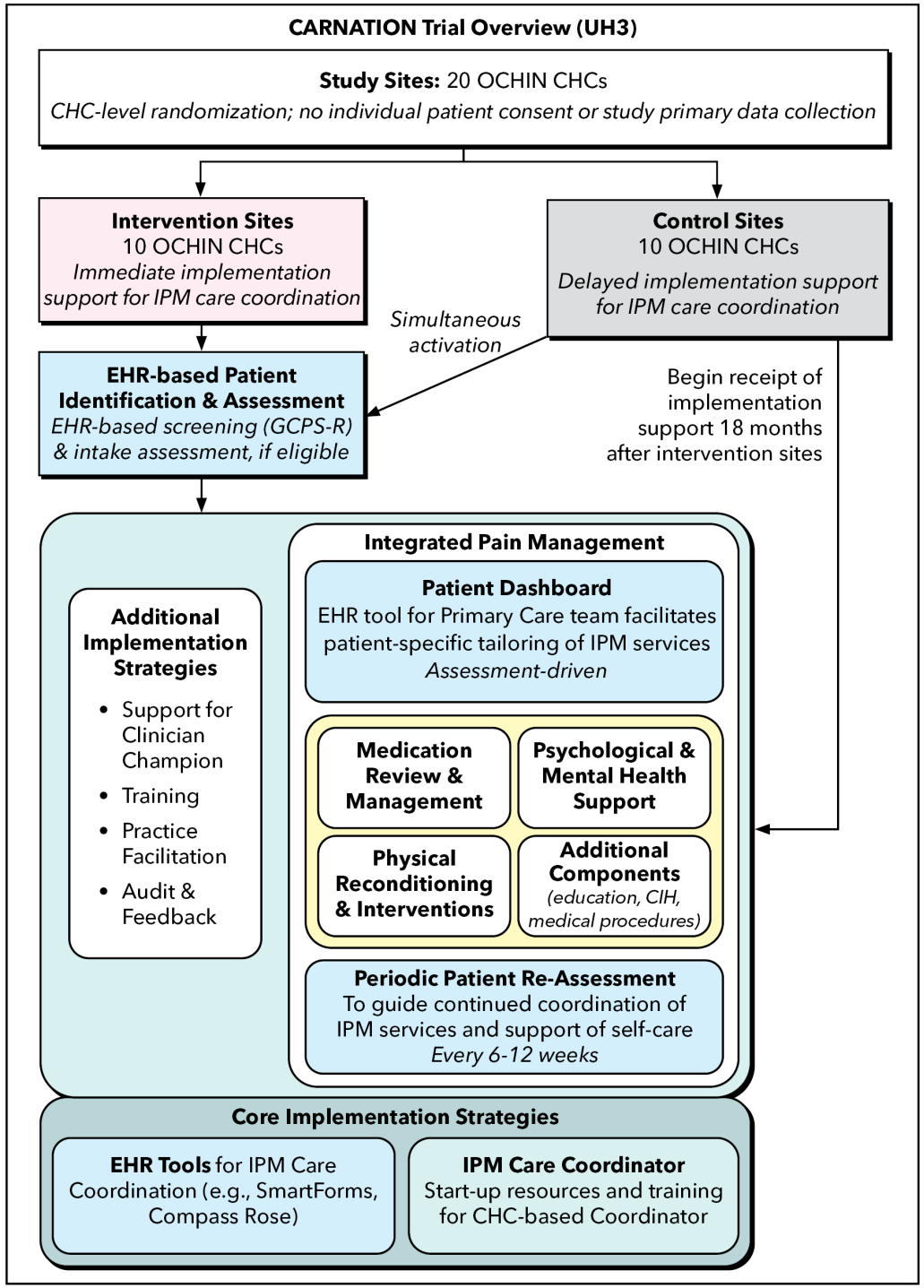
UH3 Trial Overview



A Growing National Network

We provide the solutions expertise, clinical insights, and tailored technologies needed to **connect care locally and transform health outcomes** on a national scale.

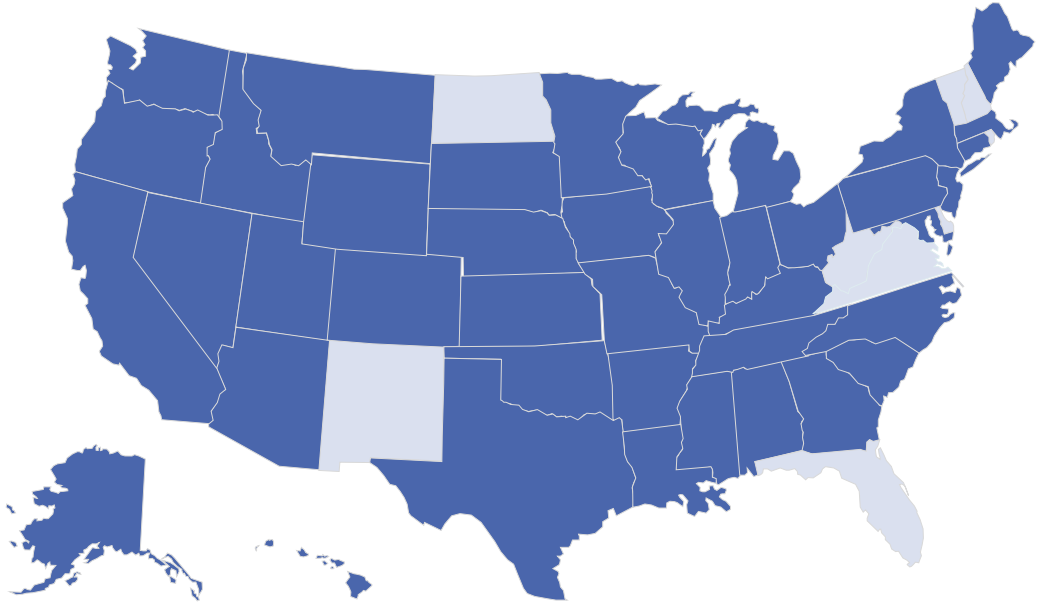
7.6M+
active patients across

300+
independent organizations with

2,100+
health care delivery sites in

41
states with

173M+
clinical summaries securely exchanged last year



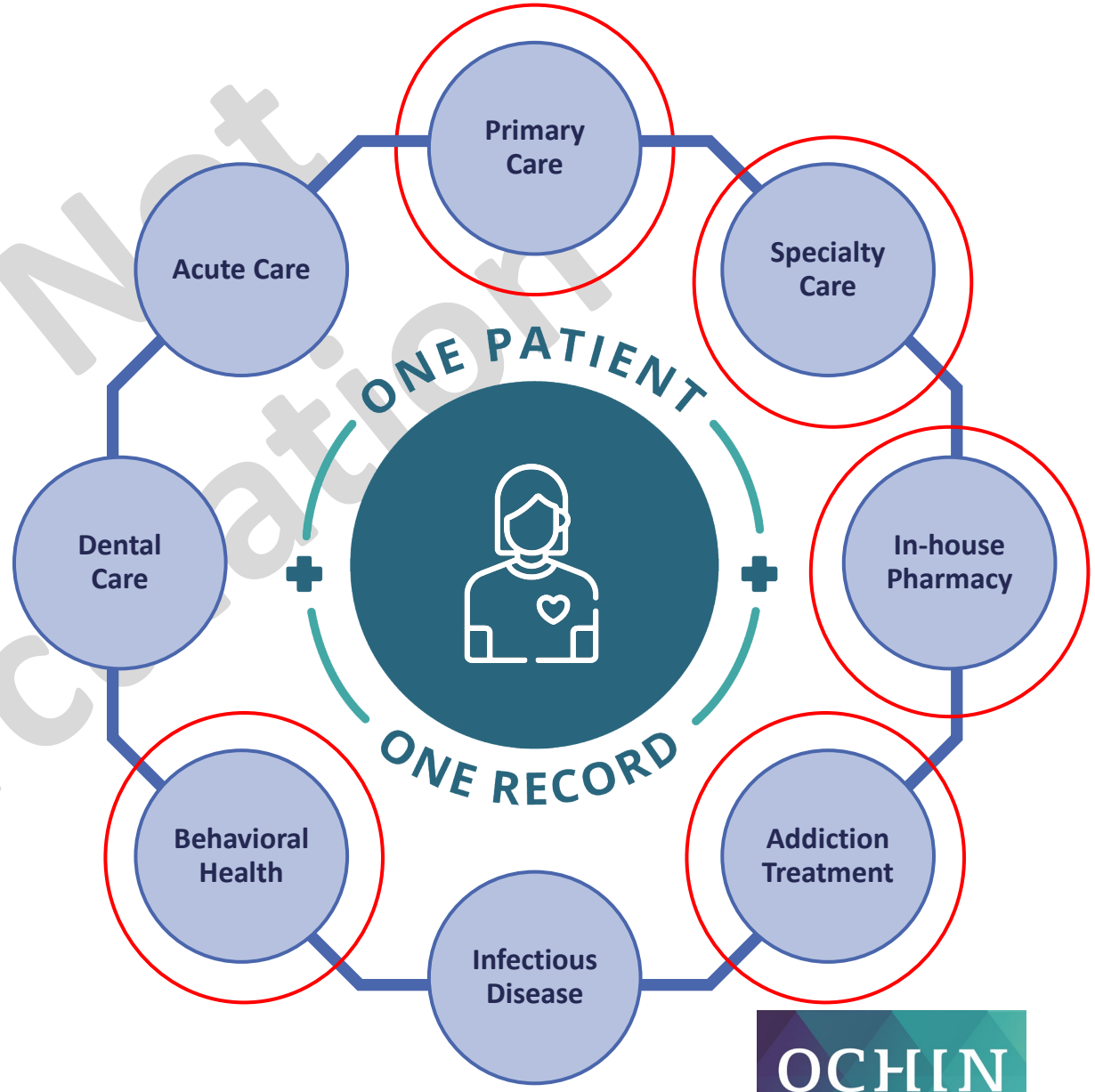
Proudly serving

- Rural hospitals
- Rural health clinics
- Community health centers
- Indigenous and tribal health organizations
- School-based clinics
- Correctional facilities
- Behavioral health providers
- Dental clinics
- Public health departments
- HIV/AIDS care organizations
- PACE organizations

Connecting Care with OCHIN Epic

- **279** OCHIN Epic ambulatory organizations in 40 states*
- **16** OCHIN Epic acute organizations in 10 states*

*Includes onboarding members



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Drivers of Health

29% of patients

with a social need*

11,000 Epic-integrated referrals

for social support last year

***DOH screening domains:** transportation, housing status, food insecurity, financial strain, utilities, stress, social isolation, education, employment, interpersonal violence

Patient-level **Screening**

EHR-enabled tools, workflows, and clinical practice coaching to enhance social risk screening and build whole patient health records.

Digital Data & Technical **Standards**

Recommended standards to streamline data collection and improve health IT interoperability nationally.

Referral & Community **Connection**

Integrated social service resource locators (SSRLs) and referral tools to help providers connect their patients with community support.

National Quality **Measures**

Championed CMS adoption of the first quality measures for social risk screening into federal programs, paving the way for fair access to quality care and value-based pay.

Practice-based **Research**

Detailed population health data to identify disparities and improve health outcomes through practice-based research.

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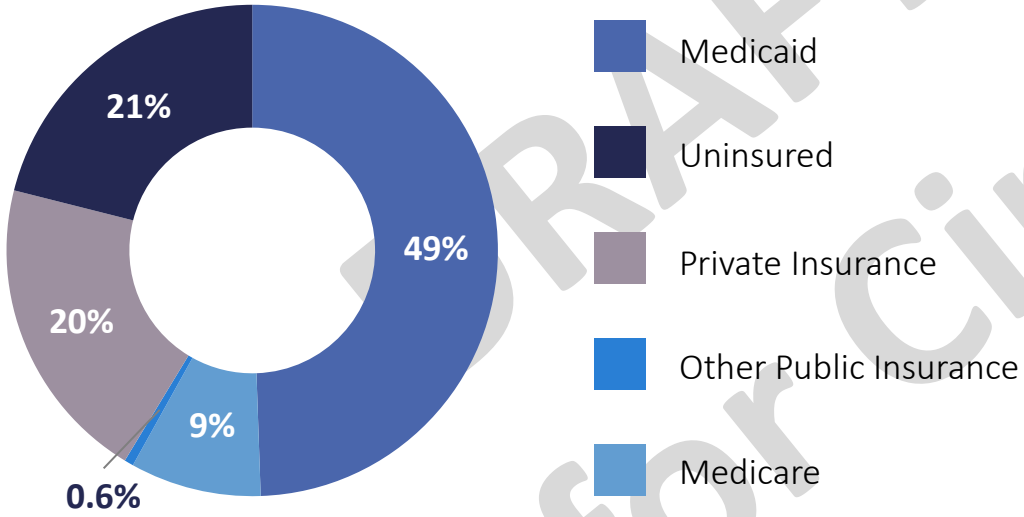
The OCHIN Network Supports

7.6M+ Active Patients

55% Female | **24%** Children | **11%** Adults over 65

55% Federal Poverty Level | **17%** Rural Communities

Insurance Coverage



From Underserved Communities

Nearly 2 out of 3
network patients are **publicly uninsured**

Nearly 1 out of 4
network patients is **uninsured**

Nearly 1 out of 5
network patients identifies with a **racial minority group** (non-white)

1 out of 3
network patients is of **Hispanic or Latino ethnicity** (any race)

1 out of 3
network patients is best served in a **language other than English**

228
languages spoken by network patients

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CHC (and Patient) Eligibility +

CHC Eligibility

20 CHCs total with back-up clinics identified each with ≥ 50 eligible patients per clinic

EHR data indication and confirmation that means of providing core IPM services for qualifying patients

Ability/willingness to routinely administer Graded Chronic Pain Scale and Clinical Assessment (Health Services) Survey

Ability/willingness to identify/assign a Clinician Champion and IPM Care Coordinator

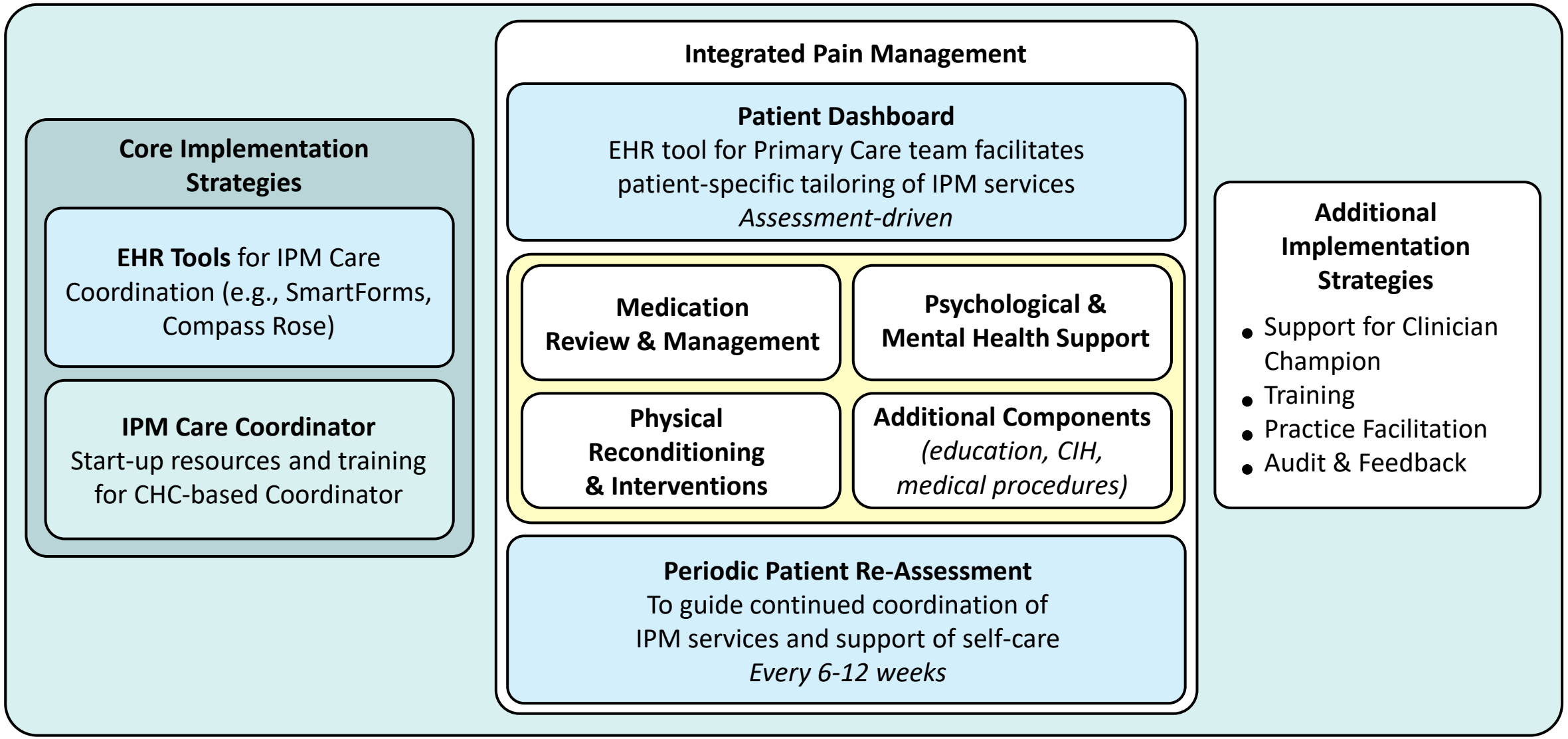
Benefits of participation: support for coordination and enhanced availability of IPM services (e.g., painTRAINER), FTE support for Care Coordinator and training/practice facilitation in use of HIT tools, tailoring to local community needs and opportunity to shape infrastructure tools development, clinic impact fee

Patient Eligibility

- Meet criteria for high impact chronic musculoskeletal pain (EHR dx + Graded Chronic Pain Scale identification)

Not consented as using clinic collected data for secondary effectiveness outcomes

CARNATION Implementation Intervention Overview (UH3)



CARNATION Implementation & Effectiveness Quantitative Outcomes

Variable	EHR Source	PC encounter with MSK pain diagnosis	Within 6 months of PC encounter
Implementation Outcomes			
Primary: Overall Composite Measure of IPM-Congruent Care *Binary (0/1); 1=All five criteria met* 1. Initial pain screening and ≥1 re-assessment 2. Medication review and management completed 3. Physical reconditioning services received 4. Pain-related psychological support services received 5. Evidence of IPM-care coordination	Administrative	X	X
Secondary: ***Expanded*** Overall Composite Measure of IPM-Congruent Care *Binary (0/1); 1=All four criteria met* 1. Medication review and management completed, ***and type/dose is consistent with EBP*** 2. Physical reconditioning services received, ***and type/dose is consistent with EBP*** 3. Pain-related psychological support services received, ***and type/dose is consistent with EBP*** 4. Evidence of IPM-care coordination	Administrative & Patient (Pain Service) Assessment	X	X
Effectiveness Outcomes*			
Resolved high impact chronic pain *(binary; measured by Graded Chronic Pain Scale – Revised [GCPS-R])*	Patient (Pain) Assessment	X	X**
PEG score (*continuous; 3-item subset of GCPS-R)*		X	X**
MCID (≥ 30% / ≥ 50% improvement) in PEG score *(both binary)***		X	X**

CARNATION (Detailed) Implementation Outcomes

Variable		EHR Data Source	PC encounter with MSK pain diagnosis	Within 6 months of PC encounter
Implementation Outcomes				
Primary: Overall Composite Measure of IPM-Congruent Care *(Binary)* • Core Components of IPM-Congruent Care: 1, 2b, 3b, 4b, 5		Administrative (Admin)	X	X
Secondary: ***Expanded*** Overall Composite Measure of IPM-Congruent Care *(Binary)* • Core Components of IPM-Congruent Care: 2b, 3b, 4b, 5 ***plus 2d, 3d, 4d***		Admin & Ppt (Pain Svc) Assessment	X	X
Core Components of IPM-Congruent Care (Secondary Descriptive Outcomes)				
1. Initial pain screening and ≥ 1 re-assessment		Ppt (Pain) Assessment	X	X
2. Medication Review and Management	a. Flagged for review/referral	Admin		X
	b. Completed by clinician			X
	c. Patient indicates use	Ppt (Pain Svc) Assessment	X	X
	d. Type/dose consistent with evidence-based practice	Admin & Ppt (Pain Svc) Assessment	X	X
3. Physical Reconditioning- related Care (e.g., physical therapy/ occupational therapy, guided exercise)	a. Referral	Admin		X
	b. Services received by patient			X
	c. Patient indicates use	Ppt (Pain Svc) Assessment	X	X
	d. Type/dose consistent with evidence-based practice	Admin & Ppt (Pain Svc) Assessment	X	X
4. Pain-Related Psychological Support (behavioral health provider delivered or painTRAINER)	a. Referral	Admin		X
	b. Services received by patient			X
	c. Patient indicates use	Ppt (Pain Svc) Assessment	X	X
	d. Type/dose consistent with evidence-based practice	Admin & Ppt (Pain Svc) Assessment		X
5. Evidence of IPM-care coordination		Admin		X

Analytic Approach, Power Estimate & Data Sharing

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Sample Size and Power

Sample Size: 20 CHCs (cluster-randomization)

- Assumed 50 eligible patients per CHC (conservative limit)

Primary Outcome: Overall Composite Measure of IPM congruent care within 6 months of encounter

- Binary with control outcome rate 0.05 to 0.10

GOAL Effect Size: 10% improvement (risk difference scale) in intervention vs control

ICC: ranged 0.01 to 0.05 to achieve 90% power given sample size (see Table)

Related UG3 Goals: Obtain real data from CHCs to update outcome rates, Adjusted ICC, and conduct sample size simulation applying analysis approach (e.g., Modified Poisson Regression to estimate RR)

Effect Size (Risk Difference) for 90% power given 20 CHC's randomized ranging ICC and baseline proportion with composite outcome within Control CHCs

	Proportion with Composite Outcome in Control CHCs		
ICC	0.050	0.075	0.100
0.01	**0.069**	**0.079**	**0.087**
0.02	**0.082**	**0.093**	**0.102**
0.03	**0.094**	**0.106**	0.116
0.04	**0.106**	0.118	0.129
0.05	0.116	0.130	0.141

* Assumes 50 patients per cluster

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Constrained Randomization

Balance randomization of clusters to 10 intervention and 10 control

Planned balancing CHC-level covariates:

- Mix of insurance type
- Eligible population size
- Rurality
- Average patient age
- Racial and ethnic diversity of patient population

During UG3: will likely reduce number of planned CHC-level covariates once obtain data from CHCs (i.e., 5 balancing factors for 20 clusters is likely too many)

Primary Outcome Analysis

Estimation: Adjusted Relative Risk comparing intervention to control

Method: Modified Poisson Regression using GEE with independent working correlation and bias-correction for small number of clusters

Pre-specified Adjusted Covariates:

- Constrained Randomization Covariates
- Patient-level age, sex, insurance coverage type, number of pain conditions, mental health diagnoses, Federal Poverty Level, and patient language

Data Sharing

Data sharing plan and obstacles foreseen

- Per OCHIN policy, policy, patient-level datasets, qualitative data, and Epic/Clarity EHR code and variable names will not be shared

Information required by IRB about data sharing beyond the study in order to waive informed consent, if applicable?

- Not applicable, patient-level data sharing not planned

Data planning to share from project

- Aggregate data, qualitative codebooks, and statistical analytic code will be shared with relevant publications or by the end of the project period

Challenges Scorecard

Challenge	Level of Difficulty*					
	NA	1	2	3	4	5
Regulatory issues (e.g., IRBs, consent)		X				
Study design issues (e.g., ICC, power, sample size, confounders)				X		
Using community-centered research methods		X				
Engaging with patient partners to inform the study			X?	X?		
Engaging with clinicians and health systems to identify or recruit participants				X		
Engaging with clinicians and health systems to deliver the intervention		X				
Data access (e.g., approval, privacy, security) and data management planning		X				
EHR integration and/or data extraction, including data management and quality assessment		X				
Collecting prospective data, including PROs				X?	X?	
Optimizing intervention sustainability and planning for sustainment		X				

*Your best guess: 1 = little difficulty; 5 = extreme difficulty

Questions?

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