

Implementation Research

RAMS Scholars, May 2, 2024

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Outline

- Introductions
- Developing an implementation research project
- Optional: dissect a pragmatic implementation trial -- key design issues, lessons learned

Gaps in quality

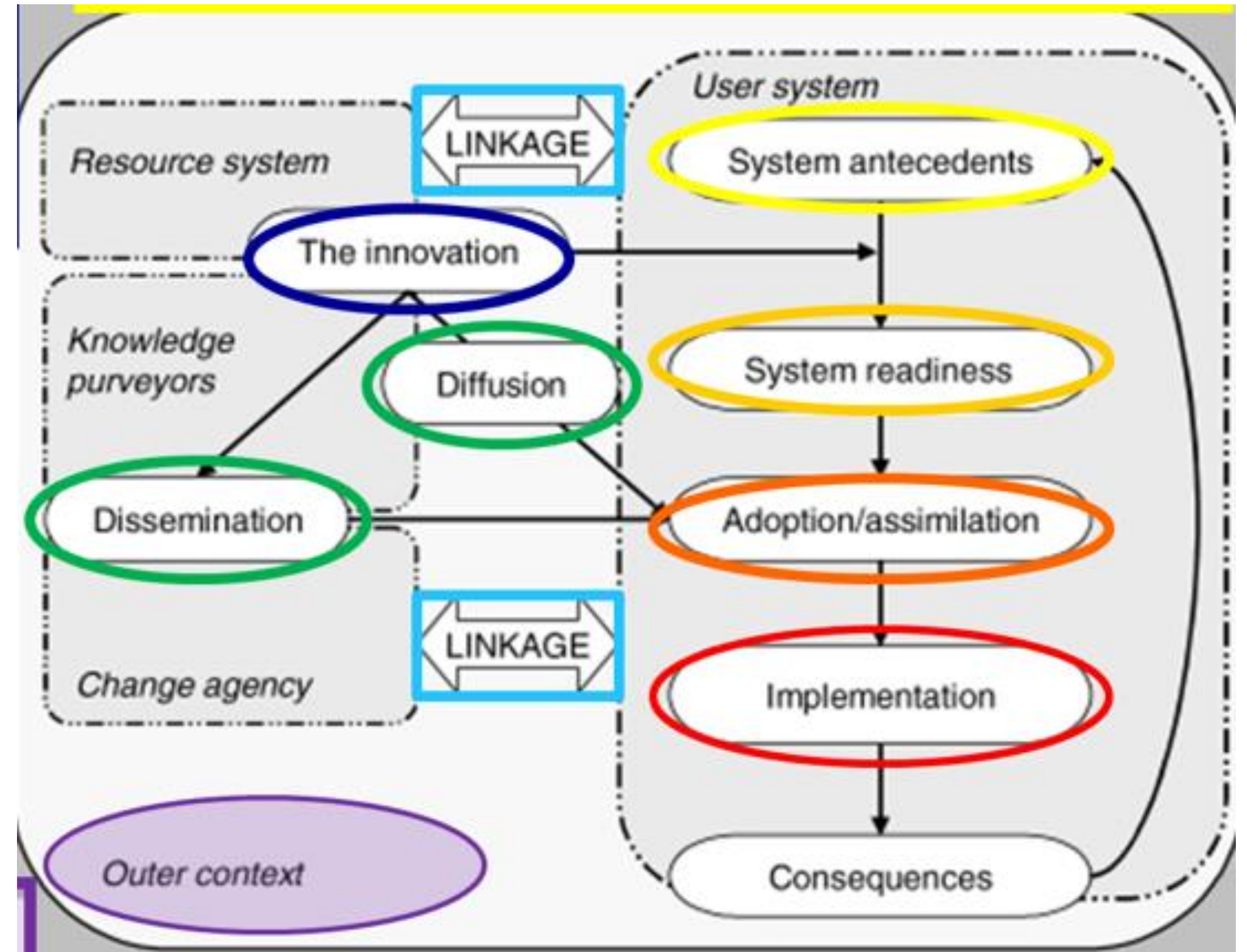
- What is one evidence-based practice that is not widely used that you would like to find a way to implement with your research?

OR

- What is one specific way you'd like to improve the quality of care with your research?

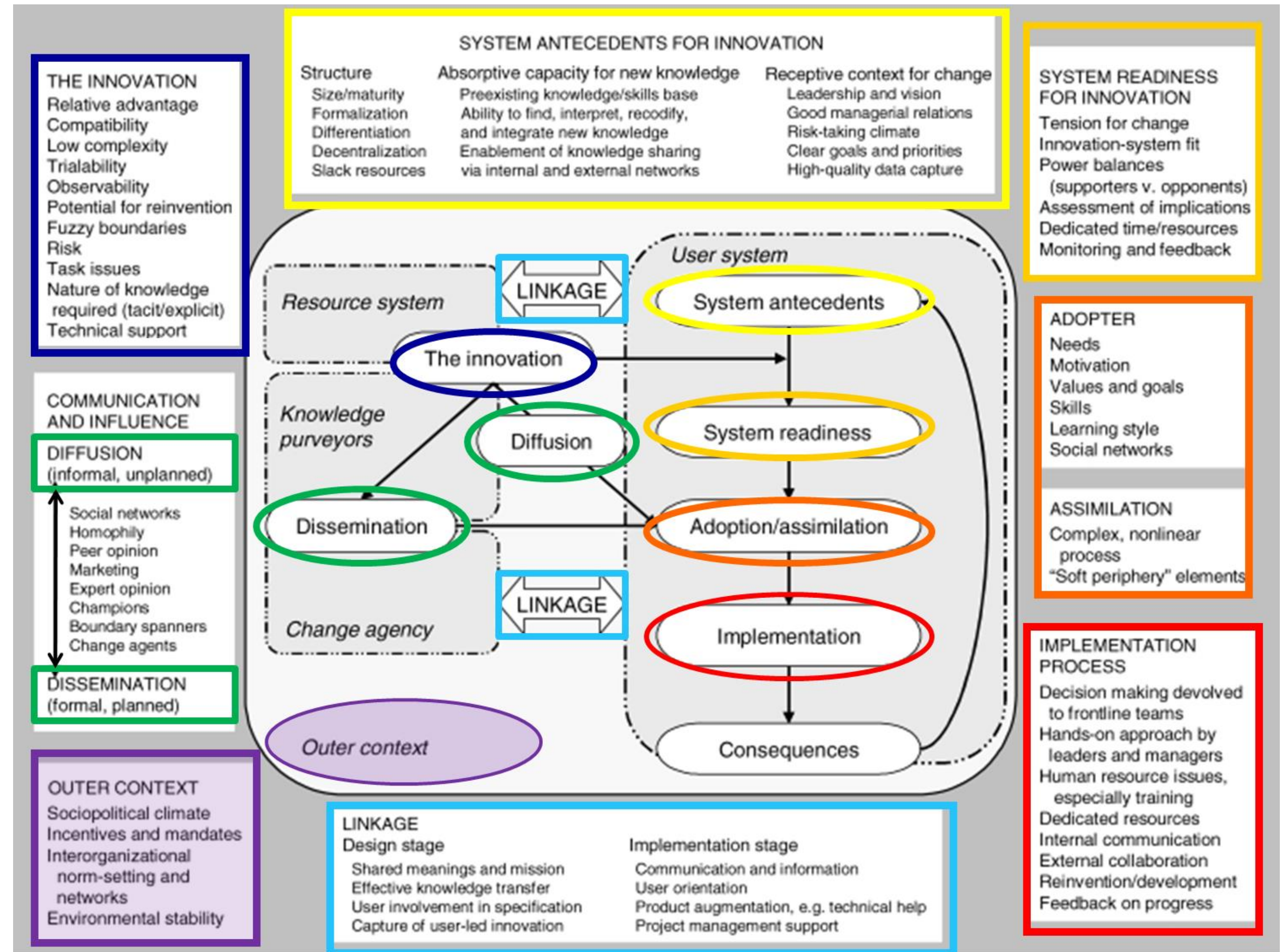
Greenhalgh Model

T. Greenhalgh
Milbank Quarterly
2004



Greenhalgh Model

T. Greenhalgh
Milbank Quarterly
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PRimary care Opioid Use Disorder (PROUD) Trial

Society of Teachers of Family Medicine
Los Angeles, May 5, 2024

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Acknowledgements

- NIDA Clinical Trials Network (CTN) Health Systems Node – UG1 DA040314 (Campbell/Bradley)
- CTN 0074 – PROUD Trial (Bradley/Saxon)
- PROUD Trial Team ...

PROUD Trial Team

- Operations Core: Andy Saxon – Co Lead; Jennifer Bobb, Paige Wartko, Denise Boudreau, Amy Lee, Cynthia Campbell, Megan Addis, Andrea Altschuler, Colleen LaBelle, Jeffrey Samet, David Liu, Jennifer McCormack, Abigail Matthews
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- Protocol Investigators: Jennifer McNeely, Gavin Bart, Robert Schwartz, Jane Liebschutz, Joseph Merrill
- Emmes: Dikla Blumberg, Julia Collins

PROUD Trial Background

Question:

If you had to test an intervention to increase OUD treatment in primary care how would you decide what to test?

The Opioid Epidemic Persists

PROUD Trial Background

Two medications for OUD prescribed in PC

- Buprenorphine & long-acting naltrexone
- Effective & save lives
- Long-term treatment recommended
- Can be provided in primary care

< 8% of PC providers prescribe buprenorphine

PROUD Trial Background

- Massachusetts Model of office-based addiction treatment (OBAT)
- Promising model for increasing OUD treatment in PC
- Nurse care managers share and support care for OUD
- Case series in Massachusetts
 - ✓ ~100 patients per nurse (1-2 new/week)
 - ✓ 70% new to the PC clinic

Question:

What is the optimal sample for an intervention that attracts NEW patients into primary care?

PROUD Trial Background

What was not known was whether OBAT

- Increased access to OUD treatment more broadly
- Increased quality of OUD care
- Improved patient outcomes

PROUD Trial Objectives

To evaluate whether implementation of the Massachusetts (MA) Model

1. Increased OUD treatment, compared to Usual PC, over 2 years follow-up (primary)
2. Decreased acute care utilization among PC patients with recognized OUD

Secondary Objectives

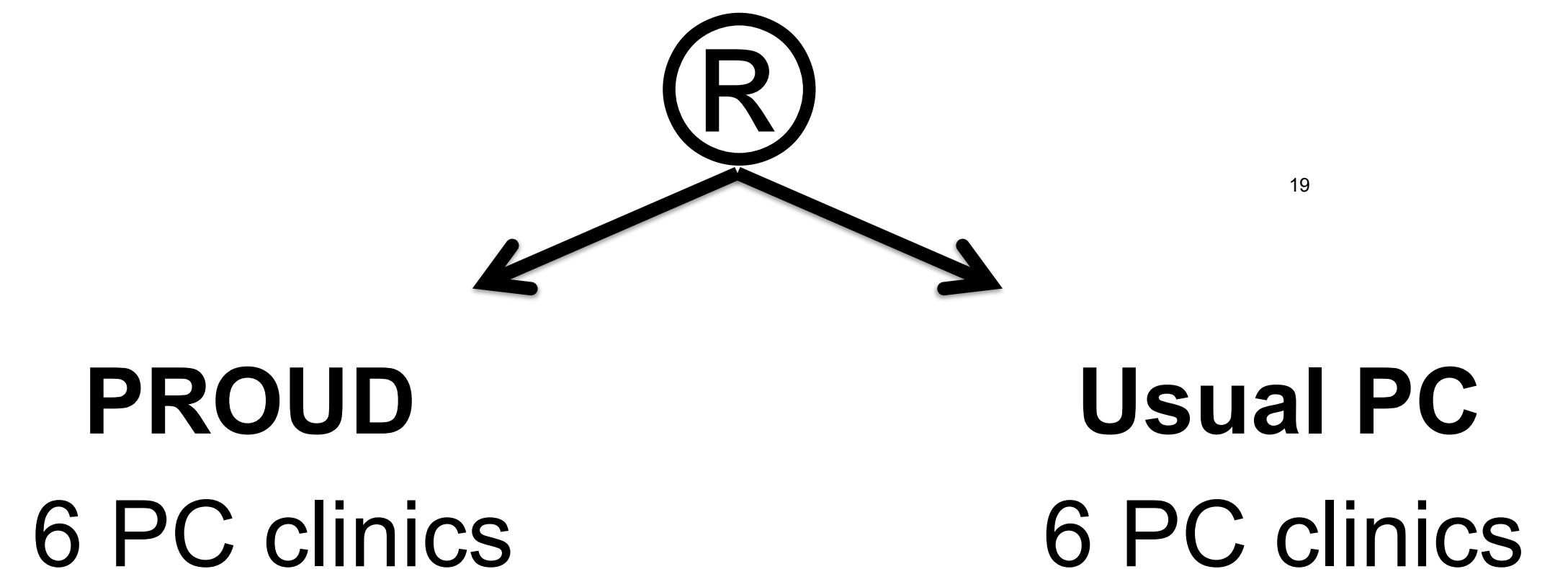
- A. To evaluate whether the effect of the intervention on treatment differed across patient sex, race or ethnicity
- B. To evaluate whether the intervention increased OUD treatment over 3 years follow-up
- C. To evaluate whether the intervention increased the duration of treatment

Methods

Design

- Pragmatic cluster-randomized trial (Hybrid Type III)
- 6 health systems (12 clinics)
- PC clinic randomization 1:1
 - ✓ Stratified within health systems
- All quantitative data were secondary
 - ✓ Electronic health records
 - ✓ Insurance claims

6 Health Care Systems each
with 2 Primary Care (PC) Clinics



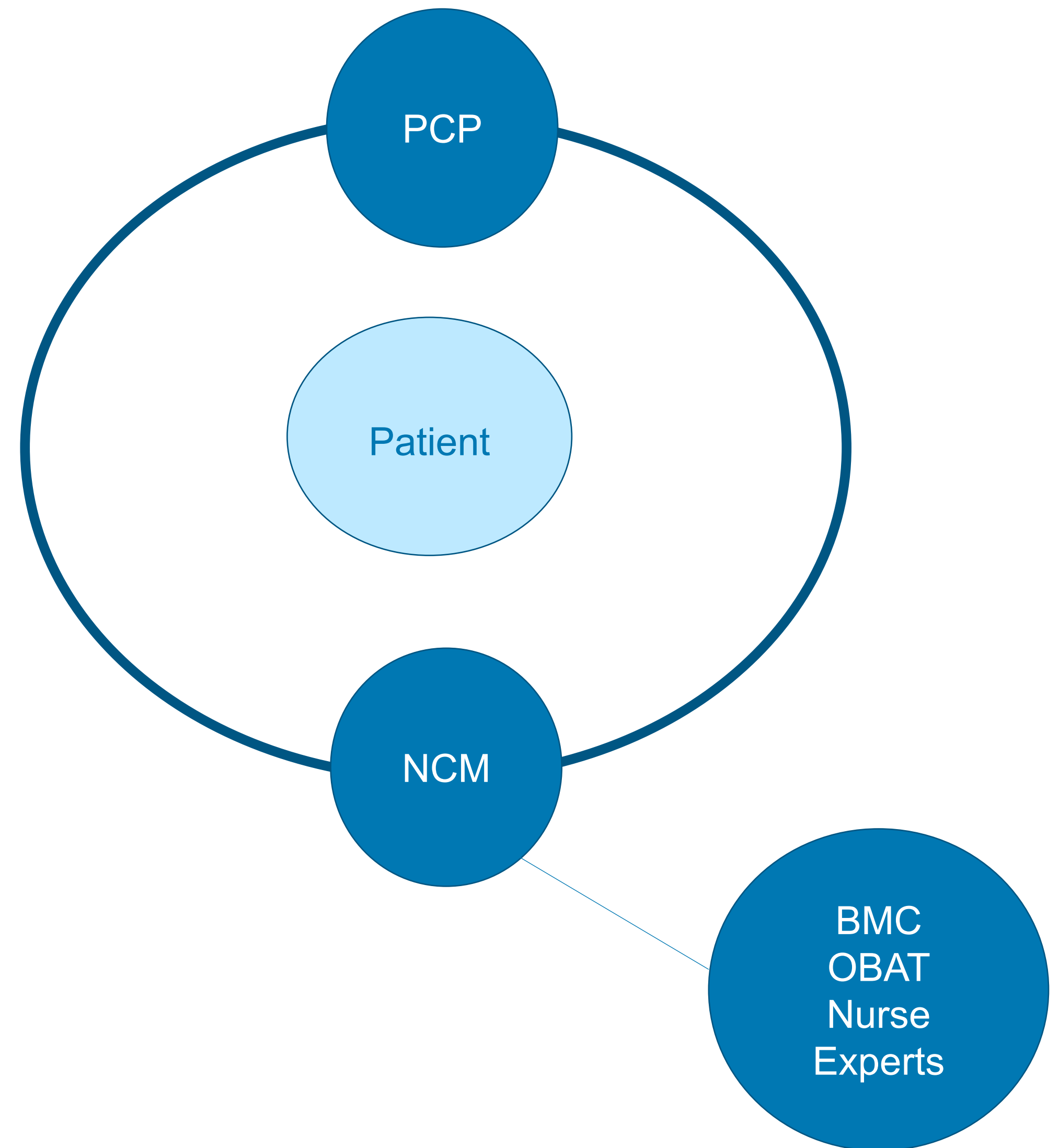
Question:

What biases could be created by this design?

Intervention

Implementation intervention:

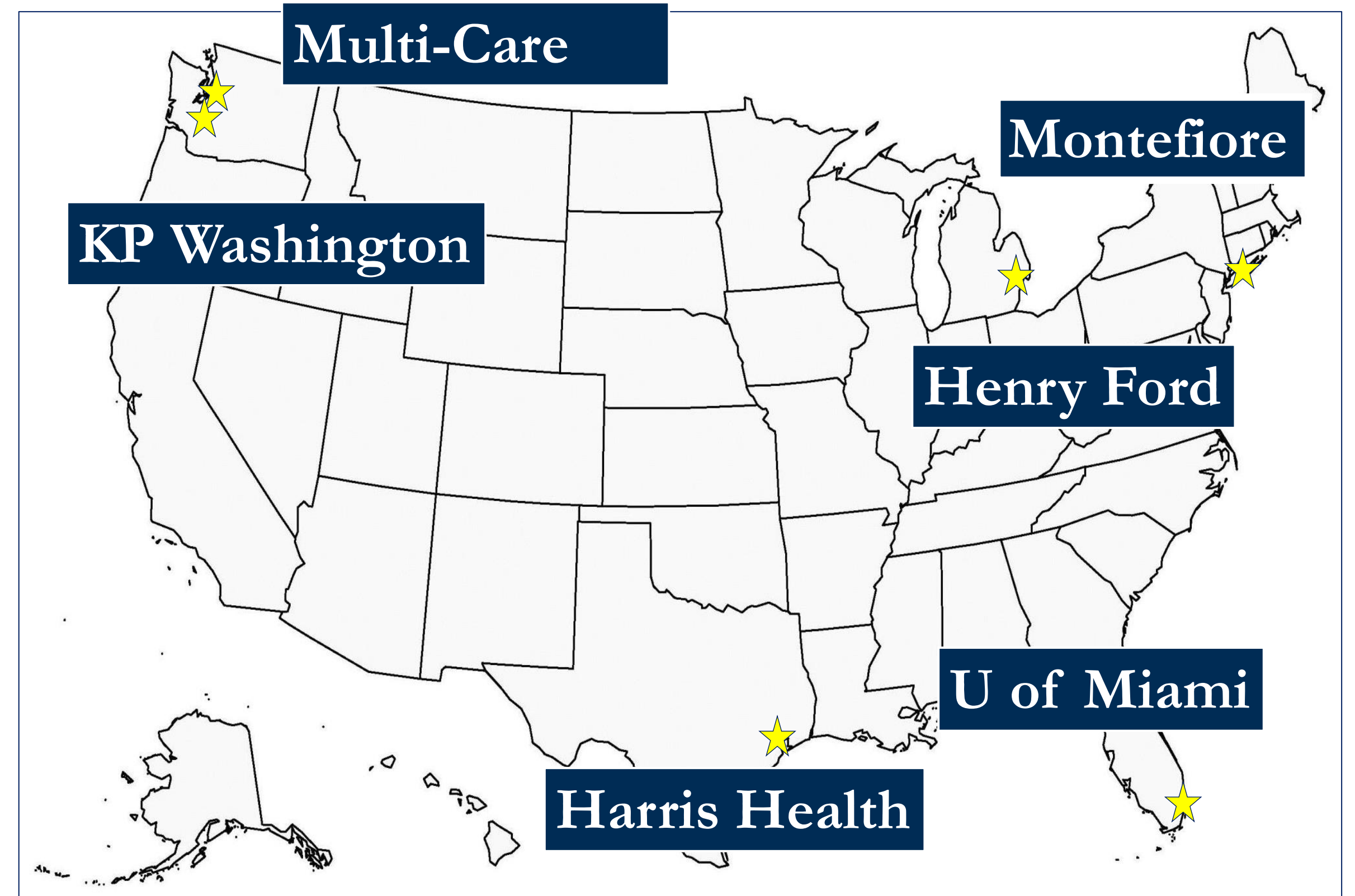
1. Funding for full-time nurse hired by the health system to implement MA model
2. Experts at Boston University: training & technical assistance
3. Three physicians agreed to prescribe buprenorphine in each clinic



Sample

PC patients

- ≥ 1 visit(s) to trial PC clinics:
 - ✓ 3 years pre-R and/or
 - ✓ 2 years post-R (3 years, secondary outcomes)
- 16-90 years old initial visit



Primary Outcome

Days of OUD treatment

- EHR orders or procedure codes for buprenorphine or XR-naltrexone
- Measured per 10,000 PC patients seen in the 2 years post-
- Reported as patient-years of OUD treatment
- Reflects both access and duration

Question:

What are the limitations and strengths of this outcome?

Primary Analyses

- Intention to treat at the clinic level (n=12)
- Estimated the mean difference in outcomes between PROUD and Usual Care clinics
- Linear mixed effect model adjusted for the baseline value of the outcome in the clinics
- One-sided hypothesis test ($\alpha = 0.05$)

Secondary Analyses

- Pre-planned analyses designed to assess access (new initiation)
- Differences across sex and race or ethnicity
- Qualitative results from Implementation Monitoring Team
- Results after 3 years
- Acute care utilization assessed in patients with documented OUD (secondary effectiveness outcome)

Results

Baseline Clinic Characteristics

	PROUD	Usual Care
PC patients/trial arm	130,623	159,459
	Clinic Mean	
# PC patients/clinic	18,485	22,557
# PCPs	31.7	36.8
# PC BUP prescribers	1.5	1.5

Baseline Clinic Characteristics

	PROUD	Usual Care
	Clinic Mean	
Medicare	21.1	18.3
Medicaid	27.7	35.7
Other insurance	57.7	53.1

Baseline Clinic Characteristics

	PROUD	Usual Care
	Clinic Mean	
Age	48.8	46.7
% Women	59.3	64.0
% Hispanic	26.4	33.4
% Black (non-Hispanic)	18.5	18.9
% White (non-Hispanic)	41.3	31.6
% Asian	5.2	5.0

Baseline Clinic Characteristics

	PROUD	Usual Care
	Clinic Mean	

Baseline patient-years of OUD treatment per 10,000 PC patients	6.8 (5.50)	10.6 (7.42)
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Question:

Why didn't randomization balance the value of this measure at baseline across trial arms?

Primary Outcome:

Patient-years of OUD treatment per 10,000 PC patients seen post-randomization

PROUD > Usual Care	
Mean Difference*	P
8.2	0.002

* Adjusted for baseline value of the outcome

How to interpret this outcome?

Interpreting Patient-Years of OUD Treatment Per 10,000 Patients

- Each nurse manages 8.2 patients for a year per 10,000 patients (mean)
 - Clinics have ~20,000 patients
 - So mean of 16.4 patients per clinic
 - If patients retained 6 months on average...
- PROUD clinics treated ~ 32.8 patients more than usual care on average

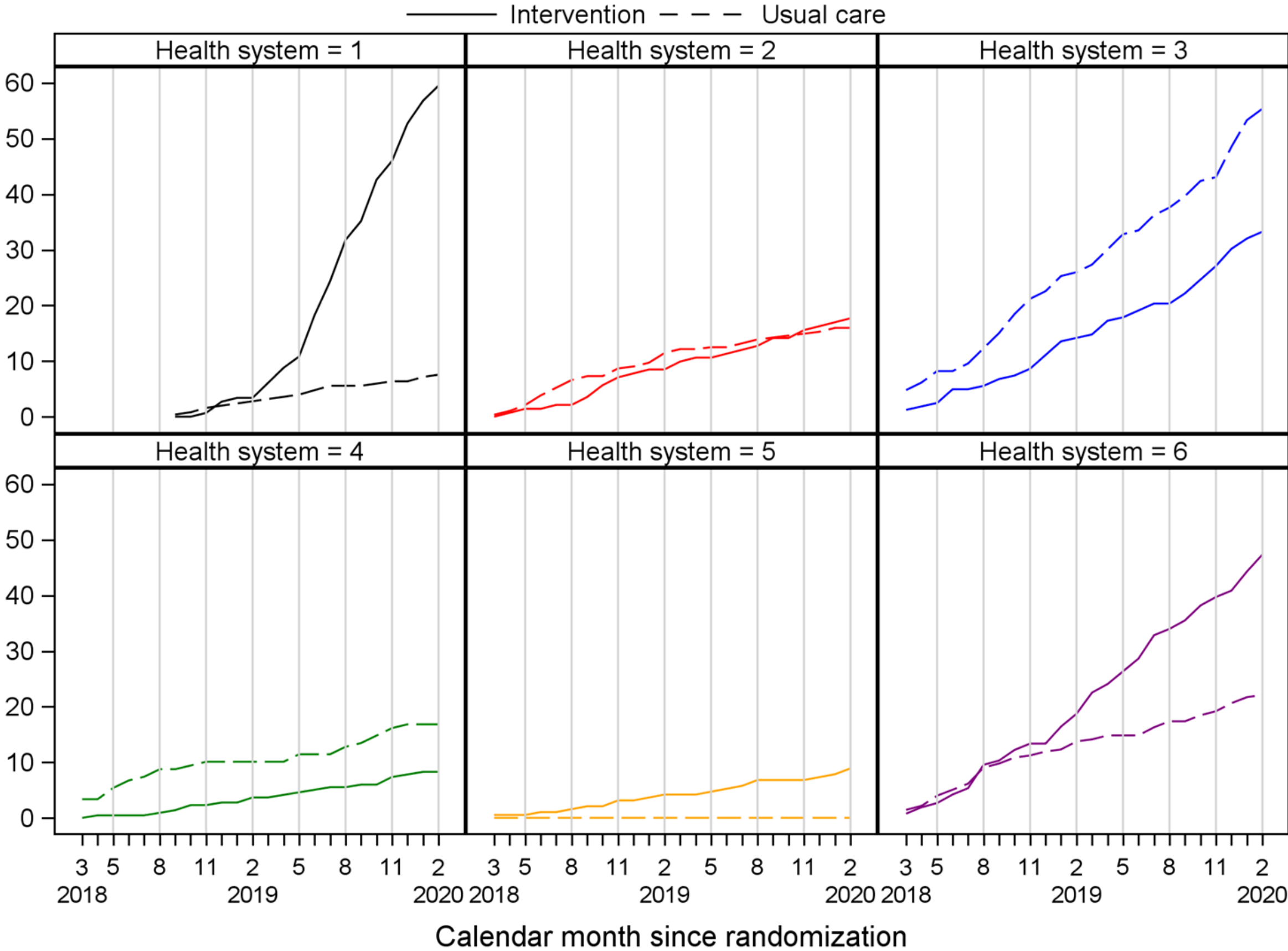
Primary and Secondary Implementation Outcomes

Patient-years of OUD treatment per 10,000 PC patients seen post-randomization		
	PROUD > Usual Care	
	Mean	
	Difference	P
2 years follow-up (primary)	8.2	0.002
Newly initiated post-randomization	8.3	
New to clinic post-randomization	5.8	

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Year 2 Difference Across Sites

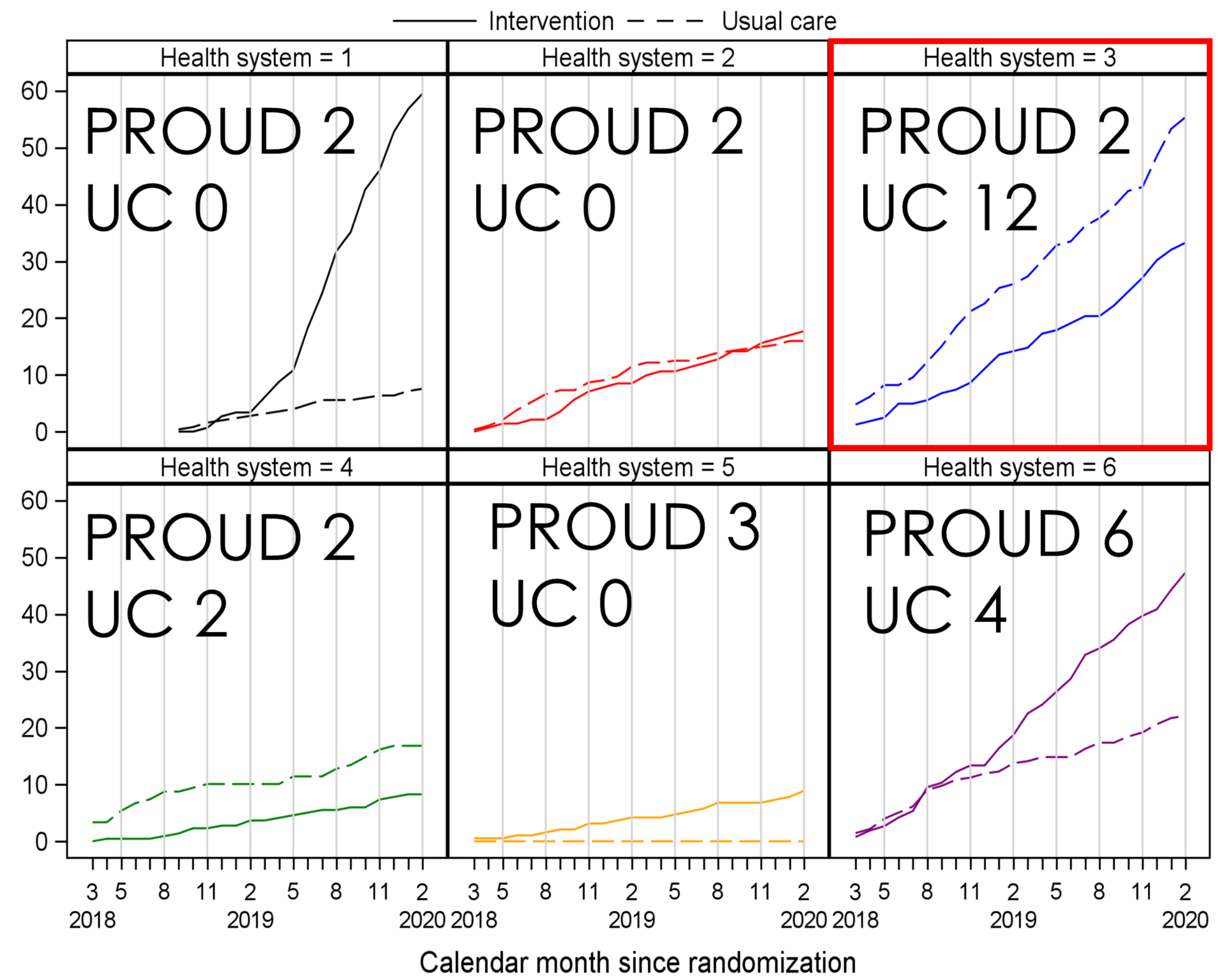
Cumulative Number of
Patients Treated



Question:

What do you think could have caused this? How could we know?

Number of PC Buprenorphine Prescribers in the 2 Years Post-randomization



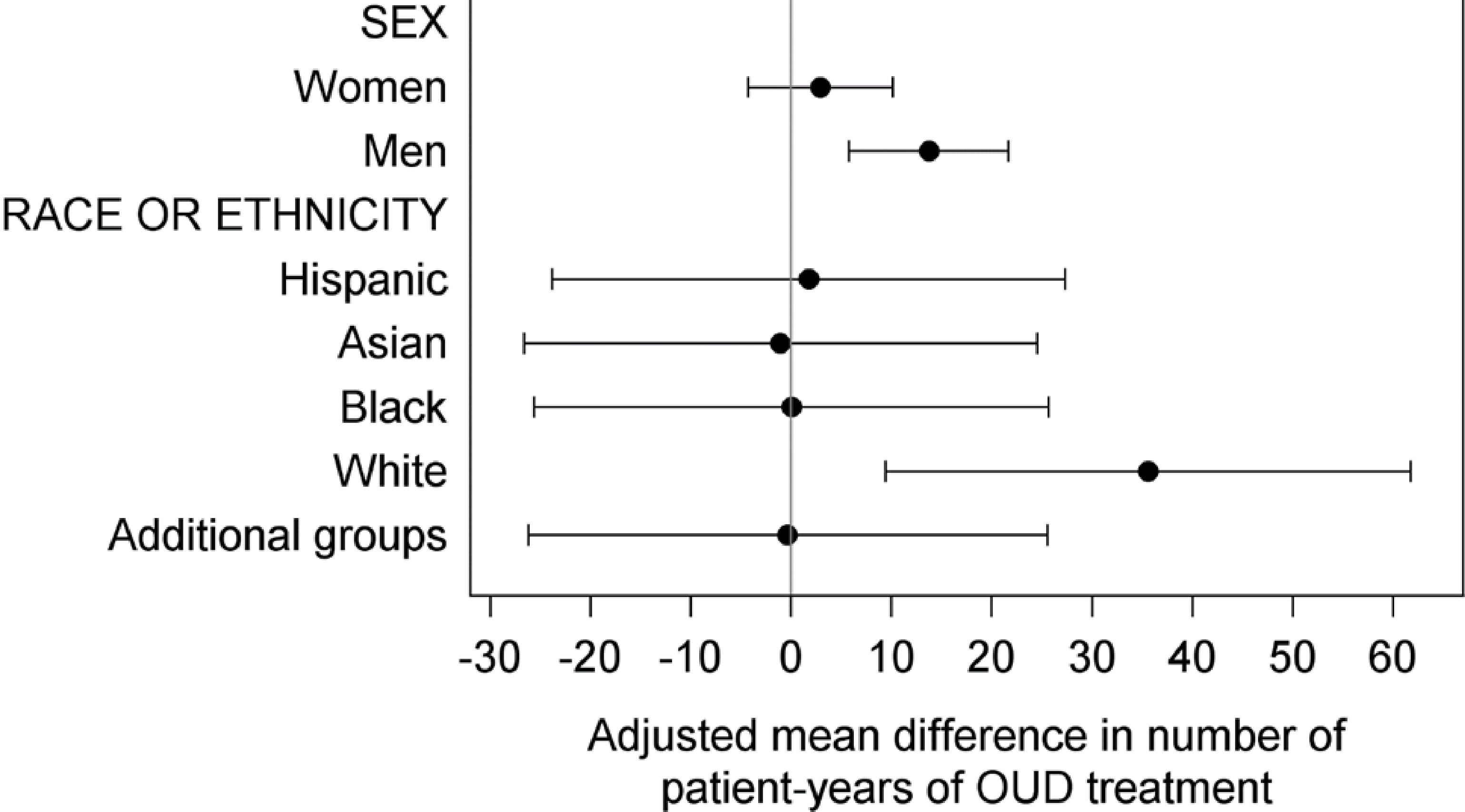
Factors Associated with Success

- Health system staff wanted to treat OUD
 - ✓ Primary care providers
 - ✓ Leaders at all levels of the organization
 - ✓ Nursing peers and leadership
- Easy access/ referral pathways to nurse
- Coverage for OUD treatment in PC
 - ✓ Health system
 - ✓ Payers, and/or
 - ✓ State

Question:

How would you evaluate quality across sex, and race or ethnicity?

**Primary
Implementation
Outcome
Across
Sex, Race or
Ethnicity**



Secondary Effectiveness Outcome

- No decrease in acute care utilization in 2 years follow-up among patients with OUD documented pre-randomization
- No decrease in acute care utilization in any subgroup of patients with OUD documented

Year 3
Primary
Outcome

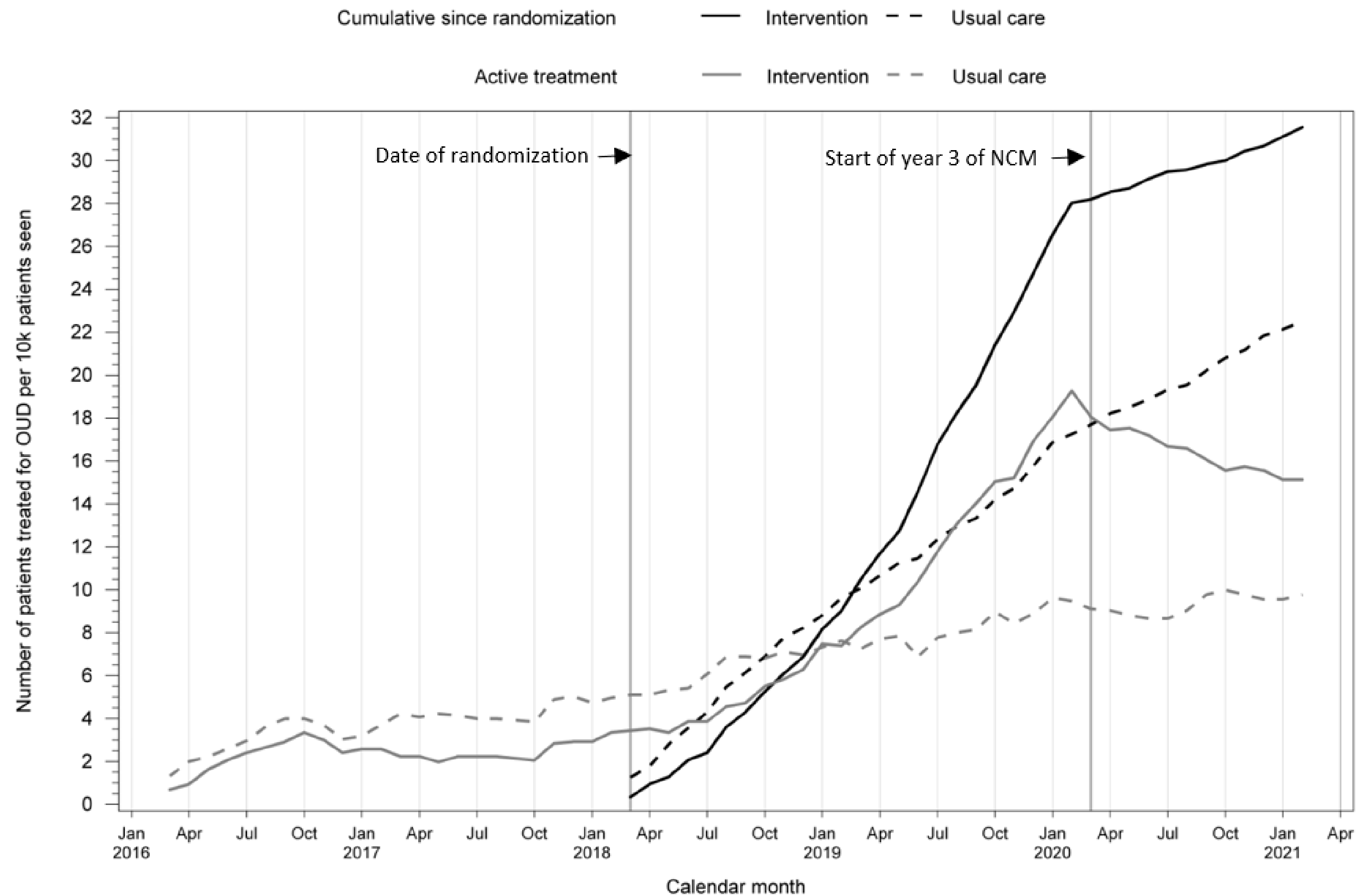
Patient-years of OUD treatment per 10,000
PC patients seen post-randomization

	PROUD > Usual Care	
	Mean Diff.	P
2 years follow-up (primary)	8.2	0.002
3 years follow-up	19.7	(11.1, 28.4)

* Adjusted for baseline value of the outcome

Year 3

- 3 systems increased primary outcome
- 4 health systems increased newly initiated treatment



Summary

Limitations

- Secondary data
 - ✓ EHR orders not the gold standard
 - ✓ OUD treatment and acute care outside the health systems not captured
- The Year 2 increase in OUD treatment was ...
 - ✓ Among patients with newly initiated treatment
 - ✓ 71% new to the PC clinic
 - ✓ Results driven by 2 health systems
 - ✓ No decrease in acute care utilization
 - ✓ May be early to observe full benefit
- The Year 3 increase in OUD treatment was ...
 - ✓ Impacted by COVID
 - ✓ Unable to capture care received by new patients

Strengths

- Tested promising model in diverse systems
- Information on pace of implementation
- Different types of health systems
- Sample: racially and ethnically diverse
- Extensive secondary analyses
- Contextual information from implementation monitoring

Implications

1. OBAT by a nurse meaningfully increases OUD treatment in primary care
2. Early benefits among patients newly initiating treatment
3. Continued increases in benefits Year 3
4. Not uniform improvement across sites, sex or race and ethnicity

Thank You!

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Comments?
Questions?



PROUD Trial Team

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