



PRimary care Opioid Use Disorder (PROUD) Trial

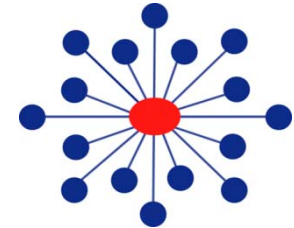
CSAT-NIDA CTN Webinar October 19th, 2016

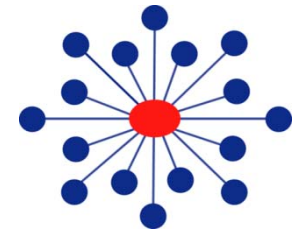
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Research Associate VA Puget Sound HSR&D





Overview The PROUD Trial

Increasing Access to High Quality
Medication Treatment for OUD
in Primary Care

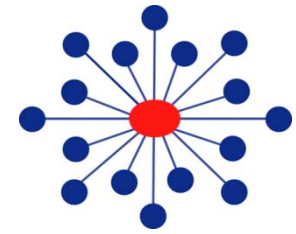


PROUD Trial Design

Protocol Development

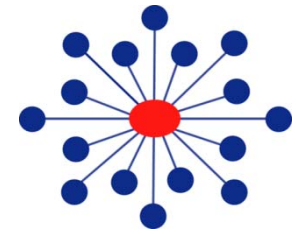
Betty Tai
John Rush
Andy Saxon
Denise Boudreau
Jeffrey Samet
Cynthia Campbell
Gwen Lapham
Jennifer Bobb
Gavin Bart
Robert Schwartz

Coleen Labelle
Jennifer McNeely
Jane Leibschutz
Abby Wright
Jennifer Bobb
Jennifer McCormack
Zoe Weinstein
Joe Merrill
Judy Tsui
Allison Lin

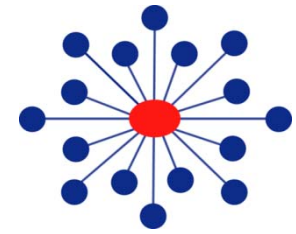




Overview My Presentation



1. Background
2. Design of the PROUD Trial
3. PROUD Phase 1

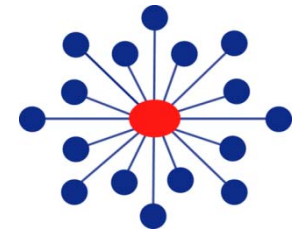


Part 1

Background



Background



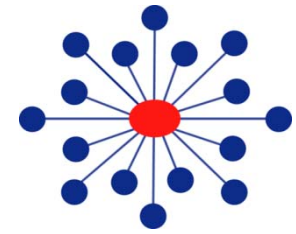
- Opioid epidemic
- Need to increase treatment for OUD
- Effective medications for OUDs
 - ✓ Methadone
 - ✓ Buprenorphine
 - ✓ Injectable naltrexone
- Persistence for 12 mo. improves outcomes

Mattick Cochrane Database 2008, 2009.

Lo-ciganic, Addiction 2016



Background



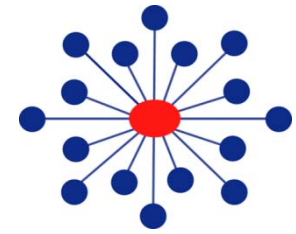
Gaps in care

- 85% no treatment
- Only 15% receive treatment
- ~ 21% still on meds at 12 months
- ~ 3% receive persistent treatment

Becker DAD 2008; Lo-ciganic, Addiction 2016



Background

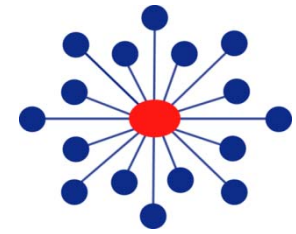


High quality OUD treatment will

1. Attracts those with OUDs into treatment
2. Treats OUDs with medications
3. Keep patients on medications 12 mo.
4. Improves health outcomes



Background

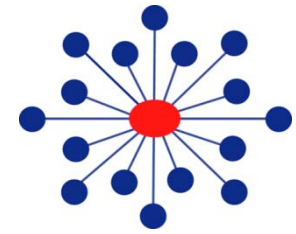


Barriers...

1. Stigma keeps people with OUDs hidden
2. Barriers to buprenorphine prescribing
 - ✓ Time
 - ✓ Complexity
3. Health Systems believe current treatment is adequate – no one is asking for more!

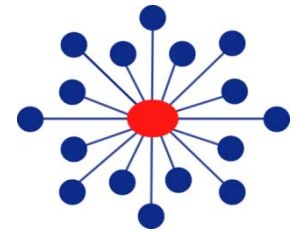


Background



Efforts to date:

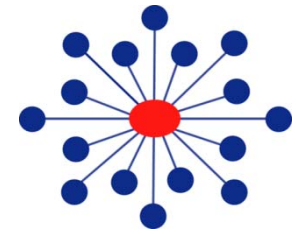
- Education-based: buprenorphine
- Increase waived MDs
 - ✓ Most do not prescribe
 - ✓ Low rates of persistence at 12 months (21%)
- Implementation strategies for primary care (PC)
 - ✓ Collaborative care – “Massachusetts model”
 - ✓ 11 other models



Massachusetts (MA) Model



Massachusetts (MA) Model



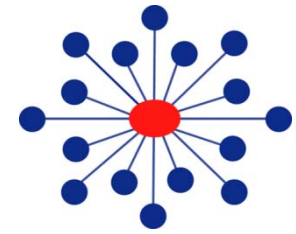
Components

- Nurse care manager: 100 patients
- Nurse does all but diagnose & prescribe
- MDs: diagnosis and prescribe
- Technical assistance/training
- Public reporting

Alford Arch Intern Med 2011; LaBelle JSAT 2016; Clark Health Affairs 2015



Massachusetts Model



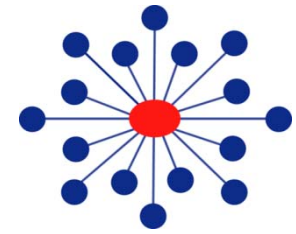
Effects to Date

- 70-93% of patients NEW
 - ✓ “Build it and they will come”
- Most evidence
 - ✓ Only model with high rates of persistence
- 50-67% engaged at 12 months
- Mostly public financing and FQHCs
 - ✓ 53% of people with OUDs: private insurance



Part 2

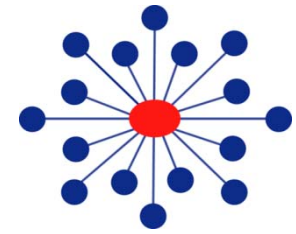
The PROUD Trial



A cluster randomized, pragmatic
comparative-effectiveness trial
of Massachusetts Model
vs Usual Primary Care



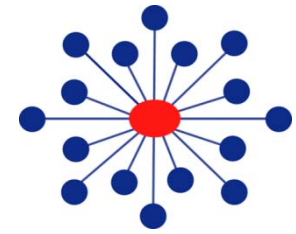
PROUD Trial – Research Question



Does the MA Model—when compared to Usual PC—increase the number of days of medication treatment for OUDs per 10,000 patients at least 2 fold?



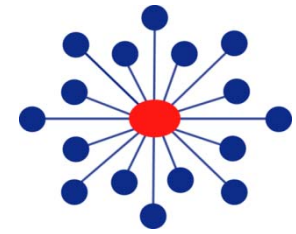
PROUD Trial – Secondary Aims



1. Does the MA Model—when compared to Usual PC—increase the proportion of primary care patients who:
 - a. Are diagnosed with OUDs?
 - b. Receive medications for OUDs?
 - c. Receive high quality OUD treatment
 - ✓ Persistent for 12 months?



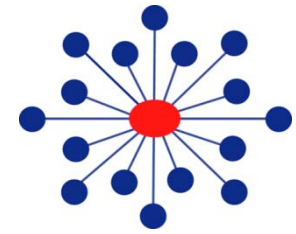
PROUD Trial – Secondary Aims (continued)



2. Does the MA Model—when compared to Usual PC—decrease the proportion of PC patients with OUDs who use acute care services in the following year?
 - ✓ Urgent care
 - ✓ Emergency department care
 - ✓ Hospital care



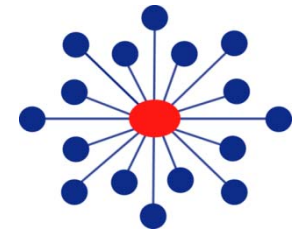
Overview of PROUD Design



- Hybrid Type II
 - ✓ Effectiveness-implementation trial
- Pragmatic cluster randomized (®) trial
- Setting: large health care systems
- Data – all secondary
 - ✓ EHRs → sample, diagnoses, medications
 - ✓ Claims data: pharmacy, ICDs, utilization
 - ✓ Death data (later)



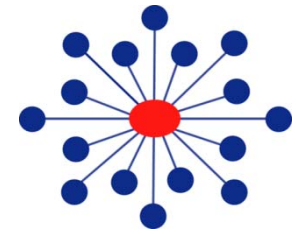
Overview of PROUD Design



- Data – all secondary
 - ✓ EHRs → sample, diagnoses, medications
 - ✓ Claims data: pharmacy, ICDs, utilization
 - ✓ Death data (later)
- Waivers
 - ✓ Informed consent
 - ✓ HIPAA waiver
- 42CFR does not apply: data de-identified
 - ✓ Dates & zip codes not identifiers in 42CFR



Overview of PROUD Design



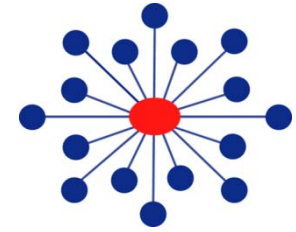
- Six health care (HC) systems
- 2 primary care clinics each (12 total)
- > 10, 000 patients each
- Stratified randomization (within HC system)



Overview of PROUD Design



~ 6 Health Care Systems
2 Primary care clinics each



MA Model

6 PC clinics

>60,000 pts

> 540 w/ OUD

Usual PC

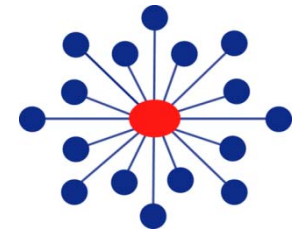
6 PC clinics

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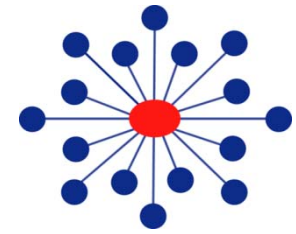
PROUD Trial: Implementing the MA Model



- NIDA funds RN care manager
- HC system implements MA model
- Study provides technical assistance



Overview of PROUD Design

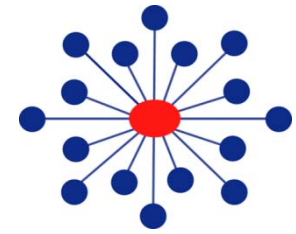


Primary sample:

- All patients who visit the PC clinics in the 6-18 months after randomization



Overview of PROUD Design



Primary outcome

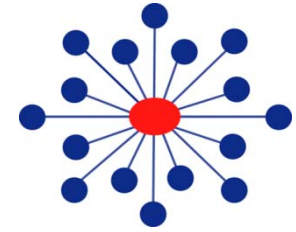
- # days OUD medication treatment/10,000 pts

Secondary outcomes

- OUD diagnoses
- OUD treatment
- Persistent treatment 12 months
- Acute care



PROUD Timeline Overview

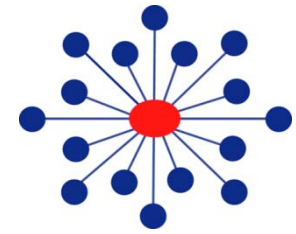


Trial starts here





PROUD Timeline Overview



Trial starts here

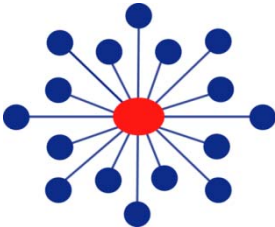


Look back:
24 mo.
covariates





PROUD Timeline Overview

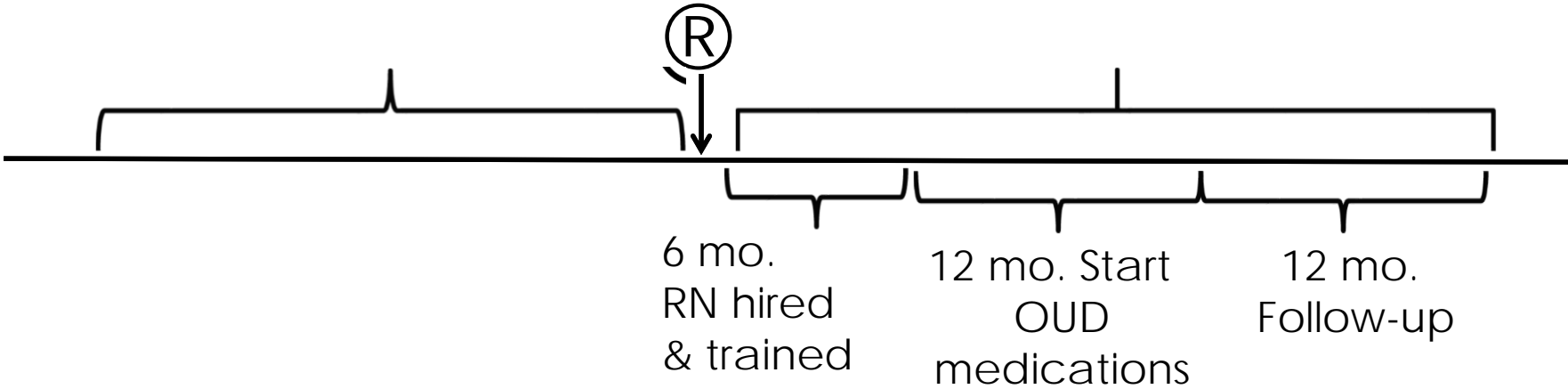


Trial starts here



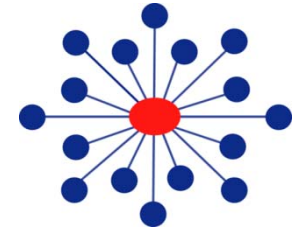
Look back:
24 mos.
covariates

Outcomes
EHR/claims data





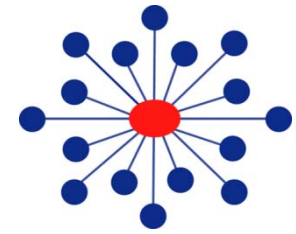
PROUD Innovations



- Pragmatic implementation trial
 - ✓ Sample generalizable
 - ✓ Diverse health systems
 - ✓ All data from EHRs



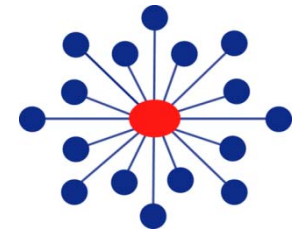
PROUD Innovations



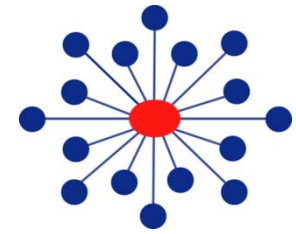
- Primary outcome reflects both:
 - ✓ Access (# of patients treated)
 - ✓ Quality (persistence of treatment)
- Secondary outcome, persistent OUD treatment:
 - predicts health outcomes
- Evaluate OUD in insured population



Secondary Grants?



1. What are the barriers and facilitators to improving outcomes with the MA model in large integrated health care systems or health insurance plans
2. Cost-effectiveness of MA model or the “business case” for payers



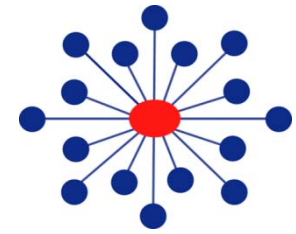
Part 3

PROUD - Phase 1

Preparing for the Trial



PROUD Phase 1 Goals



- Demonstrate ability to extract data on:
 - ✓ Sample
 - ✓ Outcomes
 - ✓ Covariates
- Obtain data for
 - ✓ Statistical power simulations
 - ✓ Selecting clinics
- Understand barriers and facilitators
- Identify and engage willing HCs



Participating Healthcare Systems



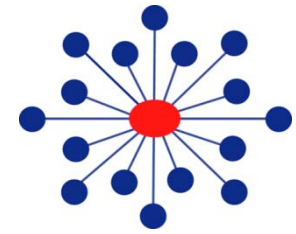
PROUD Phase 1 Healthcare Systems

Group Health (lead site)	Kaiser Permanente Northwest
Harris Health System	Kaiser Permanente S. California
HealthPartners	Montefiore
Henry Ford Health System	MultiCare Health System
Kaiser Permanente Colorado	U Miami Health System
Kaiser Permanente N. California	





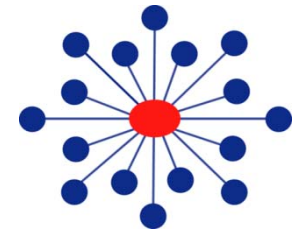
Phase 1



Summer 2016

- Phase 1 Protocol
- 11 HC systems selected
- Group Health IRB – other sites code
- Data Sharing Agreement drafted
- Data specifications

→ Phase 1

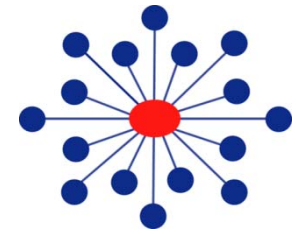


Fall 2016 – Seattle

- Subcontracts with 11 sites
- Data extraction and programming
- Design Phase 2 implementation
- Engage sites – weekly meetings
- Bi-weekly meetings support sites
 - ✓ Two sets: programmers and site PIs/PMs



Phase 1

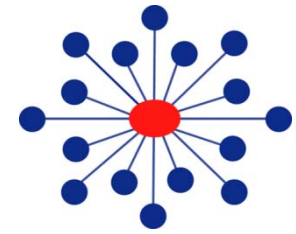


Winter 2017

- Data collection and analyses
- Letters of support
- Select sites



Phase 1

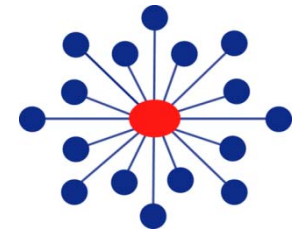


Spring 2017

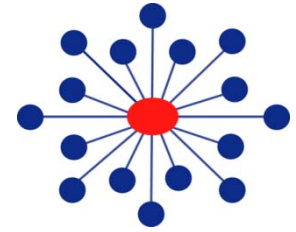
- Engage health care systems for trial
- IRB for trial
- DUAs for trial
- Subcontracts done
- Randomization early summer



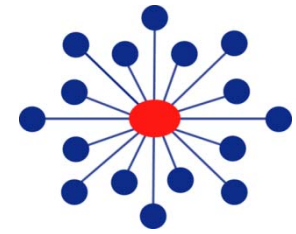
Conclusion



- Innovative pragmatic trial
- Evaluate the MA model
 - ✓ Increase access & quality?
- Rapid launch
 - ✓ Designed April → launched September
 - ✓ Phase 1 – selects 6 HC systems
 - ✓ Phase 2 – starts June



Thank You!



Questions?
Comments?
Discussion?