The CLARO Clinical Trial:

Implementing Collaborative Care for opioid use disorders with co-occurring depression and/or PTSD in low-resource settings

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collaboration leading to addiction treatment and recovery from other stresses

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Overview

- What is the Collaborative Care Model (CoCM)?
- What is CLARO?
- How did CLARO operationalize and implement CoCM for co-occurring disorders?
- How might decisions about how we operationalized the model be related to the implementation outcomes of adoption, reach, and fidelity?

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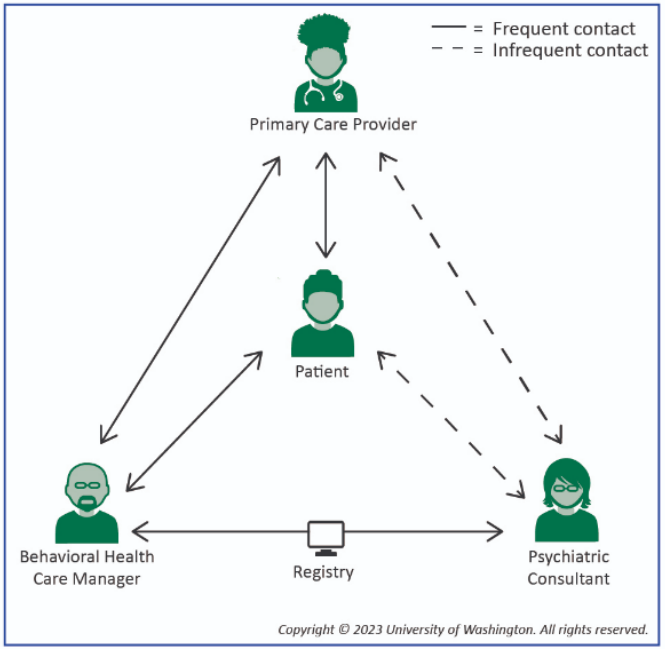
What is the Collaborative Care Model (CoCM)?



https://www.youtube.com/watch?v=zXZTgq3GyPw

What are the core features of the CoCM?

The CoCM changes the structure of primary care

- Adds a **Care manager** and **psychiatric consultant** to the primary care provider

  ➡ **Team-based** behavioral health care

- Adds a **clinical registry** to support the delivery of **population**- and **measurement-based** care

The CoCM can support the delivery of any combination of evidence-based clinical interventions. The specific choice of which clinical interventions is up to the clinic/health system

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- CLARO is a randomized controlled trial testing whether Collaborative Care can improve the quality of care provided to patients with co-occurring mental illness (depression and/or PTSD) and opioid use disorders, → improved outcomes

- The CLARO project is a collaboration between RAND and 5 healthcare systems in NM and CA

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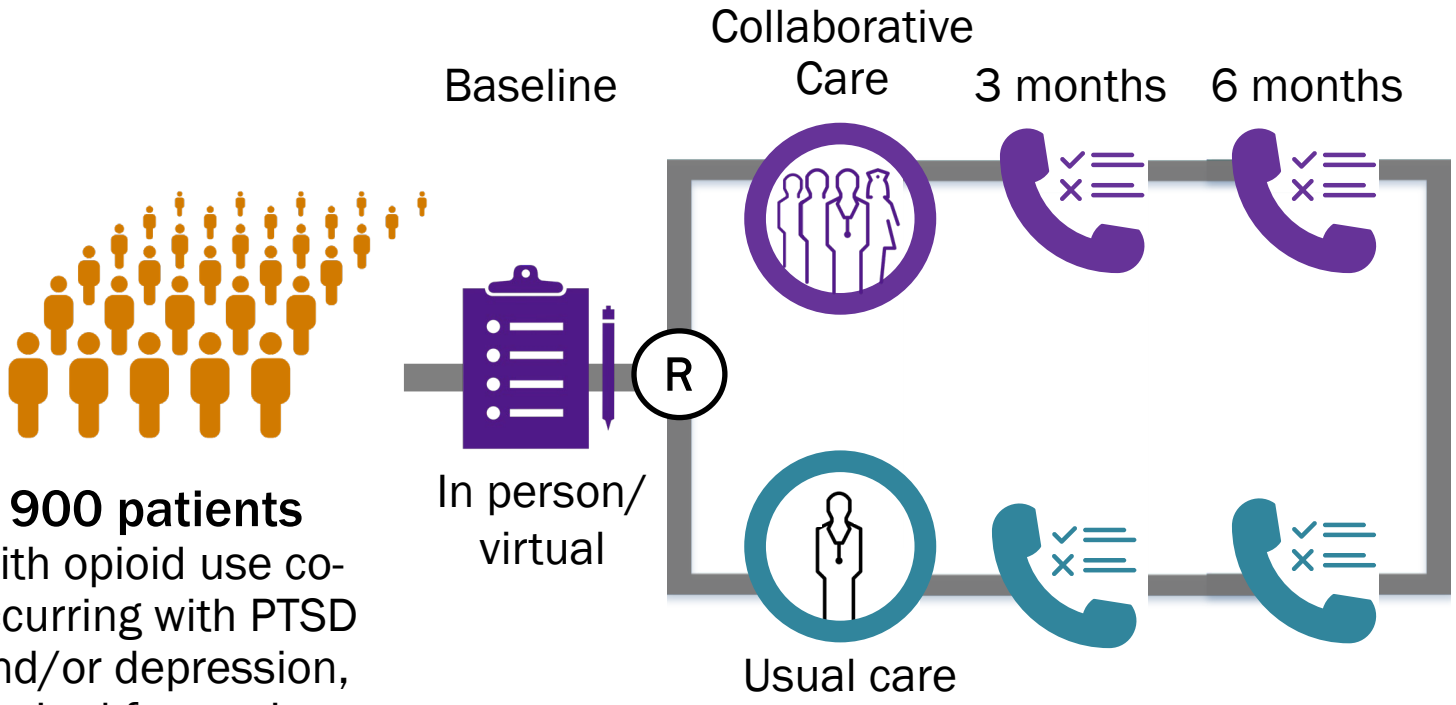
CLARO study design



900 patients
with opioid use co-occurring with PTSD and/or depression, recruited from primary care

What data is CLARO collecting?

- Patient interviews at baseline, 3 and 6 months
- Data from the electronic health record on patient visits and medications prescribed
- Data from the Prescription Monitoring Program (PMP) on buprenorphine prescriptions
- Data from the clinical registry used by the care coordinators
- Provider surveys and interviews
- Minutes from monthly meetings with each health system

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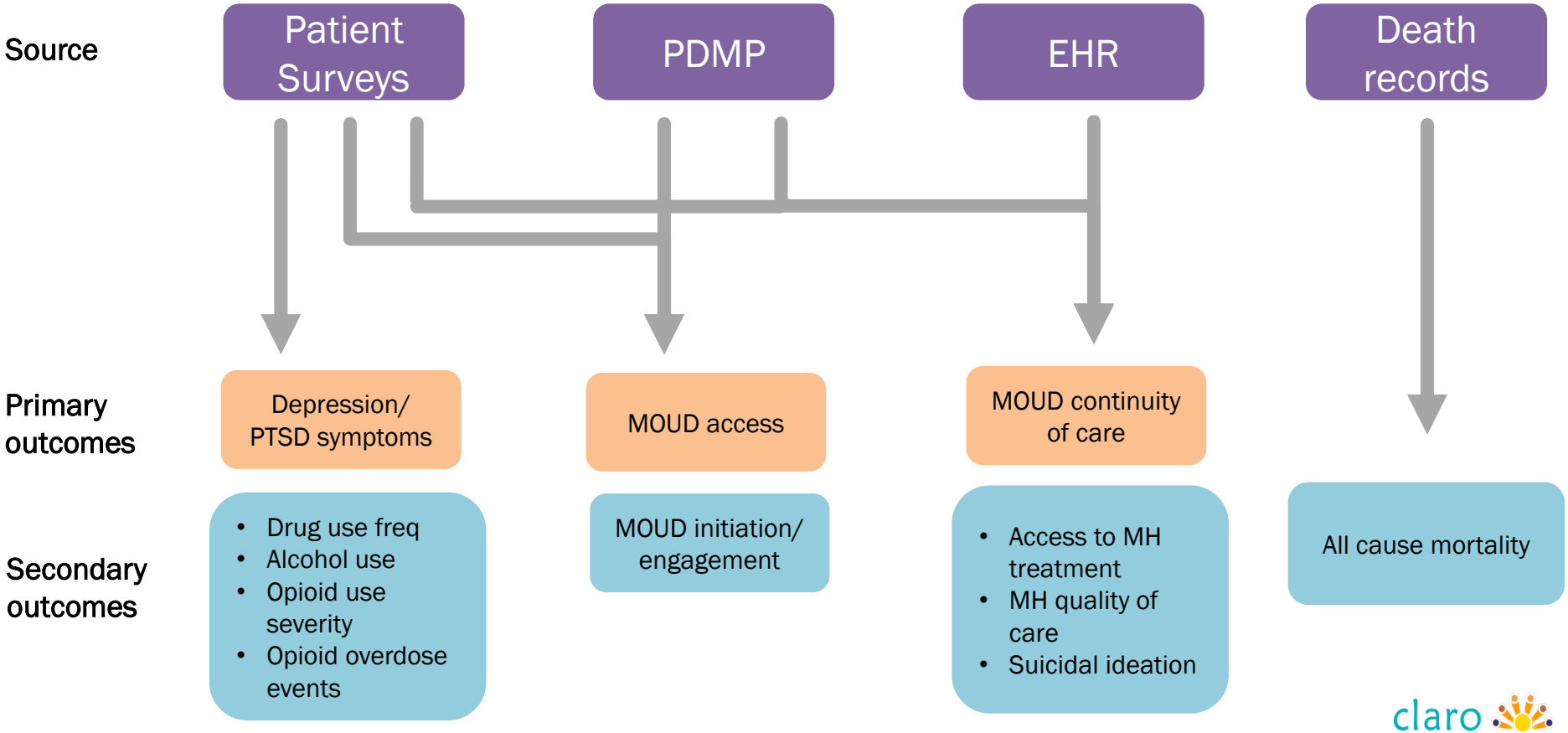
Outcome Data



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Our decisions about how to put the CoCM into practice were made collaboratively with our clinical partners

We adapted the CoCM for low-resource settings

- Re-defined roles and activities
- Care modified for population with multiple health disorders and negative social determinants of health
- More complex clinical registry

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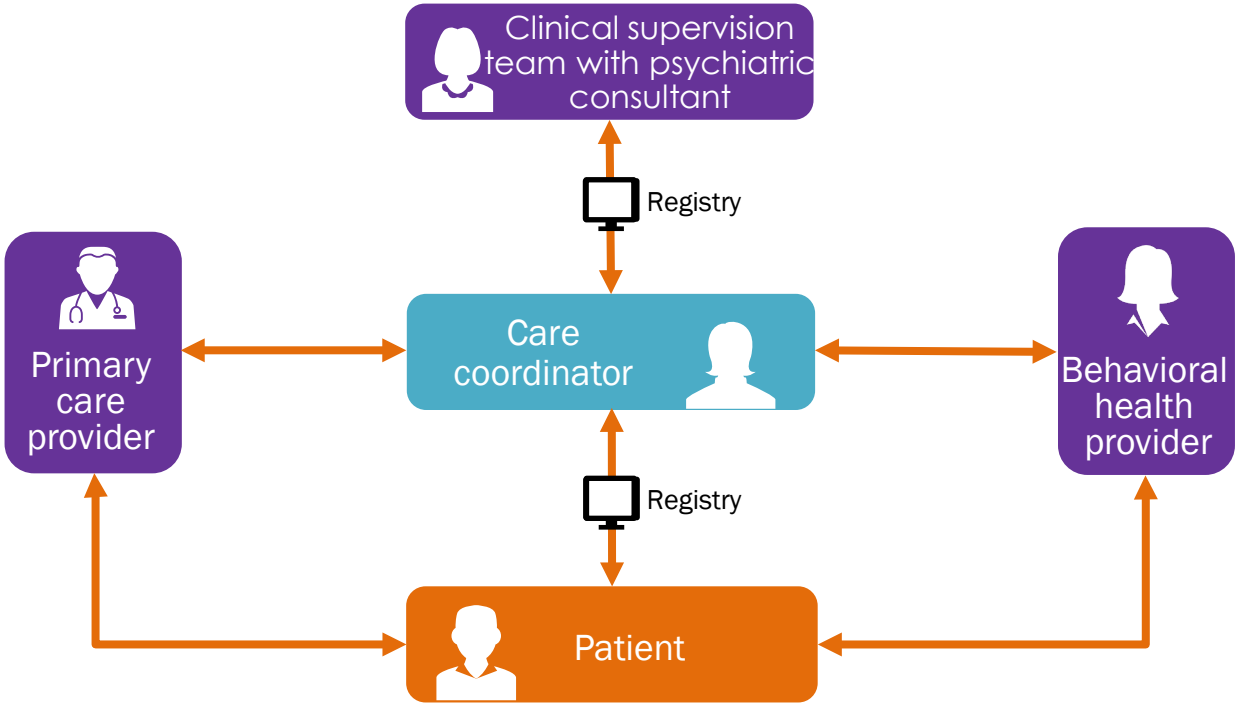
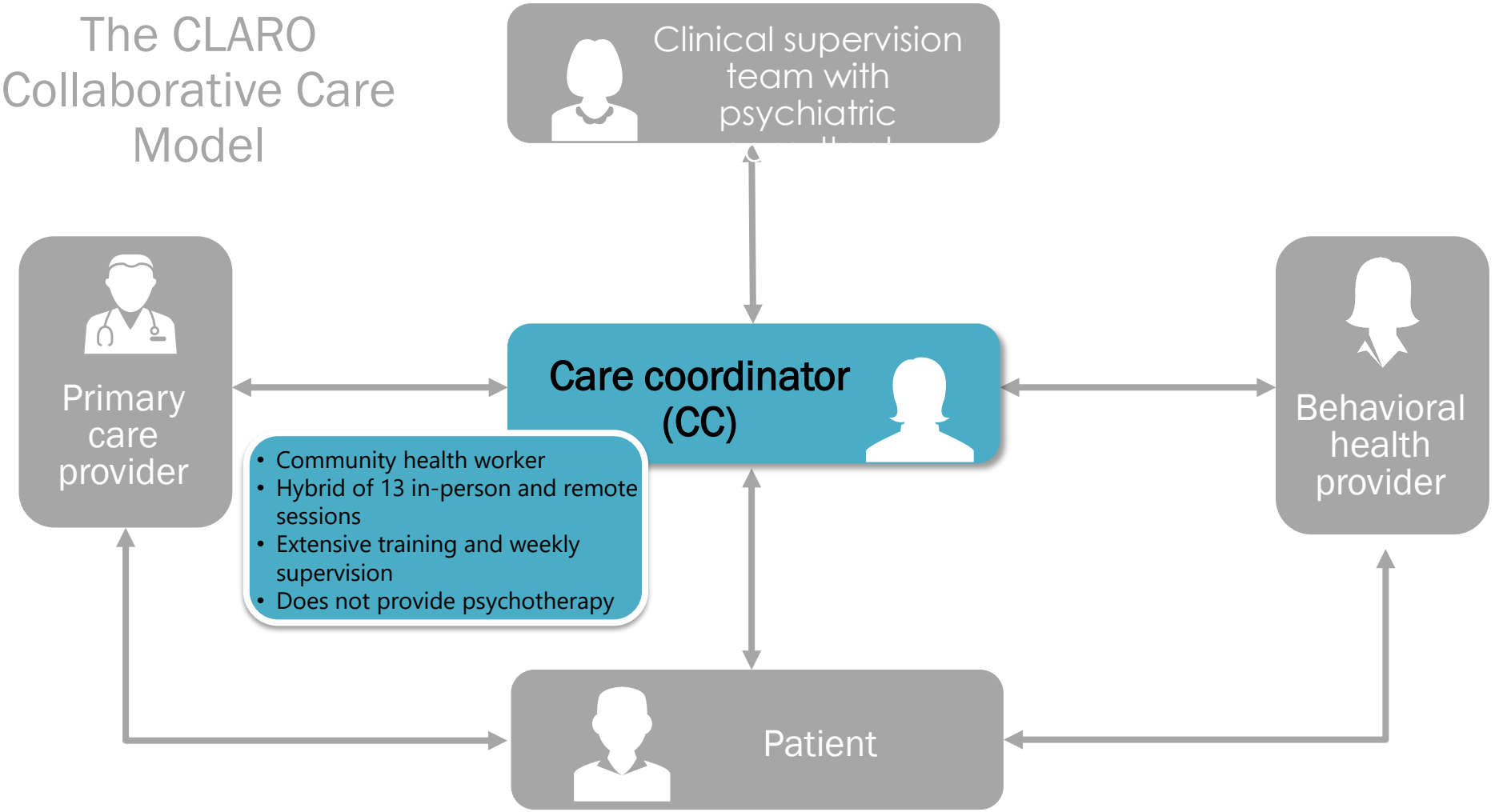
We redefined some roles and responsibilities

Key differences from the AIMS Center model:

- Psychotherapy provided by a separate behavioral health provider, not the care coordinator
- Registry guided coordinator interactions with patients



The CLARO Collaborative Care Model



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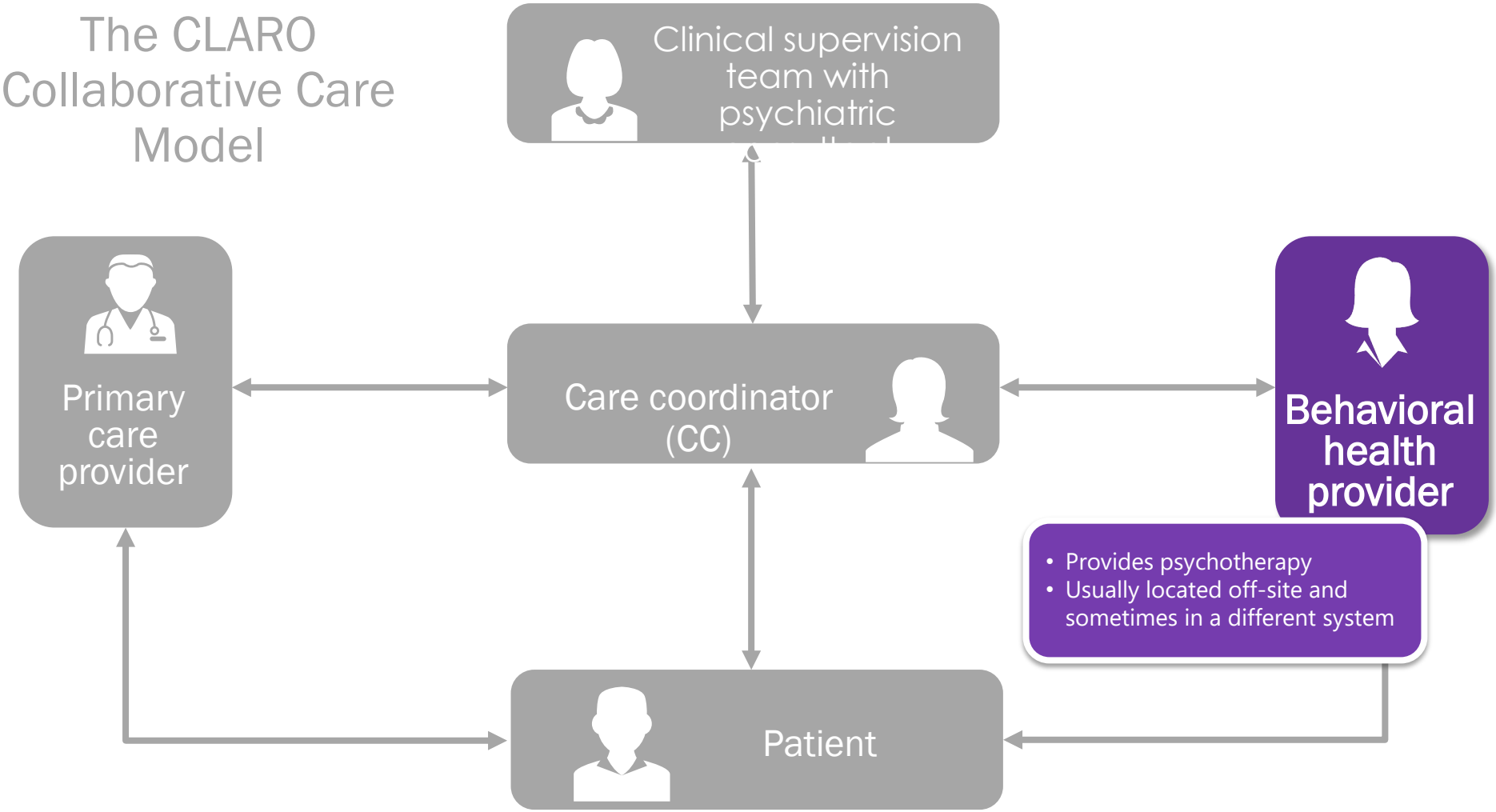

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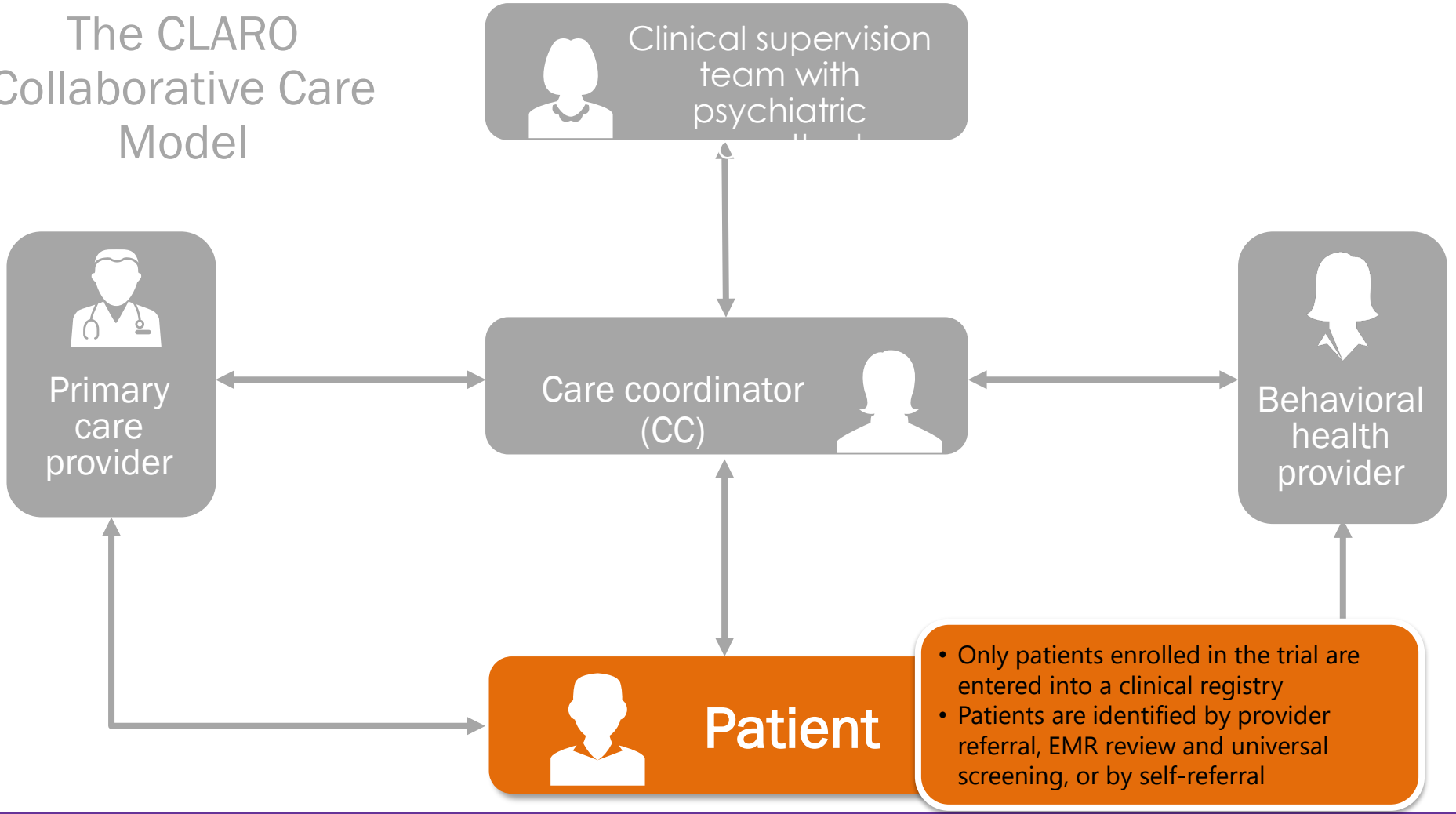

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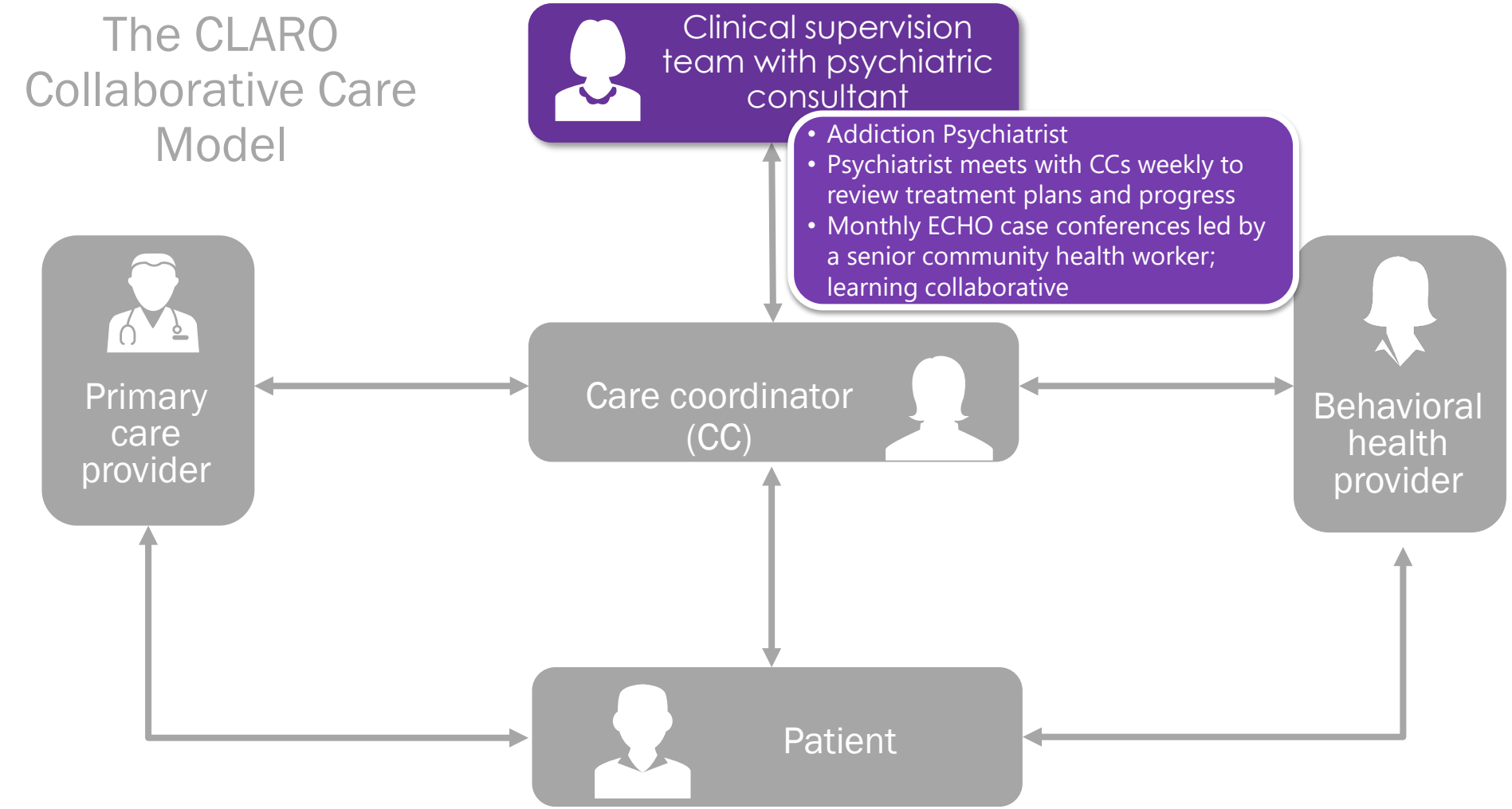

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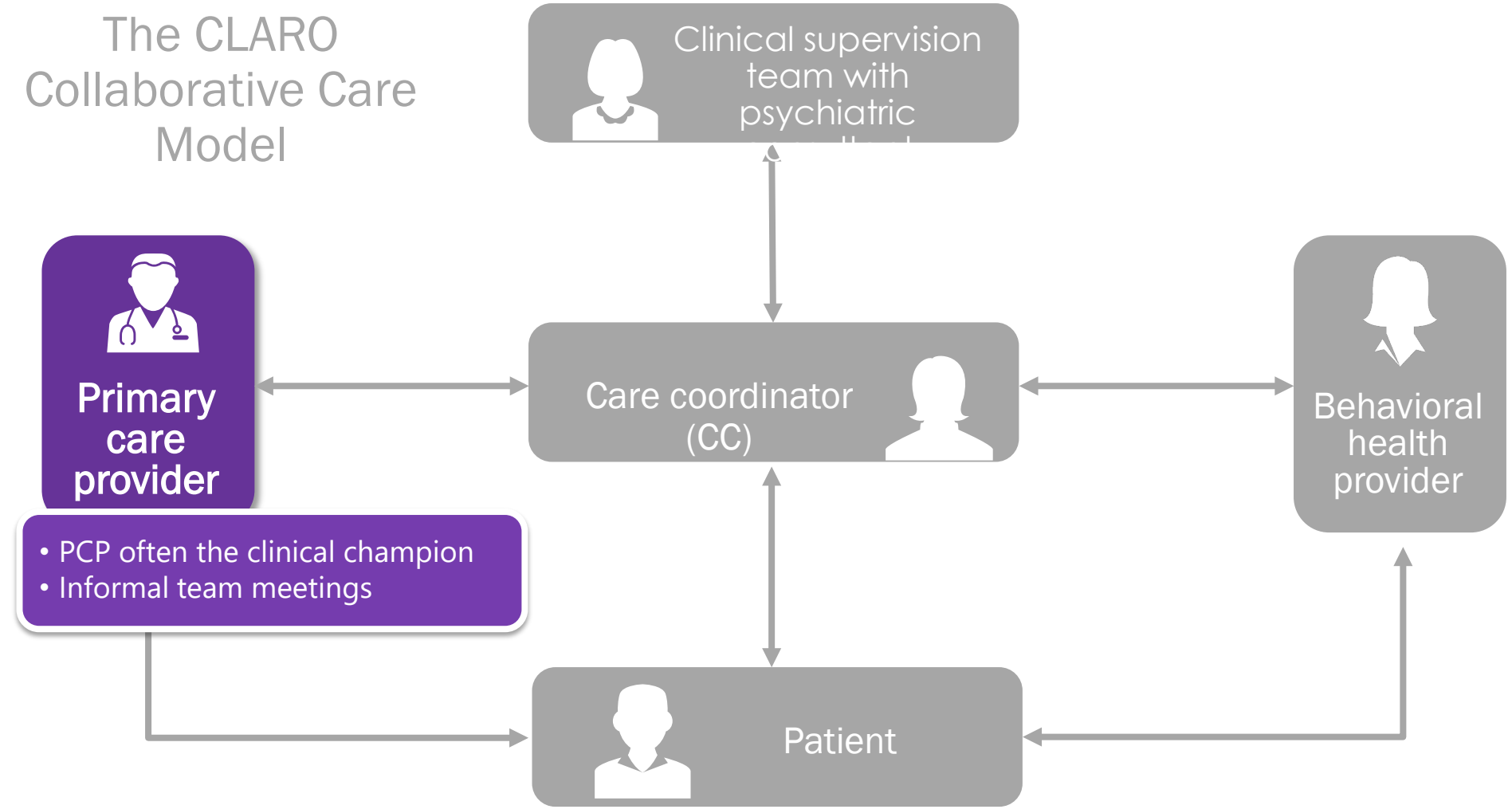

We allowed for flexibility in terms of what care was provided for each disorder

- **Multi-morbid population** meant that care coordinators had to work with patients on what treatments to prioritize
- **Population with many negative social determinants of health—**care coordinators assessed and addressed most important ones.
- **Ongoing tension** between assessment/measurement-based care vs. engagement/relationship-building; engagement complicated by Covid and clinical severity of population

Decisions around the clinical registry

- Population-based, stand-alone registry, separate from medical record with some duplication of effort. Tracked:
  - Treatment plans and goals
  - Encounters and referrals
  - Outcomes/symptoms
  - SDoH assessment and changes
- Supported care coordinator interactions with the psychiatric consultant & clinical supervision team and the patient
- Developed by AIMS Center, fairly complex, cost associated with use.

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CLARO Intervention and Implementation manuals

- CLARO Intervention manual

  Available at:

  https://www.rand.org/pubs/tools/TLA618-1.html

- CLARO Implementation manual

  Available at:

  https://www.rand.org/pubs/tools/TLA618-2.html

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CLARO implementation outcomes and data sources

- Adoption-provider interviews
- Reach/penetration-registry data
- Fidelity/adherence-registry data

Adoption

- We engaged 5 health systems (18 clinics). 2 health systems (4 clinics) subsequently disengaged because of difficulty identifying and enrolling patients and lack of provider interest
- One health system (8 clinics) completed the trial but did not continue to deliver model because of organizational difficulties and no source of ongoing funding
- 2 health systems (6 clinics) are still enrolling patients

Who was enrolled in the trial? (N = 341)

- Data are from both New Mexico and California
- 72% Hispanic or Latino
- 54% Female
- 32% Less than high school education
- 58% Have OUD, PTSD and depression
  - 20% OUD and depression
  - 22% OUD and PTSD

Who was enrolled in the trial? (N = 341)

- 80% Taken MOUD past 30 days
- 32% Co-use stimulants
- 13% Unstably housed
- 12% Socially isolated
- 21% Current legal problems
- 28% With suicidal ideation

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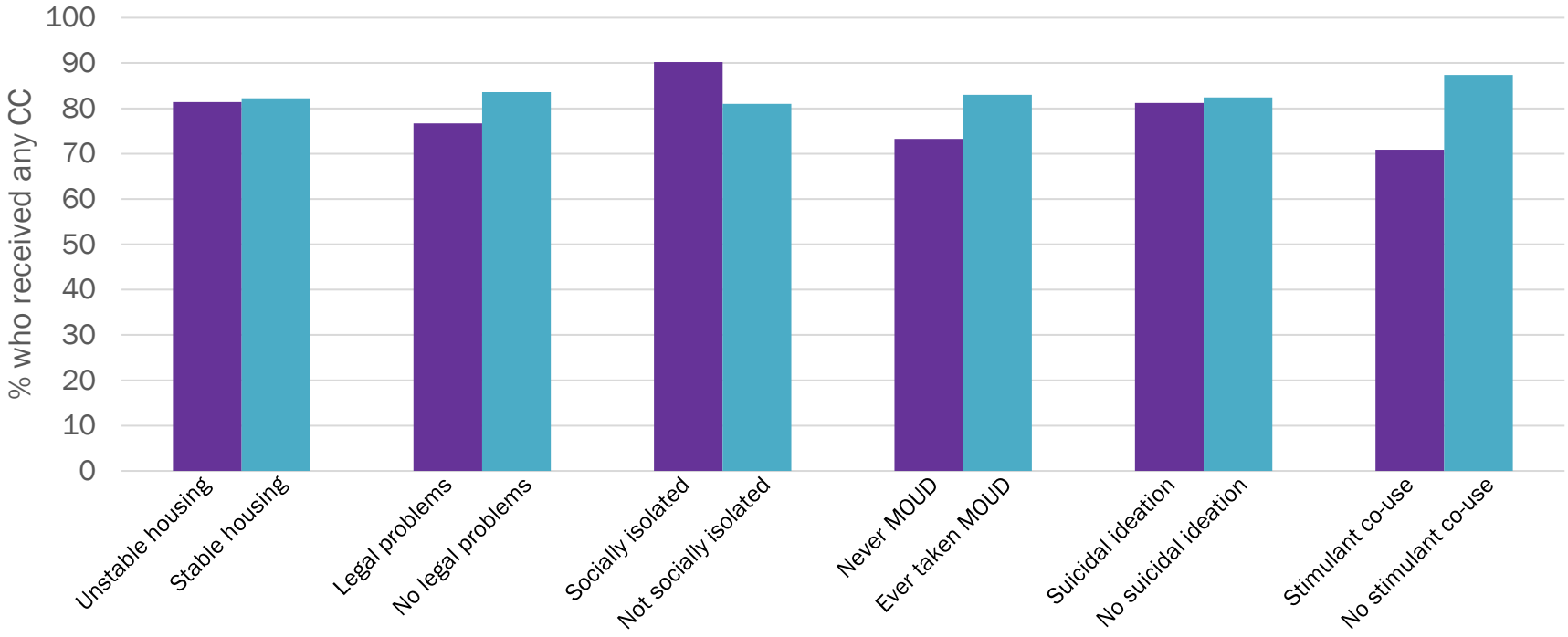
“Reach”

- COD population is typically hard to engage/reach
- Mixed/limited evidence regarding CC reach, none specific to co-occurring mental illness and OUD
- Reach = $\frac{\text{Those with 1+ care coordinator encounter}}{\text{Eligible population}}$
- Eligible population = those enrolled in trial and assigned to intervention. This is **not** the population of potentially eligible patients at the clinic.

Reach was high despite complexity of eligible population

- 100% (N=341) of those assigned were entered into the clinical registry and had attempted contact by the care coordinator;
- 82% (N=280) had at least one encounter with the care coordinator

Care coordinators reached patients at highest risk of non-engagement, morbidity, and mortality at similar rates as other patients



Fidelity/Adherence

56.6% received all components of the model

- Had two or more care coordinator encounters
- Treatment plan and progress reviewed by addiction psychiatrist
- Received measurement-based care for both OUD and mental health disorders

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Limitations

- Observational study, within a pragmatic implementation trial
- Not hypotheses testing

Challenges and implications

- Decision to use a community health worker as the care coordinator and emphasis on addressing SDOH had downstream impacts on implementation outcomes
  - Able to engage a large proportion of the population despite the population having many challenges
  - But psychotherapy provided outside of core CoCM team → uptake of psychotherapy was low
  - Registry more complex and prescriptive → tension between engagement vs. assessment and measurement-based care, but also relatively high fidelity

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Challenges and implications

- Time-limited model, yet engagement could take months
- Limiting eligible population to those enrolled in the trial means that eligible population is probably larger
- Future health systems should assess the fit of the model given local needs and patient population
  - Prevalence of target population varied substantially between sites

Questions?

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AntonioGuillem via GettyImages

Research question

Operationalization of CoCM  Implementation outcomes

How might decisions about how we implemented the CoCM be related to the implementation outcomes of adoption, capacity for sustainment, reach and fidelity?

Putting the model in practice

Core features of the CoCM can be operationalized in different ways:

- How is team-based care delivered?
- What are the expectations of primary care providers?
- What clinical background and support do care managers have?
- How often, and with what measures, is progress tracked?
- Who is the eligible population?
- What activities does the registry support?
- Is the model time-limited?

Capacity for sustainment