Integrating Behavioral Health and Primary Care for Comorbid Behavioral and Medical Problems

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Research Questions

Does integration of behavioral health and primary care services, compared to simple co-location, improve patient-centered outcomes in patients with multiple morbidities?

Aim 1: Determine if increased integration results in **better** patient-centered outcomes.

Aim 2: Determine if protocolized process techniques are effective in **increasing** BH integration.

Aim 3: Explore **contextual factors’** affect on implementation and patient-centeredness of integrated BH care.
Design: Cluster Randomized Trial

- 20 practices randomized to integration
- 20 practices randomized to stay in co-location
- Recruit a random sample of 75 patients per practice
- Assess patients (& practices) every 12 months
- Unit of randomization is the practice (n=40)
- Unit of analysis is the patient (n=3,000)
Intervention

– Online **Skills** training for BH providers, PCPs and staff
– A **Toolkit** of suggested tactics for integrating
– Protocolized Process for facilitated redesign of Primary Care practices
  • Remote coaching of in-house facilitator
  • 12 hour intensive team exercise to plan changes
  • Toyota Production System LEAN method
– Each clinic decides how to better integrate !!
Outcomes

• Practice
  – Degree of integration achieved (i.e., PIP)
  – Qualitative analyses (i.e., surveys and focus groups of staff, providers, patients)

• Patients
  – Community sample randomly selected (1000/BHP) to catch 300 target patients (i.e., “complex”)
  – 75 patients/clinic for semi-annual phone surveys
  – Clinical biomarkers and utilization
## Timeline

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<th>Study year:</th>
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### Early practices:
- Early Integration (12 practices)
  - Redesign
  - Integration
  - Baseline subject measures: ↑ Follow-up: ↑

- Early Co-location (12 practices)
  - Co-Location
  - Baseline subject measures: ↑ Follow-up: ↑

### Late practices:
- Late Integration (8 practices)
  - Redesign
  - Integration
  - Baseline subject measures: ↑ Follow-up: ↑

- Late Co-location (8 practices)
  - Co-Location
  - Baseline subject measures: ↑ Follow-up: ↑

**Final analyses:** ↑
Steps in Practice Site Onboarding (1)

• Practice Expresses Interest in Study & provided project description

• Site Lead Conversation Checklist

• Determine Practice Eligibility (e.g., BHP of .5 FTE & Medicare providers, not too integrated/PIP Completion, Practice Eligibility Survey, EHR data sharing capability assessment)

• Review of SOW with Practice Leadership

• BAA & DUA with DARTNet
**General Responsibilities and Deliverables**

2.1. Site Leadership

2.1.1. Each site’s leadership must provide ongoing support of the project, including garnering appropriate institutional support and attention at the system and practice levels.

2.1.2. Site leadership and project staff will communicate and coordinate with an assigned member of the research team (the Cluster Leader) as needed and respond to queries from the research team within 5 working days.

2.1.3. The site (or its controlling organization) must agree to notify the Cluster Leader or Principal Investigator promptly of any substantial change in operations including recruitment or termination of a Behavioral Health Clinician, change in location of clinical services, discontinuation or major interruption of clinical services, change in site leadership, or withdrawal from the study.

2.1.4. Each site’s leadership must provide a total of approximately 8 hours of leadership time for Primary Care Behavioral Health core service planning.

2.1.5. Each site’s leadership must provide additional time to support other activities throughout the project as described below.

2.1.6. In the event that site (or other organizational) leadership changes during the Study Phase, the study will proceed without pause or substantial change.

2.2. Behavioral Health Provider

2.2.1. The site must hire or have in place a Behavioral Health Provider during the Study Phase.

2.2.2. The Behavioral Health Provider must be present for at least 20 hours per week.

2.2.3. The Behavioral Health Provider must be licensed to provide behavioral health, mental health or substance abuse care in the state the site operates in.

2.2.4. The Behavioral Health Provider must be located in the same physical location (same street address) as the site’s Primary Care Providers.

2.2.5. During the Study Phase, the site must have Behavioral Health Providers eligible to provide services for patients with any insurance plan that makes up 10% or more of the site’s annual billings.

**INTEGRATING BEHAVIORAL HEALTH AND PRIMARY CARE CLINICAL SITE SUBCONTRACT**

**SCOPE OF WORK AND ADDITIONAL TERMS OPTION 1 – 9/23/16 PAGE 2**

2.3. Electronic Health Records (EHR)

2.3.1. The site must maintain an EHR through the end of the Study Phase.

2.3.2. The site must develop and maintain a consistent EHR data set, information flow, and availability throughout the study phase.

2.3.3. The site must develop and support EHR access, documentation, and communication functions to include medical and behavioral providers.

2.4. IRB Approval

2.4.1. The research protocol must be approved and maintained by the site’s Institutional Review Board without significant modification to ensure compatibility among multiple clinical sites.

2.4.2. Any variances from the UVM protocol must be approved by the Principal Investigator.

2.5. Other integration interventions

2.5.1. Practices are asked to refrain from engaging consultants or other external resources to assist them with integration during the Study phase.

2.5.2. Practices must notify the research team and assist it in documenting and describing any non-study work done towards integration.

2.5.3. Interventions that a) require a co-located Behavioral Health Provider, and b) include facilitated, structured redesign of practice workflows for case identification, patient assessment, management, or surveillance of the Behavioral Health needs of c) patients with one or more of the qualifying conditions for the study (hypertension, heart failure, asthma, chronic obstructive pulmonary disease, arthritis, diabetes, anxiety, depression, chronic pain, headache, fibromyalgia, insomnia, irritable bowel syndrome, substance use disorder, alcohol use disorder) may on all other health care components
General Responsibilities and Deliverables

Educational Program

4.1. Designated staff must complete their role-specific on-line educational program during the first three months of the intervention. 4.1.1. Primary care medical providers (MD, DO, NP, PA, residents, etc.) must complete 4 hours. 4.1.2. Primary care BH providers (MSW, MA, PhD, etc.) must complete 12 hours. 4.1.3. Practice Manager or Supervisor must complete 4 hours. 4.1.4. Practice Redesign Team Facilitator must complete 14 hours. 4.1.5. Clinical staff performing care management functions must complete 12 hours for the core program. 4.1.6. Non-clinical staff who have contact with patients must complete 4 hours.

4.2. Behavioral Health Providers and other staff as appropriate must participate in a bi-monthly learning community calls.

5. Site Visits

5.1. The site will provide logistical coordination and meeting space in support of site visits by the funder or research study staff. 5.2. The site will make all reasonable efforts to provide access to practice leaders, clinicians, staff and patients for focus groups, interviews and surveys during site visits. 5.3. The site will allow the recording of interviews and focus groups with the permission of the individual participants.

6. During the Intervention:

6.1. General requirements during the Intervention

6.1.1. During the intervention, the site will commit to providing staff for a care management function. 6.1.2. During the intervention, the site will provide protected time for team members of the practice to meet. 6.1.3. During the intervention, the site will provide protected time for site facilitator
This HIPAA Business Associate Agreement ("BA AGREEMENT") supplements and is made a part of any and all agreements entered into by and between The Regents of the University of California, a California corporation ("UNIVERSITY"), on behalf of its University of California San Diego Health System and DARTNet Institute ("BUSINESS ASSOCIATE") and is effective as of October 3rd, 2016 ("Effective Date"). UNIVERSITY has designated all of its HIPAA health care components as a single component of its hybrid entity and therefore this agreement is binding on all other health care components of the UNIVERSITY.
Steps in Practice Site Onboarding (2)

• IRB (10+ attachments, 4 revisions)
• Successful data pull of EHR data (!!!)
• Practices Receive, Review, and Return Commitment Form Package to UVM
• Generate, review and return Practice Site subcontract
• Onboarding Process Ends ➔

Randomization & Welcome Package
Steps in Practice Site Onboarding (2)

- IRB
- Successful Data Pull of EHR data
- Practices Receive, Review, and Return Commitment Form Package to UVM
- Practice Site Subcontract: Generation, Review and Return
- Onboarding Process Ends ➔ Randomization & Welcome Package
Budget for the Practice Sites

• Payment to sites starts with randomization.
• Discussion about how to discourage attrition via loss of ALL funding

Study periods
1. The first phase of the contract is “Preparation” and shall run from the first day of the month in which this contract is finalized until the “Study” phase begins.
2. There is no minimum duration for the Preparation phase.
3. The Study phase starts at the beginning of the month in which the site is notified of their assignment to either active or control status by UVM.
4. The Study phase begins at the discretion of UVM and runs for 36 (thirty-six) months inclusive.
5. At the beginning of the 37th month after beginning the Study phase, the site enters the “Resolution” phase which runs until March 31, 2021.
6. There is no minimum duration for the Resolution phase.
7. Depending on randomization, the Intervention will occur during the first 9 months of the Study Phase (active sites), or the last 9 months of the Study Phase (control sites).

Payment Schedule
1. The site shall be eligible for $1,500 per month for participation (if any) during the “Preparation” phase;
2. The site shall be eligible for $3,313.33 per month during the “Study” phase (not to exceed $119,280 over no more than 36 months);
3. The site shall be eligible for $1,500 per month for participation (if any) during the “Resolution” phase.
4. Necessary extraordinary expenses will be reimbursed only with the prior approval of the Principal Investigator.
Intervention: Each stage = 3 months

- To start the Intervention, the sites must:
  - Re-complete the PIP
  - Receive a Welcome Package with instructions on how to:
    - Test Internet access to the curriculum and other resources
    - Set up curriculum enrollment and CE credits for staff and providers
    - Start baseline staff surveys

- **Stage 1** help a small group of clinical site leaders (IBH Project Group) to plan for and support the overall project and the Redesign Team. We estimate **8 hours of discussion and coordination time**. This process will be facilitated by the Clinical Site’s Cluster PI. The IBH Project Group identifies the Facilitator and the Clinical Site’s Toolkit Coach will be introduced to the clinical site.

- During the control period, sites will:
  - Test Internet access to the curriculum and other resources
  - Have periodic check-ins with the Cluster Leader
Intervention: Each stage = 3 months

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  – Re-complete the PIP
  – Receive a Welcome Package with instructions on how to:
    – Test Internet access to the curriculum and other resources
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• During the control period, sites will:
  – Test Internet access to the curriculum and other resources
  – Have periodic check-ins with the Cluster Leader
Intervention: Each stage = 3 months

• **Stage 2** the Redesign Team to meet for **10 hours** over 2-3 months. During that time, the Toolkit Coach will work with the Facilitator by attending team meetings by phone (and after meetings **estimated at 12 hours over the same period**).
Intervention: Each stage = 3 months

• **Stage 3** is implementation of Redesign Team’s work. This usually involves the Redesign Team’s meeting every 2-3 weeks to check on progress and make adjustments if needed. The Toolkit Coach assists as needed. Implementation is usually finished (meaning that changes have finished and the process feels stable) after 3 months.
What has really happened?

- Scripps Ranch Family Medicine as beta site (Cluster PI as BHP)
- Stage 1 took awhile due to staffing and other clinic process changes, and scheduling challenges with residents
Time commitment for “Facilitator” is high due in part to ‘belabored’ process
Language issue of team member roles and “step” within a “stage”, “planning group” versus “Design team”
Difficulty with staff completing Readiness survey
Change in platform for viewing videos and time to view them with incentives
Compensation issues, and centralizing/facilitating payment with Research Assistant
FM LC, FM GEN, LIM randomized to Intervention; IM LWC and IM SOR wait list
What has really happened?

- FM SRC: delayed understanding of not just running a obesity clinic
- Focusing on community sample
- Current plan: My Chart PROMIS-10 (already in Epic) and take lowest functioning first, invite in when collaborative care can join for care management
- Other 3 Intervention sites have regular phone meetings with intervention coach, have met once with yet identified project, and varying stages of readiness surveys completed