Collaborative Care Models for Behavioral Healthcare Services Integration

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Abstract

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Despite the widespread evidence of the effectiveness of integrated behavioral healthcare interventions at improving health outcomes, particularly among patients with comorbid chronic illnesses, their adoption into primary care delivery settings remains slow. This study evaluates the Collaborative Care Model, an evidence-based integrated behavioral healthcare intervention, in two different implementation contexts: a low-barrier HIV clinic in Seattle, Washington where care for depression and opioid use disorder was integrated into primary care, and four urban diabetes clinics in India where care for depression was integrated into diabetes care. The study had three distinct aims: to elicit the anticipated barriers and facilitators to implementing the Collaborative Care Model in low-barrier HIV care, to evaluate the acceptability and feasibility of the Collaborative Care Model in low-barrier HIV care, and to conduct a mediation analysis

evaluating the effect of change in self-stigma on diabetes outcomes as mediated by depression symptom severity in urban diabetes care in India.

We found that while the patients and stakeholders at a low-barrier HIV clinic were receptive to implementing the Collaborative Care Model, they identified as barriers the availability of resources in the inner implementation setting; practical concerns about the perceived contextual fit with low-barrier HIV care; and its anticipated suitability due to the burden of other behavioral health comorbidities and complete socio-economic needs. The Collaborative Care Model was acceptable and feasible to implement in a low-barrier HIV clinic but only with key adaptations to core interventions to improve its contextual fit. Of the 175 eligible patients, 36% of were screened, 24% were referred, 15% completed an intake, and 9% progressed to the engaged step of the care cascade. Whereas logistical challenges in the inner implementation setting and staff perceptions of its feasibility hindered patient progression through the care cascade from screening through engagement, the Behavioral Health Care Manager's ability to exemplify the clinic's values and culture, qualities underscoring patient satisfaction, facilitated patient progression through the care cascade. Depressive symptoms did not mediate the effect of change in self-stigma on diabetes outcomes and self-stigma scores did not vary longitudinally comparing patients being treated for depression via the Collaborative Care Model to enhanced standard of care in urban diabetes clinics in India.

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DEDICATION

For Cameron and Noah.

Chapter 1. INTRODUCTION

Substance-use and mental health disorders represent the fourth and fifth largest causes of disability-adjusted life years in the United States (US), respectively.(1, 2) The Substance Abuse and Mental Health Services Administration's 2020 survey estimates 40.3 million adults had a substance use disorder and 14.2 million adults had a serious mental illness (5.7 million adults had both).(3)

According to the Centers for Disease Control surveillance data, relative to 2015 levels, Human Immunodeficiency Virus (HIV) incidence in the US in 2019 decreased to a rate of 12.6/100,000 (36,800).(4) Among people with HIV (PWH) who received a viral load test within six months of being diagnosed with HIV, 68.3% were virally suppressed (defined as less than 200 viral copies per milliliter of blood, viral suppression results from continually taking antiretroviral medications and in turn greatly reduces the risk of viral transmission).(5) However, substance use and mental illness are major barriers among PWH who are virally unsuppressed.(6-10) In particular, many PWH who live in core urban neighborhoods experience housing instability and are currently or recently incarcerated, thus posing additional socioeconomic barriers to engaging in HIV care.(7-9) Low-barrier HIV care is a novel, evidence-based approach to improving adherence among the 'hardest-to-reach' PWH who are virally unsuppressed despite prior public health outreach efforts. Low-barrier HIV care responds to the barriers these PWH disproportionately face by offering walk-in HIV and primary care services, wrap-around social supportive services, case management, and incentives for laboratory visits and achieving viral suppression.(11, 12)

The standard of care in most HIV clinics or primary care settings is to refer people with comorbid HIV, substance use, and/or mental health disorders out to behavioral healthcare (BH) specialists including (among others): therapists, psychiatrists, addition specialists, rehabilitation centers, or detoxification centers. However, estimates indicate that fewer than half of all people with depression follow-up with a specialist and such referral pathways can cause fragmentation of care.(13, 14)

Integrating BH services into routine primary care delivery settings increases access, enhances longitudinal care, and improves patient clinical outcomes.(13-18) Integrated BH interventions are widely endorsed by the World Health Organization in the mhGAP Intervention Guide 2.0(19), by the Institute of Medicine,(20) and are core to the care delivery model within the Veterans Health Administration and Federally Qualified Health Centers(21). Scaling up such integrated BH interventions is critical to closing access gaps for the 165.4 million adolescent and adult Americans who used substances in the past month or the 69.8 million American adults living with mental illness.(3)

Self-stigma is an important barrier for patients to initiating or continuing BH.(22, 23). Self-stigma results from the process of internalization of negative attitudes held by a community or group about an illness, condition, or characteristic that's devalued. Self-stigma may, in turn, lead to or exacerbate certain forms of mental illness like depression and anxiety.(24) Depression, HIV, and other chronic conditions are examples of stigmatized conditions, which arise from stereotyping, prejudice, and discrimination by both healthcare providers and non-healthcare providers.(24-26) Some researchers suggest that integrated care may increase uptake of BH treatment by offering treatment in one setting that does not discriminate against people based on type of illness.(27-31) Others suggest that integrated care could reduce self-stigma as primary

care settings may be more likely to emphasize whole-body wellness and patients may be less likely to internalize stigma due to removing the possibility of being seen at a specialist clinic.(32, 33) Yet, research has shown that even in integrated BH settings, self-stigma among patients may still persist and impede access to BH.(32, 34)

The Collaborative Care Model (COCM) is an example of an integrated BH intervention that has expanded access to care for patients with depression and opioid use disorder (OUD; via an adapted model known as the Office Based Opioid Treatment program, which centers around the use of medications for treating OUD like buprenorphine),(35-40) among other behavioral health conditions, with over 80 randomized controlled trials of peer-reviewed evidence in support.(14, 18, 36, 41-43) Although various definitions of COCM exist,(44) we define it based on the following intervention components: proactive and systematic screening of BH needs, task-shifting using a non-physician BH care manager (CM; who is often a nurse, licensed clinic social worker, or another cadre of non-physician BH provider), delivery of evidence-based psychotherapy for people with common mental disorders, measurement-based care (also known as treatment-to-target patient where patient care plans are adjusted according to progression in patient symptom severity which is measured at routine intervals), case conference led by a psychiatrist (allows the BH CM to consult on individual cases), and a patient registry for tracking patients and the facilitating case conference. Figure 1.1 below shows the revised team structure in care delivery settings that have adopted and implemented COCM. The success of COCM for patients with depression and OUD in primary care delivery settings has precipitated interest in its expansion to serve populations with co-occurring conditions (i.e., PWH or those with diabetes).(45-48)

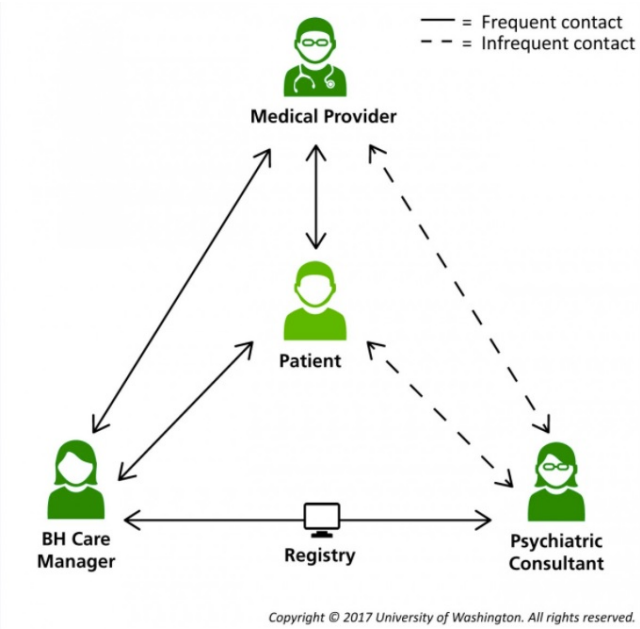

Figure 1.1. Team structure in COCM

While COCM was initially developed in the United States, it has been suggested by researchers as a potential solution for under-resourced settings globally with behavioral health burdens, including in low- and middle income countries (LMICs).(25, 49) COCM has been implemented to effectively increase access to depression care in various LMIC settings including in Uganda,(50, 51) Vietnam,(52) Zimbabwe,(53) South Africa,(54) and China.(55)

Multiple settings within South Asia have implemented COCM for depression and other common mental disorders with varying degrees of effectiveness. In Goa India, Patel and colleagues leveraged lay health counselors to deliver a stepped (patients who do not demonstrate improvement in clinical outcomes are ‘stepped up’ to increasing levels of resource-intensive interventions) collaborative care program called MANAS, which targeted common mental disorders. They observed a 30% decrease in the prevalence of common mental disorders among participants after 12 months of treatment and patients receiving stepped collaborative care were on average 1.22 times more likely to have recovered at six months relative to the comparison

group.(56, 57) Srinivasan and colleagues implemented COCM for people with depression and other comorbid non-communicable diseases (hypertension, diabetes, or ischemic heart disease) at 24 rural clinics in Karnataka India and found that, compared to comparison clinics, those receiving COCM experienced significant improvements in depression symptom severity at three, six, and 12 months.(58) To close gaps in access to care for depression in rural Nepal, Rimal, Choudhury, and colleagues implemented COCM and observed that 49% of patients reduced their depression symptom severity score (Patient Health Questionnaire-9 scores) by half after at least 12 weeks of follow-up.(59) Together, these studies further advance the growing evidence-base for COCM's effectiveness in LMICs and among patients with various comorbidities.

Each of these studies of COCM must be situated within an understanding of the contextual reality of implementation that is both dynamic and active.(60) The systematic study of the determinants of implementation – the contextual factors that act as barriers or facilitators to implementation efforts – provides an empirical basis for the selection and tailoring of implementation strategies.(60) Implementation strategies are "the methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice"(61) and in turn are the tools towards improving implementation outcomes of evidence-base interventions like COCM.(62)

A recent qualitative systematic review of the determinants of implementing COCM shows how these factors span multiple domains of implementation.(60, 63, 64) While COCM's robust evidence base generally facilitates implementation,(65) it's multiple components are often perceived as complex leading to confusion over role clarity within the team-based approach, and complications related to billing reimbursements in US care delivery settings with high percentages of patients on Medicare or Medicaid.(63, 65-72) Clinical settings that cared for

patients with complex socio-economic needs and BH comorbidities found it challenging to sustain patient engagement in COCM.(73-75) Whereas the co-location of the BH CM onsite, high quality intra-team communication systems, and ongoing access to educational resources for the BH CM helped facilitate COCM implementation, implementation sites that lacked sufficient space, human, and other resources were less ready to implement COCM.(35, 37, 38, 40, 54, 67, 76-82) In the case of implementation for OUD, getting primary care physicians to buy-in to COCM and to get wavered to prescribe buprenorphine has proved to be a barrier to implementation.(35, 37, 40) In various studies implementing COCM, the BH CMs reported low self-efficacy with one or more components of COCM which was a barrier to implementation, while access to information and resources to monitor patient progress and learn about patient success stories helped facilitate implementation.(65, 76) Experience from implementing COCM in LMICs has shown that leveraging community resources, advocacy from global mental health practitioners, and implementing COCM in the context of broader healthcare systems strengthening efforts may be particularly relevant to facilitate implementation to overcome critical human resource constraints.(83)

In this dissertation, I will pursue three aims: 1) to identify the anticipated determinants of integrating care for depression and OUD via COCM among PWH in low-barrier HIV care, 2) to evaluate the acceptability and feasibility of implementing COCM for depression and OUD in low-barrier HIV care, and 3) to evaluate the effect of change in self-stigma on type II diabetes outcomes as mediated by depressive symptoms in the context of COCM implementation.

Chapter 2. FORMATIVE QUALITATIVE RESEARCH TO GUIDE IMPLEMENTATION OF THE COLLABORATIVE CARE MODEL IN A LOW-BARRIER HIV CLINIC

2.1 ABSTRACT

Introduction: Integrated behavioral healthcare interventions are increasingly recognized as evidenced-based approaches for increasing access to behavioral healthcare. The Collaborative Care Model is an evidence-based integrated behavioral healthcare intervention that has increased access to care for people with depression and opioid use disorder. Although the Collaborative Care Model has been implemented widely, including in settings for people with various chronic comorbidities including HIV, it has not yet been implemented in a low-barrier HIV care settings where under-treated behavioral health needs remain high.

Methods: We conducted a formative qualitative evaluation to identify the anticipated barriers and facilitators to integrating care for depression and opioid use disorder for people with HIV via the Collaborative Care Model at a low-barrier HIV clinic. We conducted individual in-depth interviews with purposively selected service delivery stakeholders (n=13) and patient participants (n=16). We conducted a thematic analysis with deductive coding strategies informed by the Consolidated Framework for Implementation Research and inductive coding strategies.

Results: Patient participants and service delivery stakeholders alike expressed their enthusiasm for the Collaborative Care Model based on its perceived relative advantage over the standard of care referral system. The availability of resources in the inner implementation setting, practical concerns about the perceived contextual fit of the Collaborative Care Model with low-barrier HIV care, and the Collaborative Care Model's anticipated suitability given the burden of other

behavioral health comorbidities as well as the complex and acute socioeconomic needs of Max Clinic patients partially tempered the overall appropriateness for the Collaborative Care Model among service delivery stakeholders.

Conclusion: Patients and service delivery stakeholders were strongly receptive to the Collaborative Care Model, but felt it was moderately appropriate in the context of low-barrier HIV care and given the behavioral healthcare needs of the clinic's patients.

2.2 INTRODUCTION

Mental illness and substance use disorders remain important barriers for engaging people with HIV (PWH) in treatment adherence(84-86) and are disproportionately more common among PWH who have complex socioeconomic needs related to housing instability, incarceration, food insecurity, or a lack of employment. Low-barrier HIV care is an evidence-based care delivery model that attempts to strengthen medical adherence for the 'hardest-to-reach' populations by offering walk-in primary and HIV care, wrap-around social supportive services, case management, and incentives for both laboratory visits and achieving viral suppression.(11, 12) Yet access to BH services remains challenging for PWH and specifically among the target populations of low-barrier HIV care. The standard of care typically involves a referral to a BH specialist which often leads to care fragmentation due in part to the motivation and persistence needed on the part of the patient to coordinate care.(13, 87)

COCM is an evidence-based intervention (EBI) based on the Chronic Care Model(88) with over 80 randomized control trials demonstrating its effectiveness at improving outcomes for different common mental disorders.(13, 18, 41, 42, 89) COCM integrates care for behavioral health conditions by using a non-physician care manager (CM) as part of a team-based care

model to proactive and systematically screen patients, provide measurement-based treatment to target, and offer of evidence-based psychosocial and pharmacologic treatments. Other components include the use of a registry and case conferences between a consulting psychiatrist, the BH CM, and primary care providers. Although COCM has been adopted for use in the Veterans Health Administration (VA) outpatient HIV clinic settings,(73) to our knowledge, it has not been implemented in a low-barrier clinical setting that features walk-in access, incentives for care delivery, and supportive case management.

Despite COCM's effectiveness, the experiences and lessons learned from implementers globally demonstrate that there are many important contextual factors that can affect implementation, which are known as the barriers and facilitators (or collectively as the determinants) of implementation.(64) Although the growing evidence base for COCM facilitates implementation,(65) it’s often perceived as a complex intervention which in turn can cause confusion over role clarity within care delivery teams.(63, 65-72) In locations that serve patients with complicated socio-economic needs and other BH comorbidities, implementers found it difficult to maintain patient engagement in COCM.(73-75) Co-locating the BH CM onsite at the primary care clinic, fostering strong intra-team communication systems, and offering the BH CM educational resources (in addition to high quality training) facilitates COCM implementation, but insufficient space, human, and other resources within the primary care setting are frequent barriers to implementing COCM.(35, 37, 38, 40, 54, 67, 76-82) In the case of implementing COCM for patients with OUD, primary care providers may be reluctant to navigate the regulatory rules to becoming wavered to prescribe buprenorphine and stakeholders may negatively perceive buprenorphine’s effectiveness.(35, 37, 40) BH CMs often reported low self-efficacy with one or more components of COCM, but when equipped with access to information

and resources to monitor patient progress and to learn about patient success, this self-efficacy could be improved.(65, 76)

The HITIDES study examined integrating care for depression via COCM in the outpatient HIV clinics within the VA healthcare system.(90) PWH who experience depression can be doubly stigmatized and thus may face additional barriers to accessing care, engaging with a BH CM, and discussing their mental health needs. This underscores the importance of a care delivery model using task-shifting.(90) Additionally, primary care physicians working in HIV clinics may have self-confidence issues to diagnose and treat mental illness, harbor concerns over drug-drug interactions, and face competing priorities that limit their ability to respond to positive screens and engage with the BH care manager.(76)

The present study aimed to conduct a formative evaluation using qualitative methods to identify anticipated barriers and facilitators to implementing COCM for people with depression and/or OUD in a low-barrier HIV setting. Equipped with this knowledge, program implementers can better adapt the intervention to improve its contextual fit and tailor implementation strategies towards measuring progress against key implementation outcomes like acceptability, feasibility, and appropriateness.(91)

2.3 METHODS

2.3.1 *Study design:*

Using semi-structured guides, we performed in-depth individual interviews with both purposively sampled service delivery stakeholder (hereafter ‘stakeholders’, n=13)) and patient participants (n=16) and thematically analyzed the data to elicit the anticipated determinants of

implementation. For the thematic analysis, we used both inductive and a deducting coding approaches that were informed by a selection of constructs from the Consolidated Framework for Implementation Research.(64) Our study design, methods, and analytic approach are shaped by our identities, the implications of which are summarized in Appendix A.

2.3.2 *Study setting:*

We conducted the formative evaluation at the Max Clinic at Harborview Medical Center in Seattle, Washington. The Max Clinic is jointly operated by Harborview Medical Center and Public Health – Seattle & King County with support from the Washington State Department of Health, the Ryan White HIV/AIDS Program with the Health Resources & Services Administration, and the Ending the HIV Epidemic in the US Initiative with the Department of Health and Human Services. The Max Clinic serves the 'hardest-to-reach' patients, who are virally unsuppressed PWH who experience barriers to engaging in HIV care and are referred following re-engagement attempts from clinical and public health outreach workers. In response, the Max Clinic runs on a low-barrier care delivery model that features walk-in access to primary care providers; offers incentives including cash for completing laboratory visits and achieving durable viral suppression (RNA viral load <200 copies/ml), transportation passes, food vouchers, and clothes; and intensive medical and non-medical case management including housing assistance, care coordination, and other supportive services. PWH enrolled at the Max Clinic generally have complex medical needs and experience disproportionately high rates of mental illness, substance abuse, incarceration, and housing instability. The standard of care was referral to other BH providers either internal or external to Harborview Medical Center for patients with depression. Patients with OUD could be prescribed buprenorphine, but without frequent and systematic medication adjustments by a non-physician provider (or referral to other internal and

external BH providers including methadone clinics). Yet a retrospective chart review prior to implementing COCM, which corroborates staff experiences, found that less than 50% of referred patients ever completed a single BH visit,(92) thus underscoring the care delivery gap that motivated the Max Clinic team to consider integrating BH services via COCM.

2.3.3 *Description of COCM intervention*

COCM is an example of an integrated BH intervention that has expanded access to care for patients with depression and OUD (via the Office Based Opioid Treatment program),(35-40) with over 80 randomized controlled trials of peer-reviewed evidence in support.(14, 18, 36, 41-43) Although various definitions of COCM exist,(44) we define it based on the following core intervention components: proactive and systematic screening, task-shifting using a BH CM, delivery of evidence-based psychotherapy and medications, treatment-to-target patient plans, case conference led by a psychiatrist, and a patient registry for tracking patients and facilitating case conference.

2.3.4 *Study populations and recruitment:*

We included two different study populations to gain a comprehensive picture of the anticipated barriers and facilitators to implementing COCM: Max Clinic stakeholders and currently enrolled Max Clinic patients.

We used purposive criterion sampling (i. current employment at the Max Clinic during the formative evaluation study period which immediately preceded COCM implementation and/or ii. direct involvement in COCM planning and employment by one of the Max Clinic's partners – the Public Health – Seattle & King County Sexual Health Clinic where the Max Clinic is co-located or the Madison Clinic at Harborview Medical Center, which offers medical care

and social services for PWH) to create a sampling frame of all potential stakeholder participants.(93) We then exhaustively recruited all 15 stakeholder participants from the sampling frame. Two of the stakeholders participated in a pilot interview to refine the data collection instrument and were not included in the analysis. All stakeholders were invited to participate via email and none declined to participate, receiving a $20 e-gift card.

For currently enrolled Max Clinic patients, we used a two-stage, iterative sampling process.(94) In the first stage we used purposive criterion sampling including patients with an existing diagnosis of depression and/or OUD and excluding patients with an existing diagnosis of schizophrenia spectrum – considering that they would not be eligible for COCM as this diagnosis is exclusionary – to create a sampling frame prior to conveniently sampling from among those patients during a walk-in visit to the Max Clinic. A current Max Clinic staff member associated with the patient's care delivery – either a medical or non-medical case manager – approached potential patient participants face-to-face in an examination room with an invitation to the interview. We recruited 12 participants during this first stage who received $50 cash in compensation.

After we achieved thematic meaning saturation(95) in the analysis (see Data analysis subsection below), we presented our sample back to the Max Clinic medical and non-medical case managers to examine if and how our patient characteristics compare with the overall composition of Max Clinic patients. In response, we then used purposive stratified sampling based on socio-demographic strata (gender, race, and indigeneity) and disease condition (depression and OUD) to recruit three more patient participants, bringing the total sample to 15.(93) Eligible patient participants were approached by either a medical or non-medical case manager when visiting the Max Clinic. We did not keep track of how many participants declined

to participate in the study, but we anecdotally observed some participants who declined citing time constraints and other priorities when visiting the clinic.

2.3.5 *Ethics:*

This study was approved by the Human Subjects Division at the University of Washington (STUDY00010501). Due to COVID-19-related precautions during the study, stakeholder participants were consented electronically using the e-consent survey feature available in a Research Electronic Data Capture (REDcap) questionnaire.(96) REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. The participants had the opportunity to ask questions, understanding was verified, and the consent was confirmed during a concurrent, online meeting held via Zoom with the interviewer. For patient participants, either the research assistant (RA; SH) or the Behavioral Health Care Manager (BH CM) took written consent in a patient examination room at the Max Clinic or at the Sexual Health Clinic at Harborview Medical Center. For both participant groups, the consent included a provision to use de-identified quotes for publication purposes.

2.3.6 *Data collection:*

The RA and the BH CM conducted semi-structured, individual in-depth interviews with both participant groups. We developed separate interview guides for each participant group (see Appendix C), focusing on domains of BH experiences, perceptions of COCM, anticipated

barriers and facilitators to implementing COCM, and adaptations to COCM that could improve the contextual fit. The stakeholders were involved in consensus meetings and had become gradually sensitized to COCM prior to implementation roll-out and were thus able to respond to interview questions about what they anticipated would be easy or challenging about COCM implementation. Patient participants were given a brief verbal overview of COCM at the start of the interview. During consensus meetings among research and program implementation team members prior to implementing COCM, we identified potential barriers and facilitators to implementing COCM and mapped them to CFIR domains.(64, 97) These were in turn incorporated into the interview guides as potential probes and into the codebook for use as in deductive coding (see Appendix B). Additionally, we used a constant comparison approach(98) by reviewing notes and preliminary themes to inform additional probes in the interview guides as data collection progressed. We piloted the interview guides with two stakeholders and one patient, resulting in minor modifications to question wording and clarification (pilot interviews were not included in analysis).

The stakeholder interviews were held over Zoom, recorded using the audio only function, and lasted a median length of 38 minutes. The patient interviews were recorded using an audio recorder and lasted a median length of 27 minutes. Both categories of interviews were conducted in English and field notes were written during the interviews. Audio files were transcribed by Rev.com and analyzed in Atlas.ti version 9.1.7.0. The study data were collected and managed using REDCap electronic data capture tools hosted at the Institute for Translational Health Sciences at the University of Washington.(96, 99) During both categories of interviews only the interviewer and participant were present.

2.3.7 *Analysis:*

We conducted a thematic analysis,(100) using a combination of deductive and inductive coding techniques(101) to explore the anticipated barriers and facilitators to implementing COCM at the Max Clinic. During the small group consensus meetings, we identified anticipated barriers and facilitators and after a brief literature review, we imported the corresponding CFIR domains and constructs (see Appendix B) from the CFIR qualitative guide as our preliminary codebook for deductive coding. We then used open coding to iteratively refine the codebook and to capture emergent barriers and facilitators that did not align with the CFIR codebook. We achieved code and meaning saturation(95) after approximately half of each participant category of interviews were coded. The first author independently coded all transcripts, and another colleague conducted a code review on a sub-sample of six interviews (patients: one patient with depression, one patient with OUD, and one patient with both conditions; stakeholders: one from each job category including medical case managers, non-medical case managers, and physicians) to consider additional codes. The first author also kept memos noting reflexivity and positionality, tracking emergent themes as coding progressed, and documenting codebook changes.

2.4 RESULTS

We conducted 13 semi-structured individual interviews with stakeholders and 16 with patient participants. Seven patient participants identified as white (non-Hispanic), four as Black or African American, three as Hispanic, and two as American Indian/Alaskan Native. The median age was 44 years (see Table 2.1). 12 patient participants identified as male, two as

female, and one as transgender. 15 patient participants were durably virally suppressed at their most recent laboratory visit prior to or at the time of the interview, while one was not.

Table 2.1 Descriptive characteristics of patient participants in formative interviews

	Overall (N=16)
Race and Ethnicity	
American Indian/Alaska Native	2 (12.5%)
Black	4 (25.0%)
Hispanic	3 (18.8%)
White (non-Hispanic)	7 (43.8%)
Age	
Less than 30 years	1 (6.3%)
30-39 years	5 (31.3%)
40-49 years	4 (25.0%)
50-59 years	4 (25.0%)
60 years or older	2 (12.5%)
Gender	
Cisgender woman	3 (18.8%)
Cisgender man	12 (75.0%)
Transgender woman	1 (6.3%)
Durable viral suppression (HIV viral load, c/ml)	
Suppressed (<200)	15 (93.8%)
Not suppressed (≥200)	1 (6.2%)

Table 2.2 Summary of anticipated barriers and facilitators to implementing COCM at the Max Clinic

CFIR Domain	CFIR Construct	CFIR Sub-Construct	Barriers/ facilitators in literature	Anticipated barriers/ facilitators at the Max Clinic		Implications on implementation strategies or adaptations to COCM
				Stakeholders	*Patients*	
Intervention Characteristics	Evidence Strength and Quality		Facilitator			
	Relative Advantage			Facilitator	Facilitator	
	Adaptability			Facilitator		*Implications on implementation strategies:* • Stakeholders stressed the importance of adapting COCM to improve contextual fit at the Max Clinic so adaptability was promoted in conjunction with small group consensus discussions as an implementation strategy.
	Complexity		Facilitator/ Barrier	Barrier		
	Design Quality & Packaging		Facilitator	Facilitator	Facilitator	
	Cost		Barrier			
Outer Setting	Patient Needs & Resources		Barrier	Barrier	Barrier	
	External Policies & Incentives		Barrier			
Inner Setting	Networks and Communication		Facilitator			
	Culture			Facilitator/ Barrier		
	Implementation Climate	Tension for Change		Facilitator	Facilitator	
		Compatibility	Facilitator	Facilitator/ Barrier		
		Relative Priority		Barrier		

	Readiness for Implementation	Available Resources	Facilitator/ Barrier	Barrier		*Adaptations to COCM:* • Adjusted proactive and systematic screening to a targeted screening by led by medical case managers to improve contextual fit.
		Leadership Engagement	Facilitator			
		Access to Knowledge/ Information	Facilitator/ Barrier	Facilitator/ Barrier		*Implications on implementation strategies:* • To alleviate stakeholder concerns about the potential lack of information about COCM implementation, small and large group consensus discussions were conducted as an implementation strategy.
Characteristics of Individuals	Self-Efficacy		Barrier			*Implications on implementation strategies:* • Care Manager's with low self-efficacy can be a barrier to implementation so we employed a multi-component training strategy and facilitated site visits.
	Individual Identification with Organization			Facilitator/ Barrier		
	Other Personal Attributes		Facilitator	Facilitator/ Barrier	Facilitator/ Barrier	*Implications on implementation strategies:* • Patients and stakeholders alike stressed the importance of the key attributes for the BH CM to successfully integrate at the Max Clinic and those attributes were subsequently emphasized in multiple implementation strategies: revision of professional roles, creation of a new clinical team, and staff training.
Process	Engaging		Facilitator			*Implications on implementation strategies:* • Strong patient and stakeholder engagement during the COCM planning and implementation processes facilitates

			implementation and so we chose to involve them as an implementation strategy.
	Champions	Facilitator	
	Reflecting and Evaluating	Facilitator	

Here we present seven emergent themes about the anticipated barriers and facilitators to implementing COCM with illustrative quotes. The notational system denotes participant category and diagnosis code(s) for patients, but other descriptors are not included due to the risk of re-identifying participants considering the small number of patients enrolled in care at the Max Clinic and the small number of stakeholders.

2.4.1 *There is a strong receptiveness to COCM because the integration of BH service delivery at the point-of-care is a favorable alternative to the standard referral process*

Patient participants continually reaffirmed their preference for receiving primary care services at the Max Clinic because it was a supportive and familiar clinical setting. This comfortability combined with the nature of the low-barrier care delivery model that is based on walk-in visits and which offers incentives, set the foundation for patient enthusiasm for co-locating BH services within the Max Clinic.

> I like coming here. I like coming in, seeing my case manager… Being HIV positive, I don't have a support system with that. And my family's not very supportive… Everyone's really welcoming. I feel like they're my support system. (Patient 10, depression)

> [COCM] sounds good… That's one of the biggest problems is being referred to places… [the] appointments and stuff like that [and] talking to somebody new… Coming in here and then having somebody I can talk to would be great. (Patient 4, depression and opioid-use disorder)

Many if not all patients we interviewed had prior or current experiences receiving BH services and so had familiarity with the care components of COCM for treating depression and/or OUD including counseling and medications. These patients linked their understanding of BH services with their preference to receive care in the well-known care delivery setting of the Max Clinic, which grounded a perception that COCM was a favorable alternative to the standard

referral pathways. Stakeholders echoed this sentiment and in turn connected their own observations of patients (lack of) engagement of BH services to signal why COCM was an acceptable alternative.

> From my experience, from other work, patients who exhibit mental health concerns and/or substance use really adjust better [and] thrive better when there's consistency in their support system, be it social and be it in their medical team… And to hear a patient say that a medical team is their family, even their community, that speaks wonder to how positive of an impact we have garnered from having a consistent, regular, I guess, therapeutic relationship with them. (Stakeholder 5)

> I think that what we're talking about here is much different [than the standard referral pathway] and probably will meet the need for folks that are just not able to engage at all in mental health [care] (Stakeholder 12)

A critical element of COCM's perceived acceptability and appropriateness in the context of low-barrier walk-in care is that the BH services would also be available on a walk-in basis. The difference between when a patient expresses interest in BH services in the context of seeing a familiar primary care provider or staff member at the Max Clinic and when they attend a referral (even if its walking across the street to another clinic at the hospital via a same-day appointment) represents a temporal, distal, or emotional gap that could be addressed by the immediacy of a co-located BH provider.

> I think the hard part is that those moments, when someone is actually really ready to sit down and talk about what's happening, are so few and far between, and if you don't hit that mark right on the head, then it's not going to work. (Stakeholder 11)

Thus the perception of COCM as having a relative advantage based on it's alignment with patient needs and the model of service delivery relative to the existing referral pathways foregrounded its appropriateness and potential acceptability to both patients and stakeholders alike.

2.4.2 *The challenges attendant to BH delivery for patients with complex needs in the context of low-barrier HIV care lessens but not overrides enthusiasm for COCM*

The standard of care for enrolled Max Clinic patients with depression and/or OUD was for providers to internally refer them within Harborview Medical Center to various outpatient clinics and the emergency department depending on the patient's acuity or to externally refer them to different BH providers. For patients with OUD, some Max Clinic physicians are wavered to prescribe buprenorphine. Some Max Clinic staff members have varying levels of familiarity and experience delivering brief mental health interventions and/or evidence-based counseling for patients with depression. But all staff members have experience and knowledge of helping Max Clinic patients navigate BH services and the attendant challenges for patients with complex social and medical needs.

Without exception, all patients we interviewed received BH services at some point in their lives. They recounted their positive and negative experiences receiving BH care, which in turn shaped what they were potentially looking for from a BH provider.

> Especially when you're in rehab like that, like you obviously have to take care of yourself, but it's also nice to have [a] connection with people… with your therapist or [other] individuals [receiving care]. (Patient 5, OUD)

> I've been [to] rehab twice for drug addictions. I relapsed both times afterwards… When I went to rehab, I was like "I really want to deal with my emotional stuff before rehab,"… but they just said, "No, you['ve] got to do rehab first." And it opens up a book ... opens up too much for me sometimes, so I don't know how to deal with it. (Patient 8, depression)

Patients appreciated having strong and positive interpersonal relationships with their care providers, valued providers who appreciated their complex histories of trauma and socio-economic challenges, and generally sought counseling to address their emotional health. Yet other patients recounted challenging experiences associated with past BH services. For example,

some patients identified instances where BH providers did not consider their socio-economic needs and the underlying risk factors for their addiction and/or mental illness, expressed frustration when there was a lack of care continuity, and recognized that BH care trajectories are rarely linear.

The Max stakeholders recognized that their clinic operates on a walk-in model without appointments, which makes it challenging to routinely follow-up with patients. The Max stakeholders also recognized that the clinic's incentivized program structure often results in patients having specific priorities for their (brief) visit to the clinic (e.g., to visit the laboratory for a blood draw to get an incentive or to visit a medical case manager about housing) which may be in competition with attending to the patient's BH needs. These factors that are unique to low-barrier care at the Max Clinic could make it challenging to engage patients in BH care.

While considering these factors, Max stakeholders also acknowledged the complexity of socio-economic and behavioral health challenges facing patients. These factors gave them realistic expectations for the scope of COCM given the complicated patient populations (in terms of socio-economic needs and comorbidities) served.

> There's so much trauma, like the trauma history, the substance use, the mental illness and then the complex medical needs, [and] the psychosocial barriers that our folks have… housing instability, is one of the major ones,… no income, legal involvement, the various medical needs, because it's not just like the HIV care, but so many other medical issues that our patients face. Social relationships like family. Disconnection from family, the stigma that folks face or that they live with… There's so many different pieces that oftentimes we're just tending to the immediate like crisis needs. So, it's a challenge… (Stakeholder 8)

The Max Clinic stakeholders thus appreciated the (potentially) limited extent to which BH care via COCM could impact on these complex needs. Thus, the stakeholders located their measured optimism for COCM both within an understanding of the context of the upstream socio-economic factors and complicated comorbidities that make delivering BH care

challenging. Their understanding of the anticipated challenges associated with BH delivery was a barrier to implementation, which lay at the intersection of COCM's relative priority compared to other services, the complexity of patients' socio-economic needs, and the available time and human resources at the clinic.

2.4.3 *The practical inner setting challenges overshadow the facilitators to implementing COCM, but are surmountable with adaptations to improve contextual fit*

Depending on their job position, other Max Clinic stakeholders besides the BH CM would primarily be involved in COCM by recruiting and screening potential patients, managing care handoffs to the BH care manager for referred patients, and consulting on care management plans. The stakeholders generally anticipated that COCM would be feasible to implement.

> Yeah, it's worth it to try [and implement COCM]. Definitely, I think it will [be feasible to implement]... Personally, I think it will be great… I think it will be really good, really helpful for all of us. (Stakeholder 3)

However, all staff emphasized the importance of a team-based approach to care delivery and were keenly aware of the dynamic of layering a new team member and a new program into the existing Max Clinic workflows and systems. Consequently, stakeholders identified multiple resource constraints and practical challenges specific to the inner delivery setting at the Max Clinic that they anticipated would be relevant to implementing COCM.

> One issue is hard that [the Max Clinic] share[s] a space with the [Public Health – Seattle & King County] Sexual Health Clinic… we've been working for three plus years to try to identify another space for [the] Max Clinic… anytime you add another [staff member] to the clinic, it's a strain on our space limitations. (Stakeholder 4)

The Max Clinic has access to three examination rooms within the Sexual Health Clinic and all COCM program components would be delivered within the existing rooms rather than in

an additional room. Stakeholders, being cognizant of the duration of COCM program components including counseling and the Max Clinic's walk-in model, were concerned that implementing COCM will cause disruptions, especially during times when multiple patients present to the clinic simultaneously, thus causing backlogs and the resulting potential for frustrated patients.

> If we are taking the time to really work with our patients, to do the PHQ-9 [Patient Health Questionnaire-9], or do this assessment, there will be that backlog of other patients waiting to be seen… That's going to be a major thing. A backlog create[es a] sense of [feeling] overwhelm[ed] and trying to attend to those that are waiting, their anxieties and wanting to be seen and get their incentive and their frustration. So, being able to handle that. That might not always come out in a positive and healthy way in [the patient's] interactions with staff. (Stakeholder 8)

> The Max Clinic is a walk-in clinic. So, we don't know when patients are going to come. And sometimes… we don't see patients for the whole morning. And then, all of a sudden, within one or two hours, we see five or six patients showing up. (Stakeholder 9)

Echoing some concerns brought forth by patient participants, other stakeholders recognized that the trust-building process of establishing patient rapport varies between patients and can take substantial time, especially given the infrequent attendance of some patients at the Max Clinic. COCM was presented to the stakeholders as an approximately six-month, time-limited program for patients with depression, based on other implementations globally and general practice guidelines of seeing patients on average bimonthly.

> It's always difficult for our patients to open up to someone new… It's a very slow process. … I fear that there won't be enough time from an implementation standpoint to establish the relationship that will be needed in order for this to be effective for some of our patients. (Stakeholder 7)

Importantly, medical and non-medical case managers used two different electronic record systems for documenting patient visits and care plans. This is a result of their employer being one of the two Max Clinic operating partner organizations, Public Health – Seattle & King

County and Harborview Medical Center respectively, despite administrative efforts to streamline access to records. “I think a lot of the difficulty will be from a practical standpoint. Working in two [electronic record] systems is annoying.” (Stakeholder 7)

Taken together, these practical challenges that were unique to the Max Clinic featured prominently in discussions about whether COCM would be feasible to implement. By comparison, stakeholders did not emphasize as strongly characteristics about COCM, such as its evidence base or relative advantage over alternative interventions which were perceived to facilitate implementation, nor were key descriptions of the inner implementation setting at the Max Clinic like the organizational culture of addressing structural barriers to patient engagement in (HIV) care as prominently emphasized.

Yet, the stakeholders did not anticipate these barriers as insurmountable. With the right adaptations and approaching the implementation process with a willingness to be flexible, the Max Clinic stakeholders anticipated that COCM would be feasible to implement.

> One of the things that has made Max Clinic successful is the ability to adapt and be flexible… [On whether or not COCM seemed feasible to implement at the Max Clinic:] Yeah. I think so. There'll be a lot of growing pains in the beginning to understand the roles as any new program experiences. But I think that once we figure it out, it will be successful and helpful and useful. (Stakeholder 8)

2.4.4 *Concerns about intertwined internal communication systems and role clarity partially temper optimism for implementing COCM*

COCM includes multiple inter-related structural and process components that are central to the intervention. These include but are not limited to): task-shifting BH delivery to a new, non-physician BH CM; measurement-based care for patients with depression as indicated by PHQ-9 scores; proactive and systematic patient identification and referral; and a weekly case

review involving the BH CM, a primary care physician, and a consultant psychiatrist. Stakeholders did not anticipate the individual intervention components as overly burdensome. But delivering them together and integrating them alongside primary care and wrap-around socio-economic interventions administered by the clinic was perceived as something that will be both important and challenging. The stakeholders located their perceptions within the context of ongoing challenges facing the clinic in developing strong communication systems and role clarity issues surrounding the different cadres of staff.

> [The] Max Clinic originated as kind of a marriage between Public Health [- Seattle & King County] and Harborview [Medical Center]. And I think that there is a lot of strength that comes from that… [in what] they bring. I think that has also been one of the primary challenges is that we are fundamentally in two different systems, right?... having things really either written out or clear to all team members and then also being able to update and adapt as things need to be [will be important for implementing COCM]. (Stakeholder 12)

> I think an important thing to do would be to set that up straight away, this is what communication looks like, this is how we're going to do it... We're supposed to be a team, so let's communicate like a team. That's going to be important as you implement something new in the Max Clinic with the staff. (Stakeholder 11)

These questions around role clarity and communication related to different aspects of COCM. Who would systematically and proactively identify eligible patients via screening? Considering that patients may present to the clinic for a laboratory visit in pursuit of collecting an incentive for achieving viral suppression, for a meeting with a case manager about housing, or for seeing a physician about their medical needs, the patient's first and potentially only point-of-contact during a visit to the clinic could be any one of the three different staff roles. Should all of the staff do the screening? Given the severity and at times acuity of the patient's mental health needs, having a staff member (who is doing the screening) trained in administering a suicide assessment was an essential safety measure. Considering that patients may have differing levels

of trust, rapport, and comfortability with opening up to various staff members, what should the screening process look like when the person with whom the patient has the strongest relationship with is unavailable for screening? What should be done if a patient who, having screened eligible and expressed interest in COCM, cannot meet with the BH CM for an intake and assessment because they are busy, are absent, or cannot access an open examination room (and due to the nature of the walk-in clinic model with sporadic patient attendance, they may not be able to easily return to the clinic at a different time)? And what will a warm handoff look like between a staff member with whom the patient is comfortable discussing their behavioral health needs with and the BH care manager?

These questions animated discussions about role clarity and communication regarding implementing COCM. In general, and like the practical challenges mentioned in the previous section above, these questions were not seen as insurmountable. However, these questions about role clarity and communication were wrapped up in long-standing perceptions of the working culture at the Max Clinic.

> I think because of that fundamental or maybe inherent division and team… [between Public Health – Seattle & King County and Harborview Medical Center] the Max Clinic again is pretty innovative. [But] process has not been a strength of the Max Clinic. And I think what has happened is, we lay it. And then we think about process afterwards and there's a lot of confusion. Sometimes toes feel like they're stepped on afterwards. (Stakeholder 12)

While some stakeholders viewed the Max Clinic as aspirational by innovating to engage PWH in care and solving for structural barriers to patient access, sometimes this came at the expense of solidifying workflow processes and clearly communicating roles.

2.4.5 *The understanding of patient needs and resources does not facilitate implementation, but rather underscores a realistic outlook and scope for COCM*

Stakeholders at the Max Clinic felt strongly about the importance of the connection between healthcare delivery as a response to acute and chronic medical needs, and the upstream social determinants of health. Indeed, the Max Clinic's operating model, as a walk-in clinic with various incentive and outreach programs, is designed in response to the various patient socio-economic needs to reduce barriers to accessing care. While COCM was selected for implementation to address underserved behavioral health needs and to reduce the structural barriers to accessing care for depression and OUD among the Max's patient populations, the stakeholders articulated the importance of implementing COCM relative to these socio-economic needs.

> The things that prevent our folks from engaging in mental health care are beyond the scope of this clinic. They're systems of oppression, not having a home, not having access to food, not having income. Then, add on top of that severe mental illness and substance use disorder[s]… Even though [behavioral health is] obviously a priority for us as their care team and it's something we definitely want to improve upon, it's often just not the first thing our patients think of… [but] I do think having [BH] integrated [via COCM] would be certainly better than trying to refer out. (Stakeholder 6)

The Max Clinic stakeholders are very knowledgeable about their patient's needs and spend considerable resources towards accommodating them. This includes, but is not limited to, finding housing for those experiencing housing instability and coordinating with various case workers and managers from different social service providers. These efforts are central to HIV medication adherence and improved engagement in HIV care delivery. So, while the Max stakeholders commanded a strong knowledge of patients' BH needs, which included care for depression and OUD, the importance of these BH needs were measured relative to the patients' socio-economic needs.

Furthermore, the Max Clinic stakeholders recognized the stigma associated with living with HIV and the stigma attached with depression and substance use.

> Of course having HIV is very stigmatizing, additionally, mental illness, homelessness, substance use. All of it can really lead to an exacerbation of pre-existing mental health conditions or development of mental health conditions themselves… Because we're working with such a unique population that has such difficulty with engaging in services due to all of those oppressive factors, it's really difficult to actually assist them in engaging in mental health. (Stakeholder 7)

Taking these factors together, the stakeholders expressed their measured optimism for COCM. Rather than this comprehensive understanding of patient needs being a factor that facilitates implementation – an enabling factor where COCM has been identified as a well-suited intervention in response to patient needs – it was instead something that rendered their perception of COCM as being modest in scope.

2.4.6 *A tension between the appropriateness of COCM, alternative interventions, and the need to start somewhere animates COCM implementation discussions*

All the Max Clinic stakeholders recognized the importance of treating depression and OUD, but not all believed them to be the most prevalent and/or the highest priority behavioral health conditions. “Trauma, depression,… schizophrenia,… [and] bipolar disorders are the main [forms of mental illness, while] most patients use methamphetamines.” (Stakeholder 9) But whereas there was general optimism and receptiveness for COCM as an intervention, some Max Clinic stakeholders had mixed opinions on the appropriateness of COCM given the burden of disease among the Max Clinic patient populations. For one stakeholder, this concern intersected with the evidence-base for COCM and how it compared with other interventions considering these complex patient healthcare needs.

> [COCM] works best for patients with single morbidities. I don't know if [COCM] would work as well for people with multiple comorbidities... I think often times simply supporting the patient enough so that they're willing to try an addiction treatment [specialist] with a more traditional IOP (intensive outpatient program) would probably be most helpful. In other words, that [BH CM] is not going to provide everything for that patient. (Stakeholder 10)

Considering this, how many patients could benefit from COCM given that these common co-occurring conditions may be part of COCM's exclusion criteria once the Max Clinic begins implementation? For example, patients diagnosed with depression and who experience psychosis (or those with a concurrent schizophrenia diagnosis) are typically excluded from COCM. This is due to the lack of valid clinical self-report scales for screening for schizophrenia spectrum and psychosis (and in turn the lack of a consistently accepted scale to use for measurement-based care) and the challenges of delivering evidence-based psychotherapy for people with psychosis and schizophrenia spectrum in primary care settings. This is further complicated when episodes of psychosis are induced by substances, especially methamphetamine. Even after accounting for patients without a history of psychoses, or a diagnosis on the schizophrenia spectrum, and patients who did not endorse self-endorse using methamphetamine, the burden of moderate to severe depression was still considered high. Bearing this mind, some stakeholders had reservations about the appropriateness of COCM for eligible patients since the psychotherapeutic intervention for treating depression – in this case, Behavioral Activation – was intended to be time-limited to approximately six months in duration.

> Probably methamphetamine is the biggest substance abuse problem [that the Max Clinic] confront[s], but our interventions are not good for them… If we can do a better job in treating some of the mental illnesses and substance use disorders [via COCM compared to the standard of care referral pathways], I'm supportive of doing that. (Stakeholder 13)

> [For] patients that have severe [mental health] issues, [I think] that three or six months will not be enough [treatment]. For the population that we have over here at the Max

> [Clinic], I believe the short-term therapy like three or six months probably would not be ideal for them. (Stakeholder 9)

These concerns intersected with questions around prioritizing patient needs and meeting patients where they are.

> [Previously, the hepatitis C program] was really successful because patients were constantly asking us like, “Hey, I want to get my hep C treated. I just don't have a place to store my hep C meds safely.” It's like, "Oh, we can address that. We can store your meds here." But I don't hear patients as eagerly saying, "Oh, I want to address all my trauma and mental health care." So, that's just where my hesitations lie. But I think it's a great idea. (Stakeholder 6)

Thus, the stakeholders in general felt that while BH was important for patients, it might not always have been the most important felt need or the most acute medical priority for them. However, patient participants generally stated that addressing their BH needs were important priorities. “I feel like [taking care of my mental health is] a huge priority… I do think it's important, I do feel like I should start speaking [with] somebody.” (Patient 16, depression)

In the absence of more robust interventions to address methamphetamine use and in the context of the limitations of the existing standard-of-care referral pathways for treating schizophrenia spectrum, the stakeholders recognized the potential for COCM to improve upon treatment for depression and OUD. Although several stakeholders identified that COCM did not directly align with these high burden needs, this did not fully dissuade their interests in implementing COCM. “You don't need to be able to solve them all.” (Stakeholder 13) This practical approach, of chipping away at the burden of disease where possible via COCM, buoyed staff interest to implement.

2.5 Discussion

We found that both patient and service-delivery stakeholder participants were receptive to the idea of integrating care for depression and OUD by implementing COCM, thus

underscoring a perception of the intervention being appropriate for the Max Clinic. Patients highlighted the positive elements of how low-barrier care is delivered at the Max Clinic. When taken together with stakeholder feedback on the anticipated logistical and practical concerns about COCM implementation, this led to identification of potential adaptations to both the intervention and implementation strategy to improve the contextual fit of COCM at the Max Clinic. Compared to other primary care settings where COCM has been implemented, Max Clinic patients generally have extensive experience receiving BH services. The stakeholders knew this and were cognizant of the challenges attendant to delivering BH and sustaining engagement in BH for Max Clinic patients. The stakeholders thus engendered a tempered perspective about COCM's potential to improve patient clinical outcomes, which was located in an understanding of these elements.

Our research builds on the existing literature discussing the determinants of implementing COCM. The importance of co-location of the BH care manager and primary care providers for treating depression and anxiety has been well-documented as an important facilitator for implementing COCM in other settings,(67, 77-80) thus underscoring its importance for its appropriateness in the context of the Max Clinic. Other COCM implementations similarly focus on the relevance of clearly specifying roles and responsibilities as a facilitator (or the lack thereof as a barrier)(63, 65, 67, 68) given COCM's perceived complexity as a multi-component intervention that includes team restructuring.(69-72) This is particularly salient in clinical settings that feature multiple medical and non-medical staff working collaboratively together,(40) and in under-resourced primary care settings, such as the community mental health providers who implemented COCM as part of a hurricane disaster

response in New Orleans.(81) Max Clinic stakeholders anticipated physical(54, 67, 78) and time constraints(77, 79, 82) similar to key barriers observed in other COCM implementation settings.

Whereas we did not observe any differences in the appropriateness of COCM among stakeholders comparing patients with depression versus OUD, obtaining physician buy-in to treating OUD in primary care settings has been a barrier in other settings. This discrepancy could be due to the existing familiarity with buprenorphine among Max Clinic stakeholders and their overall favorable impression of harm reduction strategies. For patient participants who were familiar with buprenorphine and/or other medications for treating OUD, their experience could either be a facilitator or a barrier to their anticipated acceptability. But regardless, patients and stakeholders alike had a more concrete understanding of what the BH CM's role will be in COCM for buprenorphine medication management and thus complexity was less salient of a determinant compared to the patients with depression.

Together, these determinants form an understanding of what may uniquely impact delivery of COCM for patients with depression and/or OUD in a low-barrier HIV clinic setting. While many of these determinants correspond to existing constructs within established CFIR domains, both patients and stakeholders alike located their impressions of the appropriateness of COCM within broader discourses of trauma and harm reduction. They also framed COCM's potential reach and effectiveness in relation to the importance of the social determinants of health given the diverse and largely low socioeconomic positions of the Max Clinic patient populations. For example, patient needs and resources is often conceptualized as a construct in the implementation science literature based on the implementer'(s) relative degree of understanding (i.e., a greater understanding of patient needs and resources is on average more likely to facilitate better implementation outcomes).(64, 102) But in the Max Clinic's case, the understanding of the

extensive socio-economic needs of patients intersected with their (often challenging) prior experiences delivering or receiving other BH services, which in turn shaped their appraisal of COCM. Likewise, the stakeholders framed the importance of trauma and harm reduction not simply as organizational values with which COCM needs to align with for successful implementation, but as overarching factors that will shape the quality of care and in turn, patient's receptivity to COCM. Patients discussed the trauma, abuse, and varying degrees of success associated with prior BH services in articulate ways that highlighted how these experiences are a crucial intermediate to uptake and interest in COCM in these patient populations.

Our findings align other COCM implementations which describe the comparative challenges of engaging patients with complex socio-economic needs.(69, 74, 75, 78) In clinical settings with racial, ethnic, and linguistically diverse patient populations, some studies have specifically recommended BH CMs with Masters of Social Work credentials, who may have training and experience in delivering social service case management support, are familiar with multiple forms of psychotherapy, and are competent in recognizing various cultural-linguistic idioms of distress.(69, 74, 103-105) Our results also necessitate critical reflection about the utility of determinant frameworks like the CFIR that emphasize organizational level implementation factors, which while helpful, did not fully explain the larger socio-ecological levels that not only affect healthcare patterns of resort, but also intersect with proximal implementation factors.

2.5.1 *Limitations*

Our study has several important limitations. By using a convenient sampling approach without proactive outreach by Max Clinic staff during a limited study period due to time

restraints, we may have selected patient participants who were comparatively more engaged in care at that time. Correspondingly as Table 2.1 demonstrates, 94% of patient participants were virally suppressed at the time of the interview (which is not reflective of the total Max Clinic active patient population which is approximately 55% virally suppressed), thus missing out on a key variant characteristic for which viewpoints would have been important. We also only used a minimal amount of patient participant demographics using routinely collected programmatic data, which may have impacted our ability to see variation of responses across other key descriptive variables (e.g., housing status, incarceration, and other behavioral health conditions). Stakeholders noted that, due to the incentives offered at the Max Clinic, some patient participants may not have been able to distinguish between the compensation offered for participating in the research interview versus an incentive for care delivery. Similarly, some patient participants who interviewed with the CM may have been confused, despite the informed consent process, over whether the research interview was actually part of enrolling in COCM. Furthermore, there may be some social desirability bias in the patient interview responses. There may have been interviewer/researcher bias as one interviewer (BH CM) was directly employed by the same clinical organization that will be implementing COCM and the other, despite not being directly employed by the implementing site, was closely affiliated with implementation. Given that there was only one site for the research study, we did not perform quantitative rankings of valence or strength for the anticipated determinants we identified.(106) We only used a single coder during the analysis due to resource constraints, which may have limited the breadth and depth of themes identified during the analysis. We attempted to address this concern by using a second author to do a code review on a subset of interview transcripts and by discussing the emergent themes with

three authors. The use of a single coder also precluded doing valence ratings on the anticipated CFIR barriers and facilitator we identified.

2.6 CONCLUSION

In this qualitative formative evaluation, we identified the anticipated barriers and facilitators to implementing COCM for patients with depression and/or OUD at a low-barrier HIV clinic. Both patients and stakeholders alike expressed a strong receptiveness to COCM, indicating its overall appropriateness as an intervention designed to respond to the BH needs of Max Clinic patients within the context of low-barrier HIV care delivery. Among stakeholders this optimism was tempered, but not completely diminished, by practical concerns around the availability of resources and intervention fit within the low-barrier HIV care delivery model as well COCM's appropriateness given the burden of disease and social determinants of health.

Chapter 3. INTEGRATING CARE FOR DEPRESSION AND OPIOID USE DISORDER USING THE COLLABORATIVE CARE MODEL IN A LOW-BARRIER HIV CLINIC: A MIXED METHODS EVALUATION OF FEASIBILITY AND ACCEPTABILITY

3.1 ABSTRACT

Introduction: People with HIV face a disproportionate burden of mental illness and substance use disorders. Low-barrier HIV care delivery models, which feature wrap-around supportive services, incentive programs, and walk-in access for primary care, have demonstrated potential at improving rates of viral suppression among the hardest-to-reach people with HIV in the United States. Overcoming insufficient access to behavioral healthcare is essential to improving HIV treatment adherence and represents a key delivery gap in low-barrier HIV care.

Methods: We evaluated the acceptability and feasibility of integrating care for depression and opioid use disorder for people with HIV in a low-barrier clinic in Seattle, Washington in this sequential explanatory (QUANT->qual) mixed methods study. We accessed data from the patient's electronic health and programmatic records to create a descriptive care cascade with the following steps: patients with one or more visits during the May-October 2021 enrollment period, screening, referral to the Collaborative Care Model, intake for the Collaborative Care Model, and engagement in the Collaborative Care Model. We compare rates of viral suppression at each of the steps and we assessed the implementation outcomes of acceptability, feasibility, and appropriateness. These care cascade results were presented to both service delivery stakeholders and patients to interpret the elements associated with progression through the care

cascade and analyzed the data using deductive coding, informed by the Consolidated Framework for Implementation Research, and inductive coding approaches via a thematic analysis.

Results: Among 175 eligible patients, 36% of patients were screened, 24% were referred, 15% completed an intake, and 9% progressed to the engaged step of the Collaborative Care Model cascade. The most important factors associated with progression through these steps were, respectively: a lack of clarity among staff about the Collaborative Care Model services being offered, staff forgetfulness of the screening process, and limited time during patent visits, which hindered completing screenings; low staff buy-in and patient complexity reduced referrals; the constraints of low-barrier care and acute patient needs limited intakes; and the behavioral health care manager's alignment with the clinic's culture and values facilitated engagement among patients. Participants found the Collaborative Care Model acceptable and feasible to implement, but only in the context of key adaptations to the proactive systematic screening process and measurement-based care intervention components to improve contextual fit and in the context of multiple barriers to implementation including behavioral health care manager's self-efficacy, compatibility with low-barrier care, and complexity.

Conclusion: Our findings show that to be acceptable and feasible to implement in a low-barrier HIV clinic, the Collaborative Care Model needs adaptations to multiple core components.

3.2 INTRODUCTION

Despite continued progress nationally towards improving rates of viral suppression over the past few decades,(4) some people with HIV (PWH) face disproportionately more barriers to adhering to HIV treatment. Of the estimated 7,364 PWH in King County, Washington in 2021, approximately 600-900 were not virally suppressed.(107) Rates of behavioral health conditions

including mental illness and substance use disorders among the virally unsuppressed are on average higher(84-86) and these conditions co-occur alongside complex socioeconomic needs like housing instability, incarceration, food insecurity, and a lack of employment.(7-9)

The Max Clinic at Harborview Medical Center in Seattle, Washington is a low-barrier HIV clinic. Low-barrier HIV care address systems-related factors that traditionally make engaging in care services difficult for virally unsuppressed PWH. By offering walk-in primary and HIV care, supportive case management, wrap-around social services, and incentives for laboratory visits and achieving viral suppression, low-barrier HIV care has shown evidence at improving rates of viral suppression among these 'hardest-to-reach' PWH.(11, 12) The standard-of-care for providing behavioral healthcare (BH) to these patients has been to refer out to specialists, which may lead to care fragmentation.(13, 87) A recent chart review at the Max Clinic showed that among their currently enrolled patients, only 33% of those referred for psychiatric services and 40% of those referred for opioid use disorder (OUD) treatment ever made a single visit.(92)

To address gaps in access to BH typically associated with such referral pathways, the Collaborative Care Model (COCM) was developed based on the Chronic Care Model (88) using a task-shifted non-physician BH Care Manager (BH CM) integrated within an existing primary care team. Together, the team proactively and systematically screens patients, provides measurement-based treatment to target, and offers evidence-based psychosocial and pharmacologic treatments. To date, COCM has over 80 randomized control trials worth of supporting evidence,(13, 18, 41, 42, 89) yet it's slow uptake into routine care delivery nationwide represents a paradigmatic example of the 'know-do' gap that animates the field of implementation science.(108) Despite being used in Veterans Administration Health System

outpatient HIV clinics, COCM has not, to our understanding, been implemented in a low-barrier HIV care environment.(73)

The numerous contextual factors associated with implementing COCM, also known as the barriers or facilitators to implementation, can help illuminate some of the reasons behind the slow uptake of COCM. According to a qualitative systematic review of the determinants of implementing COCM, these factors span multiple domains of implementation.(60, 63, 64) Despite the fact that COCM's robust evidence base generally facilitates implementation,(65) it's also perceived as complex due to its multiple components, which in turn can lead to role confusion.(63, 65, 67-72) In clinical settings where there is a large population of patients with complex socio-economic needs and BH comorbidities, it can be challenging to maintain patient engagement in COCM.(73-75) Whereas onsite co-location of the BH CM, robust communication systems, and access to educational resources for the BH CM facilitated COCM implementation, other clinical sites have noted a lack of sufficient space, human, and other resources as important barriers to implementing COCM.(35, 37, 38, 40, 54, 67, 76-82) In instances of COCM implementation for OUD, obtaining primary care physicians to buy-in to COCM and to get wavered to prescribe buprenorphine was a barrier to implementation.(35, 37, 40) BH CMs often report low self-efficacy to deliver various COCM components which can be a critical barrier to implementation, while access to information and resources to track patient progress and find out about patient success stories helped facilitate implementation.(65, 76)

We conducted a mixed methods evaluation of implementing COCM for depression and OUD in a low-barrier HIV clinic in Seattle, Washington. We quantitatively described a care cascade for patients participating in COCM as part of standard-of-care and then blend illustrative and emergent themes from qualitative interviews to explain the elements associated with

progression through the care cascade. We also descriptively analyze acceptability, feasibility, appropriateness, and organizational readiness data to contextualize our findings, present preliminary effectiveness data on rates of viral suppression, and qualitatively examine both the barriers and facilitators to implementing COCM as well as elements perceived to be associated with its sustainment.

3.3 METHODS

3.3.1 *Study design:*

We conducted an explanatory, sequential (QUANT->qual) mixed methods evaluation of the acceptability and feasibility of integrating care for depression and OUD via COCM in a low-barrier HIV clinic.(109-111) We evaluated findings from the first 12 months of implementation. To our knowledge, care cascades have not been previously used to describe COCM implementation, but they are widely used in HIV programming (such as the 90-90-90 targets: 90% of PWH know their status, 90% of those are initiated on antiretrovirals, and 90% of those are virally suppressed),(112-114) they are increasingly being used in the field of mental health,(115-119) and there is an OUD care cascade.(120) One novel cascade characterizes the steps for PWH with comorbid depression as follows: diagnosis (of depression), treatment initiation, guideline-concordant treatment adjustment, and remission.(121) Our study design, methods, and analytic approach are shaped by our identities, the implications of which are summarized in Appendix A.

COCM is an example of an integrated BH intervention that has expanded access to care for patients with depression and OUD (via the Office Based Opioid Treatment program),(35-40) with over 80 randomized controlled trials of peer-reviewed evidence.(14, 18, 36, 41-43)

Although various definitions of COCM exist,(44) we define it based on the following core intervention components: proactive and systematic screening, task-shifting using a non-physician BH care manager, delivery of evidence-based medications and psychotherapy, measurement-based treatment-to-target patient plans, case conference led by a psychiatrist, and a patient registry for tracking patients and facilitating case conference.

We employed a multi-component implementation strategy created by the Advancing Integrated Mental Health Solutions (AIMS) Center at the University of Washington designed specifically for COCM.(122) Below we specify in Table 3.1, according to Proctor's recommendations for specifying implementation strategies,(61) the components which were selected prior to implementation based on the research team's prior experience implementing COCM in other settings.(61)

We first accessed programmatic and electronic patient records to create a care cascade describing patient engagement with the following steps: number of patients with one or more visits to the clinic during the enrollment period (May-October 2021), number of patients screened for COCM, number of patients referred for COCM, number of patients completing an intake for COCM, and number of patients actively engaged in COCM or involved in care coordination services through COCM at the conclusion of the one year post-implementation follow-up period (April 2022). We described the proportion of people who were virally suppressed at each step of the cascade and we also assessed the implementation outcomes of acceptability, feasibility, and appropriateness of COCM according to Proctor's taxonomy,(91, 123) as well as organizational readiness according to Weiner's theory of organizational readiness.(124, 125)

The care cascade was presented to both patients and Max Clinic staff members during individual in-depth interviews for interpretation (QUANT->qual) to elicit the elements associated with progression

Table 3.1 Specifying the multi-component AIMS Center implementation strategy for COCM

Domain	**Involve patients & stakeholders**	**Local consensus discussions**	**Technical assistance**	**BH CM training**	**Visiting other sites[1]**	**Conduct small tests of change**
Definition	Individual in-depth interviews to identify anticipated barriers and facilitators to implementation.	Small and large group meetings on implementation decisions, planning adaptations, and improving staff buy-in.	Longitudinal supervision for the BH CM and ongoing implementation support for delivery of COCM.	A multi-component, protocolized training for the BH CM in delivery of COCM.	BH CM visited other clinics implementing COCM to establish a professional network and to observe COCM being sustained.	Interactive problem-solving process to iteratively adapt COCM to improve its contextual fit at the Max Clinic and to improve implementation.
Actors	Research team[2]	Research team[2]	Research team[2] and external partners	Research team and external partners[2]	Research team and external partners[2]	Research team and representatives from the small group consensus meetings
Actions	Collect and analyze data and prepare discussion points for consensus discussions.	Hold meetings and operationalize feedback into implementation plan.	Use evidence, experience, and data to address implementation challenges.	Combination of self-paced online didactic training sessions and 1:1 skill development sessions.[3]	BH CM visited other clinics implementing COCM to meet other BH CMs and observe case reviews.	Continuous quality improvement to respond to BH CM, staff, and patient feedback.
Action target	Patients and Max Clinic stakeholders	Max Clinic stakeholders	BH CM and Max Clinic stakeholders	BH CM	BH CM	Max Clinic stakeholders
Temporality	Pre-implementation	Pre-implementation	Pre-implementation and implementation	Pre-implementation and implementation	Pre-implementation	Implementation
Dose	One 30–60-minute interview with each stakeholder and each purposely selected patients.[4]	*Small group:* three 1hr meetings. *Large group:* two 30min presentations.	Weekly 60 minute meetings in early implementation phase; decreasing frequency later.	Approximately three months of training in total.[3]	Three half day visits in other Harborview Medical Center clinics with COCM	Two quality improvement cycles resulted in targeted universal screening and adjusted care plans for patients.
Implementation outcomes targeted	Feasibility	Acceptability, feasibility, appropriateness	Fidelity, penetration	Fidelity	Fidelity	Feasibility, penetration, sustainability
Justification	All components of the multi-component AIMS Center implementation strategy for COCM were iteratively developed in conjunction with 20 years of implementation experience in response to implementation-related challenges. An observational study found that compared to low or basic levels of implementation support, healthcare settings implementing COCM for people with depression using the multi-component AIMS Center implementation strategy had better health outcomes.(126)					

1. Included the Adult Medicine Clinic and the Mental Health and Addiction Services Clinic at Harborview Medical Center.
2. Research team includes Principal Investigator (JD), study team University of Washington-affiliated co-investigators (Lydia Chwastiak, Judith Tsui, DR, and Kenneth Sherr, RA (SH), and BH CM (Ramona Emerson). External partners includes other stakeholders affiliated with the site clinics visited by the BH CM and/or stakeholders affiliated with the University of Washington Advancing Integrated Mental Health Solutions Center, which developed the training materials.
3. Includes: self-paced, 6-8 hour online, didactic AIMS course on epidemiology of depression, COCM evidence base, team member roles, and COCM components; 1:1 skill development sessions with research team on registry, measurement-based care, systematic case review, and Behavioral Activation; 6 hour suicide prevention course offered by University of Washington Department of Psychiatry and Behavioral Sciences for Washington State physicians; a refresher training in office-based opioid treatment; psychological intervention modules with a focus on motivational interviewing and distress tolerance; and overview of HIV treatment module.
4. See Chapter 3.3.2 for details of the sampling process

(or lack of progression) through the care cascade. As part of the qualitative strand, we also evaluated the barriers and facilitators to implementing COCM in low-barrier HIV care and the perceived elements associated with sustaining COCM at the Max Clinic and scaling COCM to other low-barrier HIV clinical settings. We then bring these two strands together into a unique joint visual display(109, 111) that presents illustrative quotes and summary themes of the elements associated with progression through the care cascade.

3.3.2 *Study setting:*

We conducted the mixed methods evaluation at the Max Clinic at Harborview Medical Center in Seattle, Washington. The Max Clinic is jointly operated by Harborview Medical Center and Public Health – Seattle & King County with support from the Washington State Department of Health, the Ryan White HIV/AIDS Program with the Health Resources & Services Administration, and the Ending the HIV Epidemic in the US Initiative with the Department of Health and Human Services. The Max Clinic serves the ‘hardest-to-reach’, virally

unsuppressed PWH who experience barriers to engaging in HIV care and are referred following re-engagement attempts from clinical and public health outreach workers. In response, the Max Clinic runs on a low-barrier care delivery model that features walk-in access to primary care providers; offers incentives including cash for completing laboratory visits and achieving viral suppression (RNA viral load <200 copies/ml), transportation passes, food vouchers, and clothes; and intensive medical and non-medical case management including housing assistance, care coordination, and other supportive services. PWH enrolled at the Max Clinic generally have complex medical needs and experience disproportionately high rates of mental illness, substance abuse, incarceration, and housing instability.(11, 12) The standard of care was referral to other BH providers either internal or external to Harborview Medical Center for patients with depression or patients with OUD, prescribing buprenorphine without more frequent and systematic medication adjustments by a non-physician provider, or referral to other internal and external BH providers including methadone clinics. Yet a retrospective chart review prior to implementing COCM, which corroborates staff experiences, found that less than 50% of referred patients ever completed a single BH visit,(92) thus underscoring the care delivery gap that motivated the Max Clinic team to consider integrating BH services via COCM.

3.3.3 *Study populations and recruitment:*

For this mixed methods evaluation, we included two separate, but related study populations to capture multiple viewpoints about COCM implementation at the Max Clinic: currently enrolled patients and staff members. In the quantitative strand of the study, patients were included exhaustively via a retrospective chart review (see Ethics 3.3.3 and Data Collection 3.3.4 below).

In both the quantitative and qualitative strands of the study, staff members were recruited using purposeful criterion sampling (directly employed at the Max Clinic during COCM implementation) to create a frame and then exhaustively sampled from the frame.(93) Two staff members declined an invitation for an individual in-depth interview and three staff members did not return completed questionnaires about acceptability, feasibility, appropriateness, or readiness.

In the qualitative strand of the study, currently enrolled patients were sampled using a two-stage process. First, we used stratified purposive sampling to create a sampling frame according to the steps of the care cascade (i.e., patients engaged in COCM, patients who completed an intake for COCM but were not engaged, etc.).(93) From among the frame, we then conveniently sampled patients during a walk-in visit to the Max Clinic, whereby a current Max Clinic staff member caring for the patient – either a medical or non-medical case manager – contacted eligible patient participants face-to-face in an examination room and offered the individual in-depth interview. We recruited 14 participants who received $50 cash in compensation. Although we did not observe any patient participants who explicitly declined participation in the qualitative strand of the study, we anecdotally observed that some patient participants chose not to pursue an interview after being offered and expressing interest, citing time constraints and other priorities when visiting the clinic.

3.3.4 *Ethics:*

This study was approved by the Human Subjects Division at the University of Washington (STUDY00010501). Due to COVID-19-related precautions during the study, staff members were consented electronically using the e-consent survey feature available in a

Research Electronic Data Capture (REDcap) questionnaire.(96) REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. The participants had the opportunity to ask questions, understanding was verified, and the consent was confirmed during a concurrent, online meeting held via Zoom with the interviewer. For patient participants, one of the two Ras (either SH or a different University of Washington graduate student) took written consent in a patient examination room at the Max Clinic or at the Sexual Health Clinic at Harborview Medical Center. For both participant groups, the consent included a provision to use de-identified quotes for publication purposes.

3.3.5 *Data collection:*

For the care cascade analysis in the quantitative strand, we retrospectively extracted patient data from the Max Clinic's electronic health record system and linked these with COCM programmatic records maintained in a REDCap database hosted at the Institute for Translational Health Sciences at the University of Washington used for this study.(96, 99) From the Max Clinic electronic health record (EHR) we accessed the following variables for patients: demographics (gender, age, race/ethnicity), viral load, prior mental health diagnoses and endorsements of substance use, incarceration status, and housing status.

The REDCap database contained data collection tools which featured standardized clinical assessments corresponding to each step of the care cascade (see Appendix C). The screening included the PHQ-2 (127) and those who scored a three or above would progress to a

PHQ-9 (128) as well as a modified version of the National Institute for Drug Administration (NIDA) Quick Screen for substance use disorders (129) that also sked about opioid use (heroin, Percocet, fentanyl, Vicodin, oxycodone, etc.). The intake included the PHQ-9, modified NIDA Quick Screen, and the Generalized Anxiety Disorder 7-item (GAD-7)(130), as well as questions about HIV viral load, previous diagnoses of other severe mental illnesses (dementia, severe cognitive impairment, and/or psychosis and schizophrenia spectrum), opioid use in the past 90 days, life expectancy, and an imminent safety risk assessment. For patients engaged in COCM and/or receiving care coordination services via the BH CM, the REDCap instrument contained the following: the PHQ-9; GAD-7; questions on self-reported opioid use, withdrawal symptoms, and cravings; the Clinical Opiate Withdrawal Scale (COWS);(131) last urine test date and results (which could be accessed electronically from the patient's electronic health record); information about medication for OUD coverage and refill dates; and information for the COCM case review including interventions performed, most recent viral load, and if the patient should be flagged for discussion. All patient data in REDCap were entered by the BH CM. The REDCap database also contained electronic versions of the Acceptability of Intervention Measure, Feasibility of Intervention Measure, Intervention Appropriateness Measure,(123) and Organizational Readiness for Implementing Change(125) (see Appendix C), which were emailed as surveys to stakeholders.

We developed separate interview guides (see Appendix C) for semi-structured, individual in-depth interviews with both participant groups. Each interview guide contained questions about the participant's general experience with COCM, questions about the elements associated with each step of the care cascade, questions about the barriers and facilitators to implementing COCM, and questions about the elements influencing sustainability or scale-up of COCM. Each

patient participant interview guide was adjusted based on their progression through the care cascade (e.g., patients who completed only the screening were not asked about the intake process). The interview guide contained probes to explore the validity of the anticipated barriers and facilitators identified during the formative evaluation. Lastly, we used a constant comparison approach(98) by reviewing notes and preliminary themes to inform additional probes in the interview guides as data collection progressed. We did not pilot the interview guides, but we did adjust question wording and order based on internal discussions with the study team after conducting the first few interviews.

The staff member interviews, which were held either over Zoom and recorded using the audio only function or were conducted in-person in a conference room or office and recorded using a hand-held recording device, lasted a median length of 54 minutes. The patient interviews were held in-person in a patient examination room either at the Max Clinic or at the Sexual Health Clinic at Harborview Medical Center (where the Max Clinic is located), recorded using a hand-held recording device, and lasted a median length of 26 minutes. Both categories of interviews were conducted in English and field notes were written during the interviews. Audio files were transcribed by Rev.com and analyzed in Dedoose version 9.0.83.(132) The study data were stored using REDCap electronic data capture tools hosted at the Institute for Translational Health Sciences at the University of Washington.(96, 99) During both categories of interviews only the interviewer and participant were present.

3.3.6 *Analysis:*

In addition to the descriptive care cascade, we evaluated changes in rates of viral suppression by cascade step for the quantitative strand. For all patients, we used their most recent viral load measurement concurrent with or immediately prior to the COCM enrollment period

(May 2021) as their baseline measure. For engaged patients, we compared their baseline to their last viral load measurement during the evaluation period (April 2022) and for patients who completed an intake but were not engaged in COCM, we compared values to the most recent viral load measurement available at the time of the analysis (September 2022). We used a threshold of 200 RNA HIV viral load copies per milliliter as an indicator for viral suppression as defined by the Centers for Disease Control and Prevention(133). In the quantitative strand of the analysis, we also descriptively summarized results of the implementation outcome assessments, disaggregated by the various sub-constructs.

In the qualitative strand of the analysis, we conducted a thematic analysis,(100) using both deductive and inductive coding techniques.(101) For identifying the factors associated with progression through the care cascade, we started with a-priori defined code groups associated with each cascade step and then used open coding to iteratively refine the codebook. For defining the barriers and facilitators to implementing COCM at the Max clinic, we imported the codes associated with the anticipated determinants identified in the formative evaluation (see Chapter 2) from the CFIR qualitative guide into a preliminary codebook for deductive coding. To explore factors associated with sustaining and scaling up COCM to other low-barrier HIV care settings, we exclusively used open coding. We achieved meaning saturation for identifying factors associated with progression across the care cascade after approximately half of the staff interviews and three quarters of the patient interviews.(95) We achieved meaning saturation for defining the determinants of implementing COCM at the Max Clinic and exploring factors associated with sustaining and scaling up COCM to other low-barrier HIV care settings after approximately three quarters of the staff interviews.(95)

The RA (SH) singly coded all interviews, keeping memos noting reflexivity and positionality, tracking emergent themes as coding progressed, and annotating codebook changes. We achieved meaning saturation for identifying factors associated with progression across the care cascade after approximately half of the staff interviews and three quarters of the patient interviews.(95) We achieved meaning saturation for defining the determinants of implementing COCM at the Max Clinic and exploring factors associated with sustaining and scaling up COCM to other low-barrier HIV care settings after approximately three quarters of the staff interviews.(95)

3.4 RESULTS

There were 175 patient participants that had at least one visit to the Max Clinic during the enrollment period (Table 3.2). The median age was 39.0 years and 71% were unstably housed.

Table 3.2. Descriptive characteristics of MAX Clinic patients during COCM enrollment period

	Overall (N=175)
Gender	
Cisgender man	117 (66.9%)
Cisgender woman	41 (23.4%)
Nonbinary, Genderqueer, or Other	3 (1.7%)
Transgender woman	8 (4.6%)
Unknown or Not Disclosed	6 (3.4%)
Age	
Less than 30 years	35 (20.0%)
30-39 years	54 (30.9%)
40-49 years	64 (36.6%)
50-59 years	19 (10.9%)
60 years or older	3 (1.71%)

	Overall (N=175)
Race and Ethnicity	
Black	44 (25.1%)
Hispanic	16 (9.1%)
Other	23 (13.1%)
White (non-Hispanic)	92 (52.6%)
Housing Status[1,2]	
Stable	51 (29.1%)
Unstable	124 (70.9%)
Injection Drug Use[2]	
Injection drug use	72 (41.1%)
No injection drug use	79 (45.1%)
Missing	24 (13.7%)
Substance Use[2,3]	
Methamphetamine	133 (76.0%)
Heroin	65 (37.1%)
Cocaine or crack cocaine	42 (24.0%)
Hazardous alcohol use	30 (17.1%)
Marijuana	86 (49.1%)
Prescription-type opioids	2 (1.1%)
Benzodiazepine	13 (7.4%)
No substance use	12 (6.9%)
Psychiatric diagnoses[2,3]	
Depression	115 (65.7%)
Bipolar or related disorders	35 (20.0%)
Anxiety	64 (36.6%)
PTSD	40 (22.9%)
Schizophrenia spectrum or other psychotic disorders	46 (26.3%)
Neurodevelopmental disorders (excluding ADD)	4 (2.3%)
ADD	12 (6.9%)
Personality disorders	10 (5.7%)
Feeding and eating disorders	4 (2.3%)

	Overall (N=175)
No psychiatric diagnosis	25 (14.3%)

[1]Unstable housing includes: sleeping outside, staying in a shelter, transitional housing (e.g. medical motel), or couch-surfing.
[2]Measured at the beginning of the study, approximately one year prior to the May-October 2021 enrollment period
[3]Not mutually exclusive as patient may endorse using multiple substances and/or have multiple psychiatric diagnoses.

3.4.1 *Quantitative results*

Of the 175 patients who had at least one visit to the Max Clinic during the May-October 2021 enrollment period 38% (67) had a prior diagnosis for moderate to severe depressive disorder, 20% (17) endorsed using opioids, and 27% (48) had both a prior depressive disorder diagnosis and endorsed using opioids based on a chart review done in June 2020, approximately one year before the enrollment period (Figure 3.1).

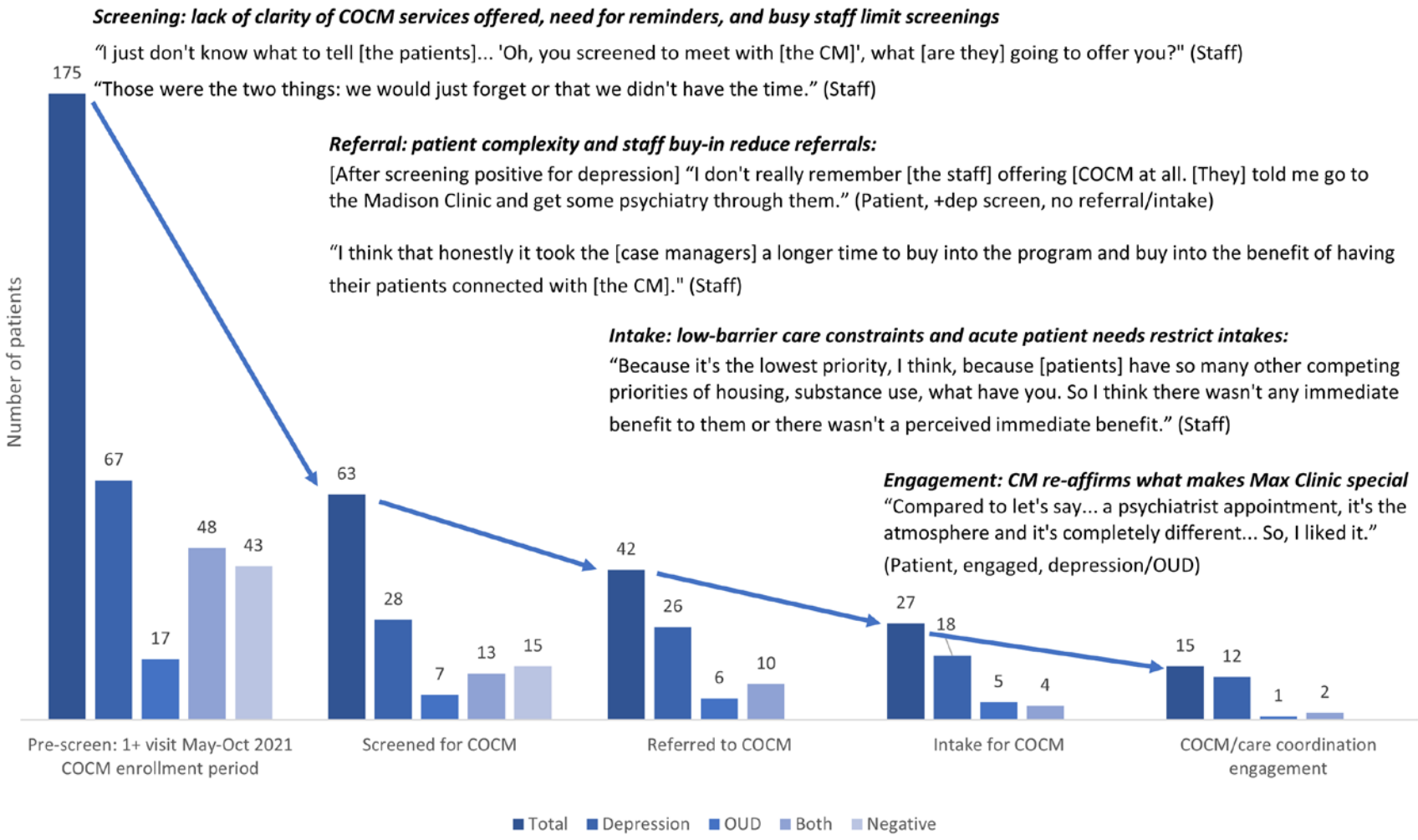

Figure 3.1. COCM Max Clinic Care Cascade with interpretive quotes and summaries of factors associated with progression

a. Each number represents the total number of patients at each cascade step and each step is denominator-denominator linked.(134)

b. We define the engagement step as initiating direct care services with the BH CM (including starting or adjusting an antidepressant medication and/or psychotherapy for patients with depression or starting a medication for OUD for patients with OUD) and/or coordinating BH care with another provider.
c. Six people who screened positive were not referred for an intake: four declined an offer for an intake and two were not referred by the screener.

Sixty-three patient participants were screened (36%) for COCM. 42% of those with a prior diagnosis for moderate to severe depressive disorder in the chart review screened positive for depression (28), 41% of those who previously endorsed using opioids also endorsed them during the screening for COCM (7), and 27% of those with both a prior depressive disorder diagnosis and who previously endorsed opioids screened positive for both (13). 24% of all patient participants (42) were referred for an intake for COCM, 39% of those with a prior depressive disorder diagnosis were referred (26), 35% of those who previously endorsed using opioids were referred (6), and 13% of those with both a prior depressive disorder diagnosis and who previously endorsed opioids were referred (10). 15% of all patient participants (27) completed an intake for COCM, 27% of those with a prior depressive disorder diagnosis completed an intake (18), 29% of those who previously endorsed using opioids completed an intake (6), and 8% of those with both a prior depressive disorder diagnosis and who previously endorsed opioids were referred (10). 9% of all patient participants (15) were engaged in COCM, 18% of those with a prior depressive disorder diagnosis were engaged (12), 6% of those who previously endorsed using opioids were engaged (1), and 4% of those with both a prior depressive disorder diagnosis and who previously endorsed opioids were engaged (10).

Figure 3.2.a below shows the number of patients virally suppressed and unsuppressed at baseline by care cascade step. 62% of the patients with one or more visit during the enrollment period (109) were virally suppressed, 67% of the patients who were screened were virally suppressed (42), 71% of the patients referred were virally suppressed (30), 70% of the patients completing an intake were virally suppressed (19), and 60% of the engaged patients were virally suppressed (9). Figure 3.2.b below shows the number of patients from the intake and engaged care cascade steps at endline: 59% of the patients completing an intake were virally suppressed

(16) and 53% of the engaged patients were virally suppressed (8). The median length of observation time between baseline and endline viral load measurements for the intake and engaged patients was 293 days (IQR: 248-367 days).

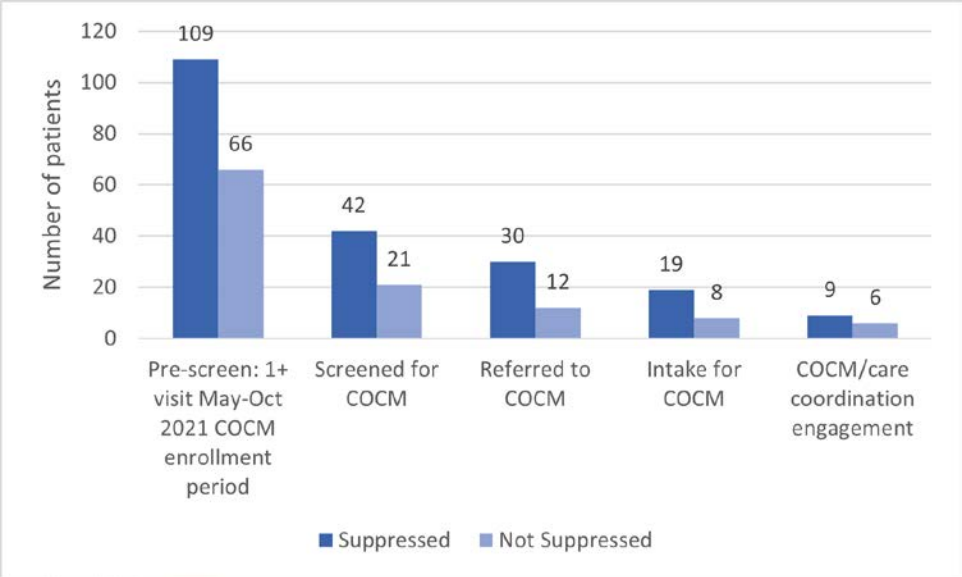

Figure 3.2.a. Baseline viral suppression by cascade step

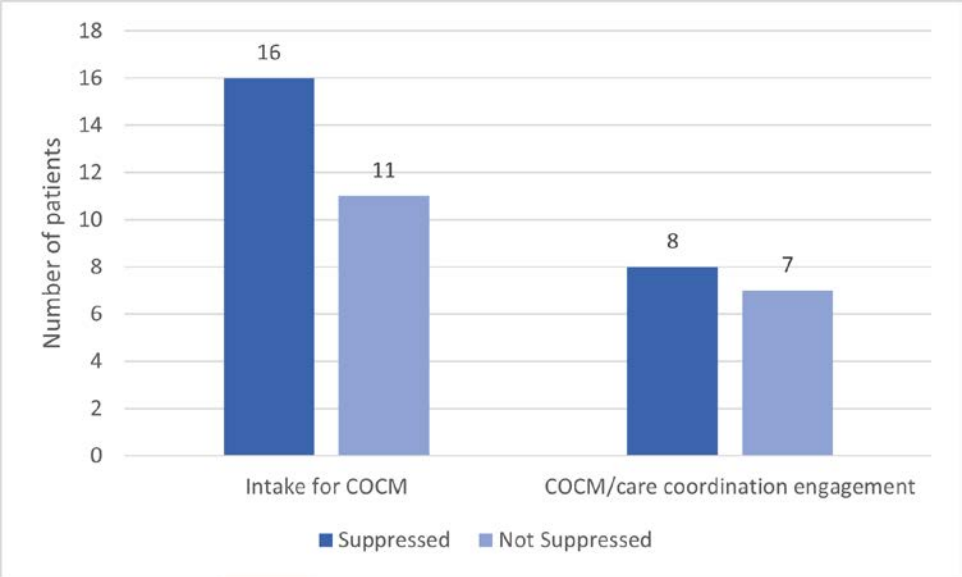

Figure 3.2.b Endline viral suppression for intake and engaged groups

We collected data on the acceptability, feasibility, appropriateness, and organizational readiness to implement COCM at the Max Clinic. Eight out of 10 eligible staff members filled out the questionnaires (see Appendix C) and we summarize the results in Table 3.3 below.

Table 3.3 Summary of implementation measures

Measure[1,2]	**Median[3] (IQR)**
Acceptability	
Meets Approval	5 (4-5)
Appealing	5 (4.75-5)
Likability	5 (4.75-5)
Welcoming	5 (4-5)
Feasibility	
Implementable	4 (4-4.25)
Possible	5 (3.75-5)
Doable	4.5 (4-5)
Easy to use	4 (3.75-5)
Appropriateness	
Fitting	5 (4-5)
Suitable	4.5 (3.75-5)
Applicable	4.5 (4-5)
Good Match	5 (3.75-5)
Organizational Readiness	
Change Efficacy	4 (3-4.25)
Change Commitment	4 (4-5)

[1] Scales include Acceptability of Intervention Measure, Feasibility of Implementation Measure, Intervention Appropriateness Measure, and Organizational Readiness for Implementing Change, respectively.
[2] Includes main measure and each sub-construct.
[3] Response options: 1 = completely disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = completely agree. Results are presented by sub-construct with readiness scores calculated as a composite of all questions related to each sub-construct.

In the feasibility assessment, the ‘easy-to-use’ sub-construct scored lowest which echoed concerns raised in both the formative evaluation and the summative evaluation (see 3.4.4 below for further discussion on barriers and facilitators) about COCM being complex, resource constraints, and logistical questions. In the appropriateness assessment, the ‘good match’ and ‘suitable’ sub-constructs scored lowest which aligned with staff concerns about the focus of COCM on depression and OUD given the burden of other forms of severe mental illness and

substance use comorbidities. The lowest score on the organizational readiness assessment was for the question relating to the staff's ability to keep track of COCM progress and this concern was re-affirmed during the qualitative interviews when staff members spoke about the importance of intra-team communication about tracking the status of patients in various steps of COCM. For example, as COCM implementation progressed, there was greater frequency of small team huddles between the BH CM and the patient's case manager to discuss individual plans which improved the staff's sense of being able to keep track of the program.

3.4.2 *Qualitative results interpreting the elements associated with cascade progression*

Here we present the findings from the qualitative strand of the study to interpret the quantitative results, starting with the explanatory elements associated with progression (or lack of) progression through the care cascade for patients with depression and/or OUD.

3.4.2.1 Screening: clarity of services offered, need for reminders, and limited time with patients

We elicited multiple elements that explained progression or lack of progression through the Max Clinic COCM care cascade. Staff members – either case managers and physicians during the targeted screening phase or all staff members during a later, staged universal screening phase – frequently mentioned either not remembering to complete the screening or de-prioritized it when competing demands on their time. "Those were the two things: we would just forget or that we didn't have the time [to do the screening]." (Staff) Periodic reminders were anecdotally helpful for staff and the switch to a staged universal screening did open up more opportunities for the screening to be done. For example, if a patient presented exclusively to visit the laboratory for a blood draw and to collect an incentive, they may not meet with either a case manager nor a physician but only a non-medical case manager. Regardless, the screening process

did contrast with the walk-in model of the clinic, which is structured around a patient's goals and in turn, often results in shorter patient visits compared to other primary care settings.

> I think for some of the patients that just wanted their gift cards and to get out the door and then we're like, "Oh, hey, I have this screening to go through with you." It's not the thing that they're wanting to do because they just were not anticipating that. I don't think anybody going into a care setting is anticipating that they're going to be having this survey about their substance use and or depression and other things like that asked." (Staff)

Additionally, staff expressed confusion over what being referred to COCM would entail for their patients. For patients with depression, the BH CM was trained in Behavioral Activation as a brief, evidence-based psychotherapy intervention(135) and would assist with adjusting medication prescribed by the patient's primary care provider. For patients with OUD, the BH CM manages and adjusts dosage of buprenorphine prescribed by the patient's primary care provider. Yet for patients with depression, the BH CM often faced numerous barriers in the context of low-barrier care that made delivering COCM, especially psychotherapy, challenging. The lack of appointments and routine follow-up often resulted in long lapses between encounters, forcing the BH CM to focus the visit on checking-in with the patient. Patients in the care of the BH CM may visit the Max Clinic but decline to meet with the BH CM. Other times patients would present in crisis or with acute medical needs that took precedence. In response, the BH CM spent a greater portion of time doing outreach over text or phone to engage patients and de-emphasized providing Behavioral Activation or completing structured assessments as part of measurement-based care. These shifts in focus in part led to confusion among staff doing screening. "I'm doing this screening with patients and I just don't know what to tell them about. 'Oh, you screened to meet with [the BH CM], what is she going to offer you?' And I don't know what to tell you." (Staff)

During the initial targeted screening phase, case manager and physician knowledge of patients' comorbidities played an important role in uptake of screening. On the one hand this extensive knowledge is a key facilitator for implementation (see section 3.4.4 below) and demonstrates a strong understanding of patient needs. This knowledge also may have importantly preserved resources and tempered any unrealistic expectations among patient with various comorbidities who may ultimately have screened ineligible. For example, patients on the schizophrenia spectrum would be ruled ineligible for COCM during the intake. Yet this knowledge also intersected with staff member concerns over the fit of COCM considering relevant comorbidities among the patient population (e.g., schizophrenia spectrum, methamphetamine use and/or methamphetamine-induced psychosis). Staff members expressed hesitancy to systematically screen patients in light of clear guidelines for all inclusion and exclusion criteria scenarios. For example, if a patient was known to have depression but also endorsed using methamphetamine and showed psychotic behaviors, staff members would express hesitancy over screening.

> I think [it] became clear, after we talked about it a couple times at staff meeting, was whether or not people qualified for the program. If they had other diagnoses that weren't just depression or opioid use disorder. So, I think a lot of people who have either a poly-substance use diagnosis or another primary psychiatric diagnosis, or who used meth, which is a lot of people didn't necessarily qualify. (Staff)

3.4.2.2 Referral and intake: patient complexity, staff buy-in, low-barrier constraints, and acute patient needs

Staff buy-in, the complexity of patients, low-barrier care constraints, and acute patient needs more prominently affected the referral and intake levels of the care cascade. Max Clinic case managers (as well as non-case managers) had extensive experience providing BH and some were trained as licensed mental health clinical social workers and/or had experience with delivering brief evidence-based psychotherapy interventions. Yet their job classification and role

within the Max Clinic as a medical case-manager was more specific to medical care coordination and offering supportive assistance for wrap-around social services (e.g., finding stable housing). Getting medical case manager buy-in and adoption of COCM was tied up with their identification with the Max Clinic.

> I think that honestly it took the [medical case managers] a longer time to buy into the program and buy into the benefit of having their patients connected with [the BH CM]. And I think that was detrimental also, because again, I think goes back to this turf issue or something. "I can meet all of my patients, social and emotional needs" or the want to [say] "I have this covered". (Staff)

Despite this, there were only two patients from the care cascade who screened positive for one or both conditions, did not decline the intake, and were not referred.

Occasionally and depending on both the BH CM's and patient's availability, a patient who screened positive for depression and/or OUD could complete the intake for COCM the very same day. More frequently though the patient would return for the intake on a different visit to the Max Clinic. In between visits (which could span weeks or months), patients' behavioral health and medical needs and priorities may have changed, they may have lost interest in COCM, or they may not have remembered being referred for COCM. This last reason was mentioned as a factor by one patient referred for depression but never followed-up for an intake despite the co-location of BH at the Max Clinic being a perceived facilitator to their engagement. "[On whether they recall being referred for an intake with the BH CM for COCM following a positive depression screen:] Not in the MAX Clinic… [On whether they'd prefer co-located BH at the Max Clinic over referral to an external provider:] Yeah, that would be easier and better… I would enjoy that very much so" (Patient, referred for depression but no intake).

In addition, there was a perception among staff members that COCM was not the highest priority to patients or that they may not have perceived immediate benefit (relative to addressing other needs).

> Because it's the lowest priority, I think. Because [patients] have so many other competing priorities of housing, substance use, what have you. So, I think there wasn't any immediate benefit to them or there wasn't a perceived immediate benefit." (Staff)

This factor also speaks to the rationale foregrounding the decision to integrate BH services by adopting COCM at the Max Clinic which was that responding to a patient's willingness to engage in BH care is time-sensitive and any delay in connecting them with a provider can lead to disengagement. At the start of COCM implementation, the BH CM was only present for 20 hours a week at the clinic and there were anecdotal instances where the BH CM was not present to meet with interested patients. "… At first she wasn't here that often. She was only here, I think it was, two days a week and then eventually it increased to three days. And I think the three days a week helped… [but five would've been better]." (Staff) Additionally, due to the walk-in nature of the clinic and the incentivized care delivery, patients may not have the expectation of seeing a BH CM during a visit.

> Yeah, I think maybe because of the drop in model. I think it's more because of just the variety of needs that our patients come in with. If we were a traditional clinic, our patients would be coming in for an appointment. So, they know that they'd be seeing their medical provider and probably [would be] asked questions by the [medical assistant] or whoever… And I think our patients don't always come in with that expectation. So, I think that can definitely be part of it. (Staff)

> People would often come in just to get their incentives. And then [the BH CM] would be like, "Hey, do you want to meet with me?"… I mean, I don't go to the doctor every two weeks, but every time I went somewhere… somewhere I go regularly and my therapist jumped out and was like, "Hey, do you want to talk?" I feel like that might feel… maybe a little bit intrusive or you're just like, "no, not right now. I came in, I was expecting this to take 10 minutes." (Staff)

3.4.2.3 Engagement: BH CM models the Max Clinic's special culture and values

For the patients who were engaged in COCM, the BH CM's ability to deliver care consistent with the values that make the Max Clinic special was essential. By bringing BH in-house at the Max Clinic – as opposed to a referral to a different provider – patients and staff expressed that the services were more accessible and welcoming. "[The BH CM] was lovely and we were great to have her. She had her way with patients and she was very good at what she did." (Staff) Another staff member remarked similarly: "I think [the BH CM] was super approachable." (Staff)

> Compared to, let's say you go somewhere for a psychiatrist appointment, it's the atmosphere and it's completely different because it's very... What's it called? White table, white wall doctor type situation. Whereas, the [Max Clinic BH CM] situation, it was very just one on one. So, I liked it." (Patient, engaged, depression/OUD)

Some engaged patients felt the BH CM's support and the COCM program helped them to better adhere to taking HIV medications.

> I was really bad at taking my [HIV] meds. I just didn't really see a point to it. And with all of the [COCM] services you guys provide here, it made it really easy to start caring again… So, I'm undetectable now. (Patient, engaged, depression)

3.4.3 *Observed barriers and facilitators to implementing COCM at the Max Clinic*

We identified multiple barriers and facilitators to integrating care for depression and OUD via COCM at the Max Clinic for PWH. Here, we present our findings thematically and summarize the results of the deductive coding for determinants using CFIR in table 3.4 below relative to our findings from the formative evaluation.

Table 3.4 Observed determinants of implementing COCM in low-barrier HIV care

CFIR Domain	**CFIR Construct**	**CFIR Sub-Construct**	**Anticipated barriers/ facilitators at the Max Clinic**		**Observed barriers/ facilitators at the Max Clinic**	
			Patients	*Stakeholders*	*Patients*	*Stakeholders*
Intervention Characteristics	Evidence Strength and Quality					Barrier/ Facilitator
	Relative Advantage		Facilitator	Facilitator	Facilitator	Facilitator
	Adaptability			Facilitator		Facilitator
	Trialability					Facilitator
	Complexity		Barrier			Barrier
Outer Setting	Patient Needs & Resources		Barrier	Barrier		Barrier
Inner Setting	Networks and Communication					Facilitator/ Barrier
	Culture		Facilitator/ Barrier		Facilitator	Facilitator
	Implementation Climate	Compatibility	Facilitator/ Barrier			Facilitator/ Barrier
	Readiness for Implementation	Available Resources	Barrier		Facilitator	Barrier
Characteristics of Individuals	Self-Efficacy					Barrier
	Individual Identification w/ Organization		Facilitator/ Barrier		Facilitator	Facilitator
	Other Personal Attributes		Facilitator/ Barrier	Facilitator/ Barrier	Facilitator	Facilitator
Process	Reflecting and Evaluating					Facilitator

3.4.3.1 Staff hesitation around use of the PHQ-9 and the NIDA Quick Screen lay at the intersection of the culture of low-barrier care at the Max Clinic and existing familiarity with patient's BH needs

Unlike in many primary care settings, the Max Clinic does not utilize a medical assistant to accompany patients to examination rooms nor does the clinic ask patients to fill out health questionnaires prior to or upon arrival at the clinic. Typically, a non-medical case manager will accompany patients from the waiting area to the examination room, determine the patient's goals for their visit, and initiate contact with case managers or physicians as needed to address those

goals. In this context and based on feedback during the small group consensus meetings during the formative evaluation, we decided to administer the assessments in the screening (as well as intake and during COCM care delivery visits) verbally. However, multiple staff members noted that “there's more of an emotional component when someone's asking you this [screener compared to the patient filling it out electronically or on paper]. I think it just hits differently.” (Staff)

Measurement-based care is a core component of COCM, especially for patients with depression and so routinely completing the PHQ-9 as a marker of tracking progress is essential to implementation. Yet completing this and the other components of the standardized screening (as well as the intake and care delivery visits) felt at odds with the culture of the Max Clinic according to some staff members.

> A lot of the reason that people like the Max Clinic is it feels like a family… You come in, you feel like you know people. And then when you switch to a standardized questionnaire, it feels really impersonal. It doesn't feel good. It feels kind of like suddenly there's this wall between you and the other person and they don't know you at all. (Staff)

Furthermore, Max Clinic staff members had extensive existing knowledge of their patient’s existing behavioral health needs. This knowledge precipitated the early-stage implementation adaptation to do a targeted screening led by case managers and physicians. But according to Max Clinic staff members, it also made the standardized screening components feel a bit redundant and insensitive.

> I had this [feeling] where there was a sense that we already knew a lot of these patients were depressed. It almost felt like turning the knife or something… “How often do you feel bad, feel like you're a failure to yourself and your family?” I mean, I don't know. That's the question that always sticks with me where I'm just like... when a lot of patients aren't in contact with their family. They don't even have a family or friends to feel bad about. It just felt like such... I don't know. (Staff)

When administering these standardized assessments in the context of existing knowledge and familiarity with the patient's (often complex) socio-economic and personal histories, these tools came across to Max Clinic staff members as problematic or even potentially triggering (in a non-traumatic way) to patients. These challenges speak to COCM's compatibility within the existing Max Clinic workflows and culture.

In reviewing patient records, the PHQ-9 was almost universally completed while the NIDA Quick Screen was sometimes not, which some staff members attributed to it being more challenging to administer. "The NIDA felt almost harder to ask… I felt people were more reticent to disclose [substance use compared to] the PHQ-9." (Staff) Another possible explanation is because staff members were generally already aware of the substances endorsed by patients and therefore chose not to administer the NIDA Quick Screen due to the knowledge that the screening would not lead to an available intervention if they did not endorse using opioids.

> In a way, I get why we put [the NIDA Quick Screen] on there with all the different substances. It's good information to get and it kind of warms people up to the opioid question. But it also felt like "why are we asking these questions about other substances we're not treating [since] we're not offering interventions specifically for the other ones." (Staff)

Another reason may have been confusion over the screening process and whether or not to complete the NIDA Quick Screen if they anticipated that the patient participant was only interested in care for depression or if they were only expected to advance through the depression cascade.

Some staff commented that their ability to properly phrase and introduce the standardized assessments, especially the PHQ-9 led to more patient willingness to be screened.

> I didn't really set it up too much. I just said, "I'm going to ask [you some] questions. Do you have five minutes of your time you can give me?" And when I asked it that way, they said "Yes," but when I [told] them that I'm going to do a screening questionnaire on depression, then it was like, "No, I don't have time…" Then I got more screening questions done. (Staff)

During the formative evaluation, some staff members highlighted the importance of how to frame and present COCM with a focus on improving the program's reach and this quote speaks about this. Although the Max Clinic staff have training in and are familiar with the use of such assessments, our multi-component implementation strategy (see Table 3.1 above) focused exclusively on training the BH CM on use of assessments including the PHQ-9 and not the Max Clinic staff members in general.

3.4.3.2 Time and physical resource constraints were not as bad as anticipated by stakeholders, though they were still perceived to negatively impact COCM's feasibility

During the formative evaluation, staff members identified multiple resource-related constraints, such as room availability and short patient visits, that affected organizational readiness to implement COCM. Room availability was mentioned prominently given that the Max Clinic only has three patient examination rooms and due to the unpredictable patient flow associated with the walk-in model, the clinic experiences patient backlogs when numerous patients arrive at the same time. The Max Clinic staff members observed that screenings, intakes, and COCM care delivery visits could sometimes last longer than other patient visits. When these lengthy visits occurred during busy hours, they could exacerbate patient backlogs.

> That became an issue a number of times where [the BH CM would] be doing an intake with somebody. And I think the intakes took a half an hour or something like that, where we would just be slammed out front and she'd be in one of the patient rooms and it would be this like, "Okay, so those are the times we need you to not be in one of the three Max [Clinic] rooms." (Staff)

The observed length of screenings was also a factor that may have affected staff member uptake and buy-in of the program. In particular, the very first screening done after the program started took over 90 minutes to complete. The medical case manager recalled that each question led the patient into a larger, emotionally-charged conversation and they had trouble redirecting the patient back to the screening questions while also responding in an empathic way.

> There was a worry that [a very long screening] would happen again and that, once again, it could take 10 minutes [or] it could take 90 minutes… I think that was a big worry for people, especially when there was a lot going on in the clinic, which often there was. (Staff)

Unintentionally, this instance may have set the tone for staff member hesitancy to complete screenings during particularly busy times.

That said, this perception of availability was not universally shared by all patients. The engaged patients in general found that the BH CM was readily available. “[There was] never a time where I came [to the Max Clinic] where she wasn't available… so I'd say that her availability was awesome.” (Patient, engaged, depression) We captured in the REDCap database and in the BH CM’s programmatic records the number of visits that patients made to the Max Clinic but during which they did not meet with the BH CM. Among patients who were referred (n=42), there were 11 patients with recorded visits where they attempted to meet with the BH CM but she was unavailable (e.g., she did not work that day or was seeing another patient), but no such visits among patients who completed an intake (n=27). Among referred patients there were four patients with recorded visits who declined to meet with the BH CM who was available, but no such visits among patients who completed an intake.

3.4.3.3 BH CM self-efficacy in delivering Behavioral Activation was low, but concerns arose if it was the best choice of psychotherapy for low-barrier HIV care

During the preparation phase, the research team decided to adopt Behavioral Activation as an evidence-based psychotherapy to be used in conjunction with COCM. As part of the multi-component implementation strategy, the BH CM received training in Behavioral Activation during 1:1 skill building sessions with research team members. But quickly after the program entered the implementation phase and when presented with patients in the context of low-barrier care delivery, the BH CM's confidence to deliver Behavioral Activation dissipated.

> I had this training in Behavioral Activation and that was good. But then we actually started the program and it was like, "Oh, well, Behavioral Activation really isn't going to work that well because it's very systematic..." I didn't feel very confident in my skills doing that. I felt like I had to adhere very strictly. (Staff)

Like the other staff comments about the standardized nature of administering the PHQ-9 and other assessments, the BH CM found the systematic nature of Behavioral Activation as they learned it in their training to sit at odds with the way low-barrier care at the Max Clinic was delivered.

> With most people, [I] never really got even started [with Behavioral Activation] because it's like you'd have the intake and then you wouldn't see [the patient] for a month… "I'm not going to jump right into it because I feel like we need to use this time to catch up. What's been going on in your life in the past month?" Then [the patient] only ha[s] 15 minutes to meet [with the BH CM]… A lot of times they're going through a crisis, and it just felt like a mismatch to [do Behavioral Activation]... I felt like I needed to do mostly supportive counseling, like listening, and empathetic listening, and validation, and that kind of stuff. It just felt weird to then try to turn it to, "Well, what are some pleasant activities you can do this week? Can you take a walk three times a week?" (Staff)

This was due to the gap between patient visits to the Max Clinic (due to its walk-in nature), the limited number of visits patients would have with the BH CM, and the complex medical and BH needs that patients present to the clinic with.

Relatedly, another adaptation to a core component of COCM that arose in response to the BH CM's self-efficacy to deliver Behavioral Activation in conjunction with the brief patient visits, and staff experiences using the PHQ-9 was to relax use of the PHQ-9 for patients with depression during each visit with the BH CM. Like the adaptation to the screening, this represented an adaptation to a core component of COCM (measurement-based care), but was deemed necessary by the BH CM in conjunction with the Principal Investigator.

3.4.3.4 Modeling the Max Clinic's culture facilitated the BH CM's engagement with patients

Max Clinic patients who interacted with the BH CM, especially those at the engaged step who had either in-person COCM care delivery visits or phone and text conversations, frequently cited the BH CM's warmth, availability, and approachability. These qualities were both mentioned in contrast to other BH services and providers through which they have previously received care and they were in sync with the culture of care delivery at the Max Clinic, which they appreciated and valued.

> [The BH CM] was excellent. She provided really good [care]... I thought the service was great because it wasn't just a psychiatrist that just prescribed me stuff and told me to get out, basically. It was somebody that was there for me to talk to about everything. Actually, I think she was the first person I told everything that was going on with me openly and honestly, and it was really great having her. (Patient, engaged, depression)

> I don't normally talk to people about that, but I felt really comfortable whereas I was able to get really vulnerable and discuss stuff like that with [the BH CM]… Trusting someone's hard [in and of] itself, so the fact that I was able to trust her, [that] was extremely helpful. (Patient, engaged, OUD)

Staff concurred and echoed these reflections. "[The BH CM] was lovely and we were great to have her. She had her way with patients and she was very good at what she did." (Staff) These traits highlighted the importance of how patients felt welcomed, valued, and listened to.

3.4.4 *Factors associated with sustaining and scaling COCM for low-barrier HIV care*

The patient participants at the engaged step of the care cascade expressed their enthusiasm for the Max Clinic to continue offering COCM based on the positive experience they had receiving care from the BH CM on-site at the Max Clinic. However, to sustain COCM at the Max Clinic a new BH CM would need to be hired due to turnover at the position. Patients responded to the question about sustainability in the context of knowing there would need to be a new BH CM and these patients located their enthusiasm within the context of the positive relationship they had with the previous BH CM. On whether or not the Max Clinic should sustain COCM, one patient remarked "Sure. I would definitely, definitely take a look at it and engage in it and see how it works for me." (Patient, engaged, depression/OUD) Another patient responded to the question about sustainment of COCM as follows: "Yeah [it should be sustained, but] I think it would be interesting to see how it would differ from person to person [different BH CMs], and if it would be the same or different." (Patient, engaged, depression) Thus, identifying a BH CM for the next phase of implementation who re-affirms these qualities will be important

Overall, there was a range of responses among staff members as to the question of whether COCM should be maintained at the Max Clinic. Some staff members were very enthusiastic:

> Definitely, 100 percent… I think it helped some people tremendously, but I think there was an element… that it helped [a lot more] to some degree… I'd like to see how the program [runs] over a longer period of time, how it engages patients because you might see that kind of flux of retention over time especially as someone got more familiar with the patients and more familiar with the team. (Staff)

Another staff member was not supportive about sustaining the program, primarily grounding their rationale in COCM's fit given the burden of other severe mental health comorbidities and

substance use disorders which were exclusionary criteria for participation and thus tempered COCM's reach.

> No, I don't think we should [sustain COCM]. I don't think it reached enough people to be effective. I also think it just caused more headaches in terms of implementation and engagement and striving for engagement. And I don't think it engaged that many people. And sure, it helped a couple people here and there, but I don't think COCM is going to help the Max Clinic patients engage [in] mental healthcare. [Instead,] I think honestly, just having a mental health practitioner here who is able to do things in a less restrictive way… and someone who can be here full time as well. (Staff)

Other staff were supportive of sustaining COCM if certain adaptations like expanding the inclusion criteria for more comorbidities were made to further improve its contextual fit. Several staff expressed a common theme around COCM needing to adapt to serve patients with additional comorbidities.

> I think we probably should continue [COCM] and just expand it [to cover more comorbidities like schizophrenia] and accept that we don't have a strong evidence base. So what?... It does seem plausible to me that if we brought additional resources to bear from people who are more knowledgeable, even if it's imperfect and there's no trial to support it, that it would still be worth giving a shot… I think that what we need is, as close as we can come to it is comprehensive psychiatric services in the clinic. (Staff)

Additional suggested adaptations included: increasing the BH CM's availability to full-time; making the screening process less-time intensive, more streamlined, and accessible to patients who could not attend in-person; and having a BH CM with more training and experience providing mental healthcare, including more training in a wider array of (brief) evidence-based psychotherapy interventions. Multiple staff members hoped that the next BH CM could be in the role for a longer time so that they could establish better rapport with patients and in turn see if more patients would engage more.

> We weren't able to have more patients integrated with her… because it took so long, just the whole process for [the BH CM] to get to the point where she was seeing a patient

> consistently or talking to them consistently, it just took so long to get there. So by the time we were able to see that effect for a few of the patients that she was able to connect with, she only had a couple of months left. (Staff)

Staff members recalled that intra-team communication about patient involvement in COCM was initially slow during the early implementation phase when the BH CM was adjusting to clinical workflows. But intra-team communication improved once the BH CM started having 1:1 huddles with case managers and other team members to collaborate on individual patient treatment plans.

> [There was a patient who] at one point had come in having really severe suicidal ideation and had a plan in place, just all the things lined up. And [the BH CM and the case manager] partnered together in terms of assessing that situation, making a plan, following through with that plan. And I just thought it was really beautiful how the two of them supported each other and supported [the patient] through that. I think [the BH CM] did this later on, but I think this… [having the BH CM] meet with the [case managers], especially after she had a session with [a patient]… [It] would be helpful to [have] started [doing this] earlier. (Staff)

Multiple staff members discussed the importance of keeping up and improving upon these forms of communication to sustain COCM.

> I appreciated having [the PI and research team members] and sometimes [the BH CM] join our staff meetings so that they could give updates about how things are going with COCM… So, I think that would be one thing that could be done to roll that in so that we're all aware and reminded that this is something that's ongoing and open to patients. (Staff)

Thus, such forms of communication would continue sensitizing staff to the program and would serve to improve collaboration.

3.5 Discussion

In this mixed methods study evaluating the acceptability and feasibility of integrating care for depression and OUD via COCM into low-barrier HIV care at the Max Clinic, we

observed that 36% of eligible patients were screened, 24% were referred, 15% completed an intake, and 9% progressed to the engaged step of the care cascade. We identified that the elements explaining progression through these respective steps included: for screening, a lack of clarity among staff about COCM services offered, the need for reminders, and limited staff time during busy periods at the clinic; for referral, the complexity of patient behavioral health needs and low staff buy-in; for intake, the constraints of low-barrier care and the acute needs of patients; and for engagement, the BH CM modeling the Max Clinic's unique culture and values. While stakeholders considered COCM acceptable and feasible to implement according to the quantitative results, our interpretive qualitative results show that this was in the context two adaptations to core intervention component (i.e., adapting the proactive and systematic screening to a targeted and then a staged screening, and adapting the measurement-based care component for patients with depression) designed to improve COCM's contextual fit and in response to multiple barriers to implementation across different CFIR domains. These barriers included the BH CM's low self-efficacy to deliver Behavioral Activation, the complexity of COCM, and limited availability of the BH CM.

Although our care cascade lacked subsequent steps around individual patient outcomes, our results of patient progression through cascade steps for those with depression compare favorably to other studies. Cholera and colleagues constructed a care cascade for PWH and depression from the Centers for AIDS Research Network of Integrated Clinical Systems' observational cohort and observed that among those with an indication for depression, 43% received antidepressants.(121) Similarly, in their construction of a cross-sectional depression care cascade among PWH using combined estimates from the HIV/AIDS Treatment Adherence, Health Outcomes, and Cost Study (136) and the National Comorbidity Study Replication,(137)

Pence and colleagues estimate that 40% of those clinically diagnosed with depression (Bayesian credible interval 30-50%) are being treated at all.(138) Here, we observed that 42% of patients who screened positive for depression and 67% of patients completing an intake for depression care through COCM were engaged in care.

To our knowledge, there is only a single empirical study – the ongoing prospective cohort associated with the AIDS Care Cohort to Evaluate Exposure to Survival Services (ACCESS) in Vancouver, Canada – documenting a care cascade for PWH who have OUD.(139) The study compares patient progression through an HIV care cascade comparing patients on opioid agonist therapy to those not on opioid agonist therapy.(139) In their cohort, 80% of PWH who endorsed using opioids daily at study baseline and who had at least one study visit during the enrollment period were on opioid agonist therapy(139) whereas we observed only a single engaged OUD patient from among seven who endorsed using opioids (14%). It's important to contextualize the relatively high percentage of patients engaged in opioid agonist therapy in Vancouver due to the expansion of heroin assistance therapy via the North American Opiate Medication Initiative.(140, 141)

The biggest single drop in the care cascade was at the screening step where only 36% of patient participants from the pre-screening step were screened. COCM screening (proactive and systematic screening is a core intervention component) was adapted to improve contextual fit following the formative evaluation. The first adaptation was a targeted screening by case managers and physicians based on the patient's anticipated eligibility for COCM and was enacted at the start of COCM implementation in May 2021. The second adaptation was a staged universal screening by all Max Clinic staff members that was enacted in September 2022.

Whereas most of the parts of the multi-component implementation strategy focused heavily on training the BH CM in delivering COCM, there was less intentional emphasis placed on maintaining and supporting high quality intra-team communication during ongoing implementation. As mentioned previously in 3.4.2 and 3.4.4.2, staff buy-in particularly among the case managers was low and multiple staff commented that improved communication would be critical for sustaining COCM at the Max Clinic. These themes underscore the importance of trust in implementing COCM, which is increasingly coming into focus as an important factor in implementation science.(142)

Relational strategies – defined by Metz et al. as "strategies undertaken to build trust through strengthening the quality, mutuality, and reciprocity of interactions among team members and implementation stakeholders" – can be harnessed as a tools for improving intra-team communication as an intermediate to improving trust.(142) Considering the feedback we received and the lessons learned from implementing COCM at the Max Clinic, an adjunct to the AIMS Center multi-component strategy could include three relational strategies: protocolizing routine bi-directional communication between the BH CM and other staff members to further align around patient plans and promote feedback loops; co-learning during the BH CM training period and at critical inflection points associated with care delivery to promote cooperation and pool shared learnings related to the patient's care; and foregrounding BH CM training in empathy-driven exchanges that value the extensive BH experience and knowledge among all Max Clinic staff members.(142-145) Here, we use Lewis' approach to specifying a proposed causal pathway for such a multi-component, relational trust-building strategy as shown below in Figure 3.3. Importantly, we propose that such a strategy could unlock a more supportive and collaborative environment towards increasing interpersonal communication and ultimately

achieving greater service penetration as an implementation outcome, where COCM is further integrated within the Max Clinic and a greater percentage of eligible patients at each step of the care cascade receive services.(91, 146)

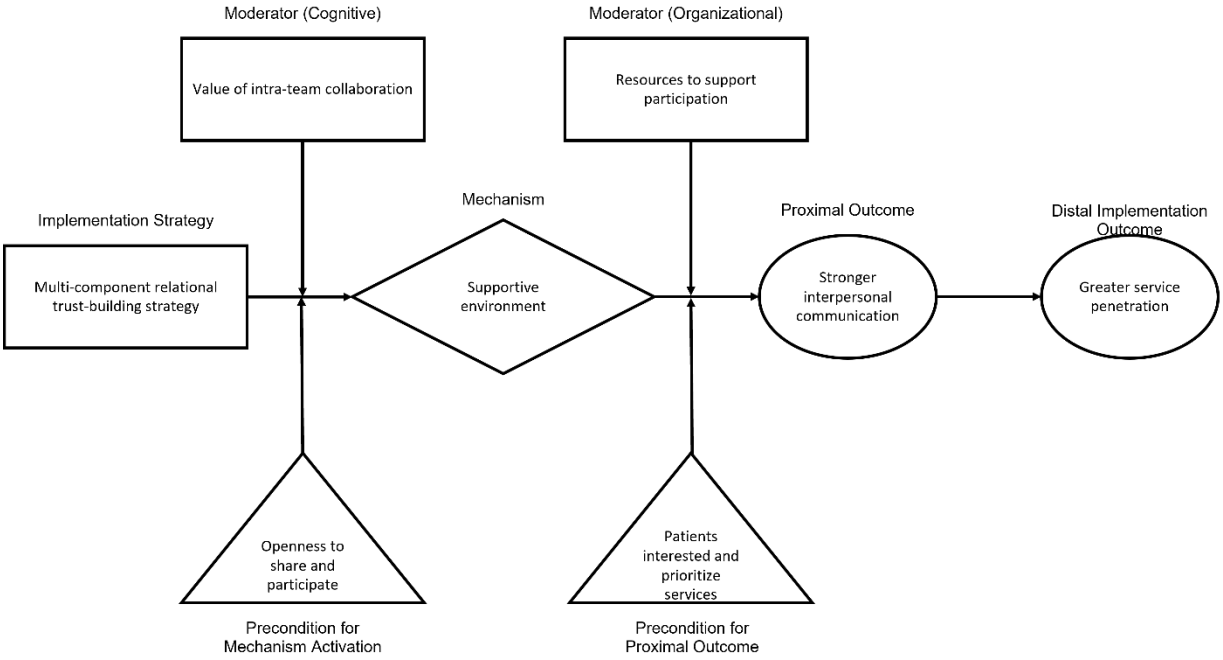

Figure 3.3 A proposed multi-component relational trust-building implementation strategy

Critically this strategy assumes two important moderators: the degree with which staff members will value having a greater sense of intra-team collaboration and that they will have dedicated resources to carry out such collaboration, specifically time resources. This moderator is critical due to the unpredictable patient-flow associated with the walk-in clinic (yet is no less relevant during busy clinic times with patient backlogs) and presumes that the BH CM's availability will coincide with other staff member availability. This strategy also assumes two

important preconditions: that staff members will be open and willing to share, and that patients prioritize receiving BH as part of COCM.

Our qualitative findings helped contextualize the staff members' qualifications on the acceptability and feasibility of implementing COCM at the Max Clinic. Specifically, staff concerns around COCM's fit given its focus on depression and OUD in the context of patient populations where 76% of patients endorsed using methamphetamine and 25% had a schizophrenia spectrum or other psychotic disorder diagnosis. Among the 112 patients not screened, 83 (74%) endorsed using methamphetamine and 32 (29%) had a schizophrenia spectrum or other psychotic disorder diagnosis. In the context of the COCM evidence base, schizophrenia spectrum and psychotic disorders (including substance-induced psychosis of which approximately 40% of methamphetamine users experience)(147, 148) are almost always exclusionary criteria(13, 89) due in part to the compatibility of these conditions with two core components of COCM: measurement-based care and both the availability and feasibility to deliver evidence-based psychotherapy in primary care settings. Measurement-based care is a core COCM component(44) but it's incorporation in the use of treating schizophrenia spectrum and psychotic disorders is complicated by the lack of valid, self-reported assessments due to the patient having limited awareness of the symptoms they're experiencing(149, 150) and the psychometric assessments for schizophrenia spectrum and psychotic disorders are complex and multidimensional, making their use in primary care settings unfeasible and challenging.(151, 152) Cognitive behavioral therapy (CBT) is often recommended as the evidence-based psychotherapy of choice for patients with schizophrenia spectrum and psychotic disorders,(153) but the recommendation for standardized CBT is 12 to 20 sessions over a four to six month period, which is challenging to administer in primary care settings.(154) There is also no

evidence comparing a brief form of CBT with six to ten sessions in under four months.(155) There are only two randomized controlled trials evaluating COCM for severe mental illness including schizophrenia spectrum and psychotic disorders(156, 157) and the overall evidence base for its effectiveness is low.(158) Reconciling these limitations, iteratively adapting COCM to improve its contextual fit at the Max Clinic, and clearly communicating decisions in protocolized ways will be essential to sustaining COCM.

Our findings compare favorably with the findings from implementing COCM for depression in three Veterans Administration Health System HIV clinics.(73) Recognizing that PWH and depression and/or OUD may be doubly (or triply) stigmatized, they may thus face additional barriers to accessing care. In this context, we both found that a BH program co-located within the primary care setting that's managed by a task-shifted CM can meet patients where they are.(99) But unlike the providers in the Veterans Administration COCM implementations, Max Clinic COCM providers did not demonstrate a lack of self-confidence around diagnosis and treatment of mental illness, express concerns about drug-drug interactions, or cite competing priorities that limited their ability to engage with the BH CM.(76)

Our findings also corroborate COCM implementation experiences in other low-resource settings in the US. In our feasibility assessment, the ease-of-use sub-construct scored the lowest which aligned with qualitative feedback about confusion over multiple elements of the program. Similarly, an under-resourced primary care clinic serving post-Hurricane Katrina New Orleans implementing COCM for depression and found that COCM was overly complex and not easy to use.(81) At a Federally Qualified Healthcare Center in downtown Miami that implemented COCM for depression for a patient population that was disproportionately experienced housing instability, researchers found that the multifaceted socio-economic needs and positions of

patients led to low patient engagement and follow-up.(75) However, our experiences differ from other implementations of COCM for OUD, which emphasized less-efficacious perceptions of buprenorphine and a lack of physicians being wavered to prescribe buprenorphine.(35, 37, 38, 40)

3.5.1 *Limitations*

Our study has several important limitations that warrant consideration. In this pilot trial evaluating the acceptability and feasibility of integrating care for depression and OUD into low-barrier HIV care at the Max Clinic, COCM was implemented as standard-of-care and thus there was no comparison group. Despite the initial programmatic intention to collect – consistent with measurement-based care as a core component of COCM – patient clinical outcomes (e.g., PHQ-9 scores for patients with depression, self-reported opioid use, and COWS scores for patients with OUD) during each care delivery visit to assess COCM's preliminary effectiveness, these data were not routinely collected considering that the BH CM focused heavily on working to engage patients. Thus we were unable to characterize individual outcome steps such the number starting (or adjusting) a medication and/or psychotherapy, the number with 50% improvements in symptom severity, or the number achieving remission.(121) The individual care trajectories of Max Clinic patients participating in COCM are very diverse and these trajectories exist at the intersection of both proximal factors related to the delivery of BH services as part of a complex intervention being layered upon a dynamic healthcare delivery environment, as well as the upstream factors such as the social determinants of health. Thus, this care cascade represents a reductionistic view of these care trajectories. Pre-screening diagnoses and endorsements of substance use were captured in June 2020, representing a cross-section that preceded the COCM enrollment period by 11 months and so there may have been important changes that occurred

during that period. There may also be a general social desirability bias that is often associated with reporting substance use. Furthermore, fentanyl use was not captured in the chart review and so we are unaware of its use among patients. We also note the small sample size (n=8) for the implementation outcome assessments given the single study site.

For the qualitative strand of this study, administrative requirements meant that the RAs were required to perform all patient participant interviews on-site at the Max Clinic or at the Sexual Health Clinic in a patient examination room. As a result, patient participant responses may be influenced by their environment and by the power produced in that clinical setting. This could manifest – despite affirmations of confidentiality during the informed consent process – in patient reluctance to speak negatively about care delivery. Due to time constraints, we were unable to use multiple coders for the deductive and inductive coding processes, thus potentially limiting the validity of the findings.

Lastly, it is important to contextualize these results within the ongoing COVID-19 pandemic. A recent systematic literature review has indicated the overall decreased level of engagement among PWH during the COVID-19 pandemic.(159) However, some Ryan White providers have anecdotally noted reductions in “no show” appointments and improved access compared to pre-pandemic times.(160) One study observed no changes in rates of viral suppression among unstably housed individuals in low-barrier care comparing pre-pandemic to pandemic times.(161)

3.6 Conclusion

In this sequential explanatory mixed methods evaluation of implementing COCM in a low-barrier HIV setting for depression and OUD, we observed that 36% of patients were

screened, 24% were referred, 15% completed an intake, and 9% progressed to the engaged step of the care cascade. The explanatory elements associated with progression through these respective steps included: for screening, confusion among stakeholders about COCM, staff forgetfulness to do the screening, and brief patient visits hindered staff members' ability to complete screenings; for referral, poor staff buy-in and the complexity of patient BH needs; for intake, the limited time, space, and human resources associated with low-barrier care as well as patients with acute medical and socio-economic needs; and for engagement, the BH CM successfully exemplified the Max Clinic's unique culture and values. Our findings indicate that while COCM was acceptable and feasible to implement at the Max Clinic, it was only so in the context of multiple observed barriers to implementation and key adaptations to the proactive and systematic screening and measurement-based care core components of COCM. Our findings suggest that implementation strategies for COCM in low-barrier HIV care should extend beyond training-focused approaches to increase intra-team communication and collaboration in order to sustain COCM.

Chapter 4. A MEDIATION ANALYSIS EVALUATING SELF-STIGMA ON DIABETES OUTCOMES AMONG PEOPLE WITH COMORBID DEPRESSION IN 4 URBAN INDIAN CITIES: A SECONDARY ANALYSIS FROM THE INDEPENDENT TRIAL FOR THE COLLABORATIVE CARE MODEL

4.1 ABSTRACT

Introduction: Fifteen percent of India's adult population lives with a common mental disorder, yet pervasive self-stigma hinders the uptake and reach of behavioral healthcare services. Research has suggested that integrated care models, where multiple illnesses can be treated in the same setting, may provide a pathway to smooth uptake of treatment. The Collaborative Care Model, an evidence-based integrated care model, has shown promise to improve access to evidence-based treatment for depression in India, including for people with comorbid chronic conditions like diabetes. Yet it remains unclear what impact the Collaborative Care Model has on self-stigma for people with depression and comorbid diabetes and if changes in self-stigma predict improvements in diabetes outcomes through the mechanism of treating depression.

Methods: Using secondary data from the INDEPENDENT trial where depression care was integrated into four urban diabetes clinics via the Collaborative Care Model, we evaluate whether change in self-stigma on diabetes outcomes is mediated by depressive symptoms. We also longitudinally analyze self-stigma scores, comparing participants receiving care via the Collaborative Care Model to those receiving enhanced standard-of-care using a linear mixed effects model.

Results: Change in self-stigma scores over 12 months did not predict diabetes outcomes (HbA_{1c}) at 12 months (total effect; β=-0.0535; 95%CI: -0.163 – 0.125; p=0.0807). Depression symptoms did not mediate the relationship between change in self-stigma scores over 12 months on diabetes outcomes at 12 months (HBA_{1c} -0.0535%; 95% CI: -0.00316 – -0.133, p=0.129). Self-stigma scores did not differ longitudinally comparing Collaborative Care Model participants to enhanced standard-of-care participants (Self-Stigma Scale for Chronic Illness-4 Item score: 0.00997; 95% CI: -0.00134 – 0.0213, p=0.0840).

Conclusion: Our study was narrow in scope, and thus, to understand the role of stigma more fully in integrated care models, we recommend further research exploring the role of stigma including the development of culturally grounded self-stigma scales.

4.2 INTRODUCTION

More than 1 in 7 Indian adults live with a common mental disorder according to the 2016 National Mental Health Survey.(162) Among those with a common mental disorder, only 5-25% have access to care and only 4% receive evidence-based care.(162) Those with chronic comorbidities are at an additional risk of receiving poor quality care due to the fragmentation associated with multiple care providers. Compared to the general population, people with diabetes are twice as likely to experience mental illness, including depression.(163, 164)

Addressing stigma is key to overcoming the barriers to closing access gaps for people with comorbid depression and diabetes. Whereas negative attitudes and beliefs held by a community or group about a disease or condition that's devalued may lead to stigmatization, the process of internalizing those attitudes and beliefs by a person living with that disease results in self-stigma. Importantly, these negative attitudes and beliefs can be reinforced by healthcare providers.(25, 26) Self-stigma can lead to or exacerbate common mental disorders like

depression and anxiety.(24) Further, self-stigmatization often limits engagement with care and uptake of treatment.(27-31)

Integrated behavioral healthcare (BH) interventions, which bring specialty BH into primary care settings, represent options to increase access to BH.(15) Considering that visiting a specialist BH provider in India can lead to or exacerbate the stereotyping, prejudice, and discrimination associated with a stigmatized condition, integrated BH interventions are one potential pathway to reducing self-stigma.(16, 17, 165) The Collaborative Care Model (COCM) is an example an integrated BH intervention that holds promise for addressing stigma, while improving access to evidence-based BH.

In the MANAS trial in Goa, Patel and colleagues demonstrated that a stepped version of COCM (patients are allocated to increasingly resource-intensive interventions depending on progression of their clinical outcomes) led to a 30% decrease in prevalence of common mental disorders after 12 months and COCM participants, relative to the comparison group, were 1.22 times more likely to have recovered at six months (56, 57) COCM has also been implemented with success among people with comorbid depression and diabetes in India as demonstrated by Srinivasan and colleagues in the HOPE trial. They observed that, compared to comparison clinics, COCM participants in rural clinics in Karnataka with depression and other comorbid non-communicable diseases (hypertension, diabetes, or ischemic heart disease) showed significant reductions in depression symptom severity at three, six, and 12 months.(58) Yet despite its growing evidence base in India and in the context of improving outcomes for people with diabetes and comorbid depression, it remains unclear whether or not COCM leads to improvements in self-stigma over time and if changes in self-stigma predict these patient health outcomes.

Here, we evaluate the effect of changes in self-stigma on diabetes outcomes as mediated by depressive symptoms in the context of the INDEPENDENT trial implementing COCM at four urban diabetes clinics in India. We hypothesize that depressive symptoms will partially mediate the effect of change in self-stigma on diabetes outcomes. We will also longitudinally analyze self-stigma over time comparing participants assigned to COCM versus enhanced standard-of-care.

4.3 METHODS

4.3.1 *Data sources and participants*

We used secondary data collected during the INDEPENDENT trial (ClinicalTrials.gov Identifier: NCT02022111) for integrating care for depression among adult participants with diabetes via COCM. The full study protocol(166) and primary trial results(167) have been previously published elsewhere. In this pragmatic trial, patients at four urban diabetes clinic sites (public hospital in Delhi or private clinics in Chennai, Visakhapatnam, and Bengaluru) were individually randomized to receive either 12 months of enhanced standard care or COCM and then passively followed up to 36 months. To be eligible, participants must have been 35 years of age at the time of enrollment (enrollment continued over 14 months beginning in March 2015), had a confirmed type II diabetes diagnosis, and had at least one poorly controlled cardiometabolic parameter (hemoglobin A_{1c} (HbA_{1c}) ≥8%, systolic blood pressure (SBP) ≥ 140 mmHG, or low-density lipoprotein (LDL) cholesterol ≥ 130 mg/dl as documented in a medical chart review. Eligible participants were screened for depression using the PHQ-9 and those with scores of 10 or above, indicating moderate to severe depression, were invited to participate. Participants were excluded based on the following criteria from the chart review: alcohol or

substance use disorders; cognitive disorder; bipolar, schizophrenia spectrum, or psychotic disorders; kidney failure; or cardiovascular disease including any myocardial infarction, unstable angina, or stroke within the past 12 months. The final study-related data collection at 24 months was completed in July 2018. The INDEPENDENT trial had 80% power, at an α significance level of 0.05, to detect a 15% absolute risk difference in the primary outcome – the between-group difference in the unadjusted percentage of patients at 24 months that had at least 50% improvement in 20 item Symptom Checklist Depression Scale scores and one of the following: at least a 0.5 percentage point (ppt) reduction in HBA_{1c}, a five mmHG reduction in SB, or at least 10 mg/dl reduction in LDL cholesterol – based on a sample size of 360 participants across three sites. A fourth study site was added later following enrollment concerns and the sample size was revised to 400.

4.3.2 *Measures*

Self-stigma was assessed using the 4-item Stigma Scale for Chronic Illness (SSCI-4; see Appendix C), a brief, non-illness specific instrument resulting from iterations over the previously developed 24-item and 8-item stigma scales.(24, 168) The SSCI-4 was chosen for brevity, and researchers had completed a non-Western cultural adaptation in a previous study.(169) However, local adaptation across the 4 clinical sites which are heterogenous with respect to language, religion, and other demographic factors was not completed. The SSCI-4 assesses four sub-constructs: social avoidance, blame, feeling left out, and embarrassment. The SSCI-4 prompts participants to self-report stigma using a five item Likert scale rating. These scores are then summed for an overall self-stigma score on a scale from 4-20. The scale also includes a prompt for participants to consider their most stigmatizing condition while completing items (depression

or diabetes). The 4-item scale at baseline (Cronbach's alpha = .839) demonstrated good internal consistency.

Depressive symptoms were assessed using the PHQ-9 (see Appendix C) while HbA_{1c} levels were measured via blood draw and laboratory analysis. The PHQ-9 was validated within the Indian diabetes context.(170) While depressive symptoms and HbA_{1c} were measured at all study-related interactions over the course of this longitudinal trial (baseline, six months, 12 months, 18 months, 24 months, and 36 months), self-stigma was measured only at baseline, 12 months, 24 months, and 36 months). Multiple demographic variables were collected at baseline including age, sex, monthly household income in Indian Rupees (INRs), and level of educational attainment.

4.3.3 *Data Analysis*

Our approach was guided by Baron and Kenny's single mediation analysis steps, which sequentially evaluate the effect of the predictor of interest, change in stigma (SSCI-4 scores) over 12 months, on the outcome of diabetes (HBA_{1c} levels) at 12 months (total effect); the effect of stigma on the mediator, depressive symptoms (PHQ-9) at 12 months; and the effect of change in stigma on diabetes accounting for depressive symptoms (direct effect) as shown in Figure 4.1 below.(171) The average causal mediation effects (or indirect effect) is the total effect minus the direct effect.(171) To determine the statistical significance and generate robust confidence intervals, we use a bootstrapping method with 1000 simulations as described by Preacher and Hayes.(172)

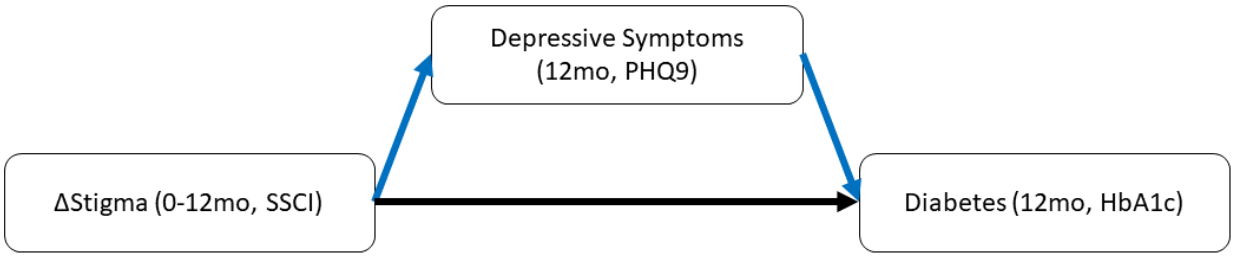

Figure 4.1 Path model diagram of proposed mediation analysis

We also conducted a longitudinal analysis comparing self-stigma over time by intervention assignment. We used a linear mixed effects model, which included a random intercept, to account for correlation within individuals over time. To account for variation in depressive symptoms and diabetes scores at baseline, we used an ANCOVA approach to adjust for these starting scores by adding them as fixed effects accordingly.(173) Although these data originated in a trial, we adjusted for the following covariates in a sensitivity analysis: age, sex, monthly household income, and level of educational attainment.(174)

For both the mediation and longitudinal analyses, we analyzed the data for patterns of missingness and found that over 6% of individuals had missing SSCI-4 scores in a pattern consistent with drop-out. As a result, we assumed a missing at random missingness model and chose to multiply impute the missing data given the availability of covariates in the data.(175) We used an expectation-maximation bootstrap algorithm based on a multivariate normal distribution to generate 30 imputed datasets for which the analyses were run followed by pooling of results.(176) In addition to SSCI-4 scores, the following variables were also multiply imputed due to missingness: stigmatized condition; level of educational attainment; HBA_{1c} levels at 12, 24, and 36 months; and PHQ-9 scores at 12, 24, and 36 months.

We performed all analyses using R Statistical Software version 4.2.2.(177) We used the following packages: tidyverse v1.3.2, table1 v1.4.2, Amelia v1.8.1, lattice v0.20-45, mice

v3.15.0, VIM v.6.2.2, mediation v4.5.0, nlme v3.1-160, mitools v2.4, broom.mixed v0.2.9.4, mitml v.0.4-4, and psych v2.2.9). Our annotated code is available in Appendix D.

4.4 RESULTS

Four hundred and four participants consented and were randomized to receive either COCM or enhanced standard-of-care. Participants across the COCM and enhanced standard-of-care groups were comparable at baseline as participants on average as shown in Table 4.1 below: were female (59%), 52.7 years old, had completed secondary school (51%), had a mean monthly income between 10,000-20,000 INRs (29%), indicated that diabetes was their most stigmatized condition (84%), had moderate depressive symptom severity (PHQ-9 score of 13), and an HBA_{1c} level of 9.1%.

Table 4.1 Descriptive characteristics of study sample

	Control (N=208)	**Intervention (N=196)**	**Overall (N=404)**
Sex			
Male	76 (36.5%)	89 (45.4%)	165 (40.8%)
Female	132 (63.5%)	107 (54.6%)	239 (59.2%)
Age			
30- 39 years	14 (6.7%)	15 (7.7%)	29 (7.2%)
40-49 years	56 (26.9%)	58 (29.6%)	114 (28.2%)
50-59 years	82 (39.4%)	79 (40.3%)	161 (39.9%)
60 years or older	56 (26.9%)	44 (22.4%)	100 (24.8%)
Level of educational attainment			
Less than primary school	20 (9.6%)	19 (9.7%)	39 (9.7%)
Primary school	30 (14.4%)	35 (17.9%)	65 (16.1%)
Secondary school	108 (51.9%)	99 (50.5%)	207 (51.2%)
Post-secondary school	48 (23.1%)	43 (21.9%)	91 (22.5%)
Missing	2 (1.0%)	0 (0%)	2 (0.5%)
Average monthly household income (INRs)			
<3,000INRs	4 (1.9%)	6 (3.1%)	10 (2.5%)
3-10,000INRs	62 (29.8%)	49 (25.0%)	111 (27.5%)

	Control (N=208)	Intervention (N=196)	Overall (N=404)
10,000-20,000INRs	60 (28.8%)	57 (29.1%)	117 (29.0%)
20,000-30,000INRs	39 (18.8%)	36 (18.4%)	75 (18.6%)
30,000-40,000INRs	12 (5.8%)	12 (6.1%)	24 (5.9%)
40,000-50,000INRs	11 (5.3%)	13 (6.6%)	24 (5.9%)
>50,000INRs	20 (9.6%)	23 (11.7%)	43 (10.6%)
Stigmatized condition			
Depression	27 (13.0%)	17 (8.7%)	44 (10.9%)
Diabetes	173 (83.2%)	168 (85.7%)	341 (84.4%)
Missing	8 (3.8%)	11 (5.6%)	19 (4.7%)
Self-Stigma score at baseline (SSCI; range: 4-20)			
Median [Min, Max]	4 [4, 17]	4 [4, 15]	4 [4, 17]
Missing	5 (2.4%)	3 (1.5%)	8 (2.0%)
Change in Self-Stigma score (SSCI; range: -16 - +16)			
Median [Min, Max]	0 [-13, 7]	0 [-10, 5]	0 [-13, 7]
Missing	12 (5.8%)	14 (7.1%)	26 (6.4%)
Depression at baseline (PHQ9; range: 0-27)			
Median [Min, Max]	13 [10, 21]	13 [10, 22]	13 [10, 22]
Depression at endline (PHQ9; range: 0-27)			
Median [Min, Max]	7 [0, 22]	4 [0, 21]	5 [0, 22]
Missing	6 (2.9%)	4 (2.0%)	10 (2.5%)
Diabetes at baseline (A1c)			
Median [Min, Max]	8.70 [5.60, 15.0]	9.10 [5.80, 15.2]	8.90 [5.60, 15.2]
Diabetes at endline (A1c)			
Median [Min, Max]	8.20 [4.40, 14.3]	7.80 [0, 13.9]	8.00 [0, 14.3]
Missing	6 (2.9%)	4 (2.0%)	10 (2.5%)

4.4.1 *Mediation analysis*

In the unadjusted analysis (see Table 4.2), for patients with a 1 unit drop in self-stigma scores over 12 months, HBA_{1c} levels were 0.0600% lower (total effect; 95% CI: -0.00644-0.131%, p>.05). Similarly, we found no statistically significant differences when accounting for depressive symptoms as a mediator, (direct effect; β=0.0535, 95% CI: -0.163 - 0.125, p>.05) and the difference in the total effect minus the direct effect (average causal mediation effect; β=0.00652, 95% CI: -0.00229 - 0.0193, p>.05). Thus, this direct effect estimate confirms that a

change in self-stigma did not have an effect on diabetes outcomes through depressive symptoms as a mediator.

Table 4.2 Unadjusted total effect, direct effect, average causal mediated effect, and proportion mediated

Effects on diabetes after 12 months	**Point estimates**	**Confidence interval**	**p-value[1]**
Average causal mediated effect	0.00652	-0.00229 – 0.0193	0.162
Average direct effect	0.0535	-0.0163 – 0.125	0.129
Total effect	0.0600	-0.00744 – 0.131	0.0807
Proportion mediated	0.111	-0.377 – 0.998	0.231

[1]All p-values calculated using bootstrapping

We also conducted a sensitivity analysis to adjust for the covariates of age, sex, monthly household income, and level of educational attainment (see table 4.3). In the adjusted analysis, while holding all other covariates constant, for patients with a 1 unit drop in self-stigma scores over 12 months, HBA_{1c} levels were 0.0636% lower (total effect; 95% CI: -0.00455 - 0.132%, p>.05). We also found no statistically significant differences when accounting for depressive symptoms as a mediator, (direct effect; β=0.0568, 95% CI: -0.00131 - 0.126, p>.05) and the difference in the total effect minus the direct effect (average causal mediation effect; β=0.00636, 95% CI: -0.000995 - 0.0191, p>.05). Thus, this estimate confirms that a change in self-stigma did not have an effect on diabetes outcomes through depressive symptoms as a mediator even after adjusting for co-variates.

Table 4.3 Adjusted total effect, direct effect, average causal mediated effect, and proportion mediation

Adjusted effects on diabetes after 12 months[1]	**Point estimates**	**Confidence interval**	**p-value[2]**
Average causal mediated effect	0.00636	-0.000995 – 0.0191	0.120
Average direct effect	0.0568	-0.0131 – 0.126	0.112
Total effect	0.0632	-0.00455 – 0.132	0.0669
Proportion mediated	0.103	-0.286 – 0.930	0.231

[1]Effects adjusted for age, sex, monthly household income, and level of educational attainment.

[2]All p-values calculated using bootstrapping

4.4.2 *Longitudinal analysis*

At baseline, individuals assigned to the enhanced standard-of-care had an average SSCI-4 score of 4.80, which was 0.304 points higher (95% CI: 0.0558 – 0.552; p<.001) than the individuals assigned to COCM. Holding all other covariates constant, SSCI-4 scores decreased on average by 0.0271 points over a 12 month time period (95% CI: -0.0353 – -0.0189; p <.001); decreased on average by 0.400 points as the mean level of educational attainment rose from primary to secondary school (95% CI: -0.685 – -0.115; p<.01); decreased on average by 0.541 points as the mean level of educational attainment rose from secondary to post-secondary school (95% CI: -0.887 – -0.195; p<.01); and increased on average by 0.102 points for a 1% increase in HBA_{1c} levels at baseline (95% CI: 0.0570 – 0.146; p<.001). However, SSCI-4 scores did not differ longitudinally over time COCM to enhanced standard-of-care as the COCM groups SSCI-4 score increased on average by 0.00997 points for each 12-month period (95% CI: -0.00134 – 0.0213, p=0.0846). No other covariates were associated with a statistically significant change in SSCI-4 scores (see Table 4.4 below for full results).

Table 4.4 Predictors of self-stigma scores longitudinally

Predictors	**Point estimates**	**Confidence interval**	**p-value**
Intercept	4.80	3.69 – 5.91	<.001
Collaborative Care Model	-0.304	-0.552 – -0.0558	0.0164
Time	-0.0271	-0.0353 – -0.0189	<.001
Age	0.000573	-0.0105 – 0.00936	0.910
Sex (Female)	0.0254	-0.149 – 0.200	0.775
Monthly household income			
3-10,000INRs	-0.337	-0.911 – 0.236	0.248
20-20,000INRs	-0.398	-0.964 – 0.169	0.168
20-30,000INRs	-0.413	-1.00 – 0.174	0.168
30-40,000INRs	-0.362	-1.02 – 0.297	0.281
40-50,000INRs	-0.253	-0.845 – 0.339	0.402
>50,000INRs	-0.0822	-0.410 – 0.246	0.623
Level of educational attainment			

Primary school	-0.0822	-0.410 – 0.246	0.623
Secondary school	-0.400	-0.685 - -0.115	<.01
Post-secondary school	-0.541	-0.887 - -0.195	<.01
PHQ-9 scores at baseline	-0.00344	-0.0373 – 0.0304	0.842
HBA_{1c} levels at baseline	0.102	0.0570 – 0.146	<.001
Collaborative Care Model * time	0.00997	-0.00134 – 0.0213	0.0846

4.5 DISCUSSION

We found that there was no total effect of change in self-stigma over 12 months on diabetes outcomes at 12 months and that depressive symptom severity at 12 months was not a mediator. We also found that compared to the enhanced standard-of-care participants, self-stigma for COCM participants increased over time, contrary to what we anticipated. However, this relationship was not statistically significant nor was the magnitude of change in self-stigma scores longitudinally – among participants who on average at baseline indicated experiencing almost no self-stigma – large enough to demonstrate any noticeable clinical change. Considering that baseline self-stigma values were low, our results suggest that the reach of mental healthcare services at these urban diabetes clinics may have been low with respect to individuals experiencing self-stigma.

Our study results contribute to a rich and expanding literature at the intersection of stigma, mental illness, and diabetes in India by adding, to our knowledge, the first empirical estimate examining self-stigma in the context of an integrated BH intervention for people with comorbid depression and type II diabetes. Although beyond the scope of this study,(166) other interventions addressing stigma have focused more on raising community awareness or knowledge about mental illness with the goal of reducing stigmatizing behaviors as a prevention strategy for internalized self-stigma. Armstrong and colleagues observed modest reductions in stigmatizing attitudes towards people with common mental disorders among allied community

health workers serving in Bengaluru Rural District in Karnataka, following a health literacy training intervention.(178) Similarly, Mindlis and colleagues observed lower stigma levels following an educational intervention targeting six villages in rural Vadodara District in Gujarat.(179) In both cases, like COCM here, stigma reduction was a secondary outcome of interest. Like COCM, the bundled intervention used in the Systematic Medical Appraisal Referral and Treatment Mental Health Project in West Godavari District of Andhra Pradesh also featured task-shifting care (leveraging Accredited Social Health Activists), but also combined a public, multi-component anti-stigma campaign.(180, 181) Researchers observed a score improvement in stigma perceptions related to healthcare seeking using the Barriers to Access to Care Evaluation: Treatment Stigma subscale in their pre-post analysis.(180) Other research studies have focused on the critical role that healthcare workers play in stigmatizing these conditions.(29) These findings highlight the importance of a multi-pronged approach to reducing stigma that incorporates community-level prevention efforts and healthcare worker sensitization programs, and underscores future strategies with which to augment COCM and other integrated BH interventions that focus on healthcare service delivery in the face of stigma.(182)

Whereas the four sub-constructs measured in the SSCI-4 – avoidance, blame, feeling left out, and embarrassment – are central to self-stigma in the context of mental illness in settings in the Global North,(24, 168) their transferability to settings in India warrants further investigation. In their qualitative thematic analysis exploring community level notions of stigma in Kerala, researchers found that while the construct of self-stigma could partially explain the lived experiences of people with mental illness, there were other locally relevant notions.(183) These included the impairment of marriage prospects as a result of mental illness; the duality of family,

friends, and/or community members as either supporters and/or as antagonists; and the role of the collective (family, community, or other) in producing and upholding stigma.(183)

Furthermore, these notions of stigma intersect with gender, caste, and religion (among other factors) to generate new dimensions of stigma. One example highlighting such intersections is the story of an Indian graduate student, Aditi, who endured the persistent and nagging question "*लोग क्या कहेंगे?*" (Hindi: log kya kahenge? English: what will people say?) following the dissolution of an abusive marriage and the lasting trauma she suffered.(184) Here, Aditi's experience is shaped both by gender, stereotypical notions of marriage in India, and familial support where despite her coming forward to her family about the abuse she experienced and her subsequent mental health needs, she is ultimately blamed by her family for her marriage dissolving, dissuaded from further mental healthcare seeking, and isolated with the intention of further shielding her family from the collective and communal stigma they face.(184) Aditi's experience, as well as the broader dimensions of stigma shown as shown in the literature, highlight the limitations of the SSCI-4 as an instrument; the need for culturally-grounded, valid and reliable instruments to capture multi-dimensional stigma; and the opportunities for further research into the role of mental healthcare service interventions like COCM on stigma in India.

4.5.1 *Limitations*

Our study has several important limitations that warrant consideration. An assumption in our proposed pathway was that depression would be the most stigmatizing condition. Yet 341 participants (84%) indicated that diabetes was their most stigmatized condition. During the formative evaluation, staff participants identified patients would be reluctant to disclose their mental illness, which could be indicative of the high percentage of participants choosing

diabetes.(185) Research staff members also anecdotally observed in this study that participants may have reflexively selected ‘diabetes’ given that they were at a diabetes clinic during the study procedures. If diabetes is truly the most stigmatized condition in the sample, then the introduction of a new non-physician care coordinator providing mental healthcare may not address their stigma as much as we hypothesized. Further, the narrow target of our analysis was whether or not depression treatment mediated the pathway. A different mediator, such as the number of visits completed with a care coordinator, may have been a better choice to investigate pathways. Using a different model where the predictor and mediator are swapped (with depression predicting diabetes as mediated by self-stigma) might be more appropriate to explore a pathway where depression leads to self-stigma. In addition, the researchers in the primary trial were unable to collect caste data, which represents a missed opportunity to examine intersectional stigma. Furthermore, SSCI-4 scores were collected only at yearly intervals in this longitudinal study (unlike PHQ-9 and HBA_{1c} scores which were collected every six months), which hindered the ability to examine predictor, mediator, and outcome scores with more temporal sensitivity. Lastly, participants with moderate to severe depression symptom severity were recruited and in the context of the risk of regression to the mean,(54, 186) our analysis (which looks at depression symptom severity at 12 months cross-sectionally) may be looking at attenuated effects.

There are three potential sources of bias in mediation analyses like this which can risk resulting in incorrect interpretations and invalid inference. These include collider stratification bias (mediator-outcome confounding), mediator-outcome confounding affected by the predictor, and exposure-mediator interactions.(187) Collider stratification bias is particularly relevant if there are unknown or unmeasured confounders on the mediator and outcome, thus inducing a

spurious effect between the mediator and predictor.(187, 188) While the trial design balanced the distribution of known confounders at baseline to reduce selection bias, there remains a risk of an unmeasured confounder with respect to change in self-stigma as a predictor in this secondary mediation analysis.

4.6 CONCLUSION

Our study findings show that the effect of change in self-stigma on diabetes outcomes are not mediated by depressive symptoms in the context of COCM implementation at four urban diabetes clinics in India. Self-stigma scores longitudinally did not significantly differ comparing participants who received COCM to those who received enhanced standard-of-care. However, given the narrow scope of our study and the local and plural notions of stigma in India, we recommend further research on the use of culturally grounded instruments to assess self-stigma. While integrated care delivery models like COCM hold promise to improve health outcomes, our findings suggest that embedding additional and multi-level stigma-reduction interventions, including those operating at the community and healthcare systems levels, may be needed to reduce self-stigma.

Chapter 5. CONCLUSION

As the burden of substance use disorders and common mental disorders continue to rise globally, healthcare systems need to adapt to improve the reach of evidence-based BH services. The integration of BH into primary care settings has increasingly been recognized as a best practice for achieving high quality outcomes and improving access, yet uptake of integrated BH interventions remains slow. COCM is a key evidence-based, integrated BH intervention that when scaled, can address this gap yet key delivery questions remain. What are the determinants of implementing COCM for depression and OUD among PWH, especially in low-barrier HIV care settings designed for the 'hardest-to-reach' patients? How acceptable and feasible is it to implement COCM in low-barrier HIV care and what kinds of implementation strategies are necessary to sustain implementation? Does COCM lead to improvements in self-stigma over time and what is the role of self-stigma among people with depression and chronic disease comorbidities?

We conducted a qualitative formative evaluation of integrating care for depression and OUD via COCM for PWH in a low-barrier HIV clinic in Seattle, Washington. Patients and stakeholders were receptive to COCM and perceived it as a moderately appropriate intervention, but available resource constraints, practical concerns about COCM's contextual fit with low-barrier HIV care, and COCM's fit given the burden of complex comorbidities and acute socioeconomic needs at the low-barrier HIV clinic diminished enthusiasm.

Using a sequential explanatory (QUANT>qual) mixed methods evaluation, we evaluated the acceptability and feasibility of implementing COCM for depression and OUD at a low-barrier HIV clinic in Seattle, Washington. Of the 175 eligible patients, 36% of were screened, 24% were referred, 15% completed an intake, and 9% progressed to the engaged step of the care

cascade. The most salient factors corresponding to progression through these steps were, respectively: a lack of clarity about COCM services according to staff members, staff not remembering to complete screenings, and limited available time in clinic with patients reduced screenings; low staff buy-in and patient complexity restricted referrals; the constraints of low-barrier care along with needing to prioritize addressing acute patient needs limited intakes; and the BH CM's modeling of the clinic's culture and values enabled engagement among patients. Although participants found COCM to be acceptable and feasible to implement, it was only in the context of key adaptations to core intervention components and multiple barriers to implementation.

We conducted a mediation analysis to evaluate the effect of change in self-stigma scores over 12 months on diabetes outcomes at 12 months as mediated by depressive symptoms at 12 months in the context of COCM implementation in 4 urban clinics in India serving patients with comorbid type II diabetes and depression. We also examined self-stigma scores longitudinally comparing COCM participants to enhanced standard-of-care participants.

We observed no significant total effect of change in self-stigma scores over 12 months on diabetes outcomes at 12 months (HBA_{1c} -0.0600%; 95% CI: -0.00644 – -0.131, p>.05) and no statistically significant effect after accounting for depressive symptoms as a mediator (direct effect; β=0.0535, 95% CI: -0.163 - 0.125, p>.05). We observed no difference between COCM and enhanced standard-of-care participants longitudinally (Self-Stigma Scale for Chronic Illness-4 Item score: 0.00997; 95% CI: -0.00134 – 0.0213, p=0.0840). Given the null findings that resulted from a narrow research question, we advocate for additional research on the role of stigma in integrated BH interventions and on the development of culturally grounded stigma scales for the local and plural notions of stigma in India.

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APPENDIX A

Researcher Positionality and Reflexivity Statement

We are a study team of researchers affiliated with an academic institution (University of Washington) in the global north, with various levels of training and experience in western biomedicine and/or public health. In the context of Chapters 2 and 3, our backgrounds, education, and training may align more closely with some categories of Max Clinic staff (i.e., primary care providers) than others (i.e., medical and non-medical case managers), our experiences may limit our ability to generate insight into the anticipated barriers and facilitators to implementation specific to these job roles. While we aim to better understand the anticipated determinants and to evaluate implementation of an integrated behavioral healthcare program in a low-barrier HIV clinic, we do not share some of the most salient characteristics of patients for whom this program intends to support (e.g., PWH, people experiencing housing instability, and people with substance use disorders) which in turn limits the level of insight to be gained.

We are also affiliated with the same academic institution (University of Washington) that developed the evidence-based intervention (COCM) being evaluated in this study. This influences our perception of COCM's status as an 'evidence-based' intervention and our western academic training in turn shapes the forms of knowledge production that we privilege in generating evidence. Our study team is privileged with respect to various intersecting forms of socio-economic position; we all have at least Bachelor's degrees with most having additional masters and professional degrees, with no team members have ever experienced housing instability. The first author (SH) is a white, cis-gendered, able bodied, educated, middle-class male currently enrolled in a graduate-level implementation science program (University of

Washington), holding a Master's in Science degree with prior training and experience in qualitative and quantitative health services research. Together, these identities influence the research questions we ask, the ways we collect data, and the analyses we perform.

APPENDIX B

CFIR constructs selected a-priori by Research Assistant and Principal Investigator

Domain	Construct	Rationale
Innovation Characteristics	Evidence Strength & Quality	Facilitator: strong evidence for COCM is likely a selling point Barrier: no evidence in low-barrier HIV care tempers support
	Relative Advantage	Facilitator: in-house BH services will meet patients where they are by increasing access whereas compared to referrals Barrier: not advantageous for patients with complex comorbidities who may be ineligible
	Adaptability	Barrier: core elements of COCM not fully understood and perception that COCM needs significant adaptation to fit with low-barrier HIV care setting
	Design Quality & Packaging	Facilitator: bundled intervention addresses numerous gaps in accessing BH care services Barrier: multiple components challenging to implement together and poor understanding of which components are core versus non-essential
Outer Setting	Patient Needs & Resources	Facilitator: patient needs are well understood by stakeholders Barrier: COCM does not intervene on the social determinants of health, which are central to patient needs
Inner Setting	Networks & Communications	Barrier: communication across stakeholders identified as an area for improvement
Inner Setting> Implementation Climate	Tension for Change	Facilitator: receptive to trying new innovations/interventions Barrier: logistical and organizational constraints make implementation a challenge, as providing the standard-of-care for BH services is considered ‘difficult enough’
	Compatibility	Barrier: different categories of stakeholders use different databases and communication systems
	Relative Priority	Facilitator: high burden of common mental disorders and OUD underscores importance Barrier: EBIs for methamphetamine use disorder and/or patients with psychosis may be considered higher priorities
	Available Resources	Barrier: physical space constraints at clinic and insufficient FTE for incoming BH care manager

Inner Setting> Readiness for Implementation	Leadership Engagement	Barrier: disjoint leadership across different categories of stakeholders
Characteristics of Individuals	Identification with Organization	Facilitator: strong sense of community among stakeholders
Process	Engaging	Facilitator: small and large-group implementation groups present to guide implementation Barrier: perception of lack of involvement among stakeholders when implementing EBIs

APPENDIX C

Formative Evaluation – Interview Guides

Implementation Study of Collaborative Care Management in the Max Clinic
Patient Qualitative Interview Guide
Version Date: 10.20.2020

Notes:

- Qualitative transcripts to be stored in REDCap during transcription/coding as audit trail in case of accidental deletion

Introduction
Thank you for participating in this interview. Let me begin by telling you a little about who I am, the purpose of this research, and how this interview will go. I'll offer a chance for you to ask any questions, and then we will get started with the discussion.

I am working with a team of researchers who are interested in improving care for mental health and substance use disorders in the Max Clinic. For this project, we are trying to learn how to start a program to improve treatment specifically for depression and for opioid use disorder. To do that, we want to understand what people who get their care in the Max Clinic think about this idea, whether they would be interested in it, and how we can best shape the program to meet the needs of patients. During this interview, I will ask you about your past experience with mental health and substance use problems and your experience with seeing medical providers about these issues.

I want to make sure that I truly hear and understand what you say today. I brought a device to record our conversation so that I can go back and listen to it. The only people who will be able to hear this recording are people on my team who are directly involved with this project and someone who is paid to type up our conversation. The recording will be deleted after my team has analyzed the results from the interviews that we conduct. I might also take some notes as we talk. To help make sure that your privacy is respected, I will use only your first name. If I ask a question that you don't want to answer, please feel free to say "pass".

Ok, I'm going to start the recorder now (turn on recorders). Can you please say your first name? Do you have any questions at this point? (Wait and respond to any questions.)

1. Can you tell me a little about your (current/past) experience with treatment for mental health (MH) or substance use problems (SUD)?
    a. Probe: ever referred to someone/provider for treatment? Meds. vs. counseling?
    b. Probe: if referred and didn't make it, why not? (other priorities, healthcare system issues like appointments, stigma)

2. Thinking of all the things in your life that you need to deal with, how much of a priority is it for you to get treatment for depression? For opioid use disorder (OUD)? For other MH and SUD?
    a. Probe: importance of receiving medication vs. counseling

Intervention Characteristics

As I mentioned earlier, we are preparing to integrate treatment for depression and opioid use disorder with your care in the Max Clinic. What that means is that there would be a new person on the team, like a nurse or other healthcare provider, who would focus on treating depression and opioid use disorder. This person would work with you and the Max team and a psychiatrist to treat your depression and/or OUD here in the clinic. That person would check in with you regularly, provide counseling, and work with a psychiatrist and the Max Clinic doctors to adjust your medications in between visits. It would be a time-limited treatment, probably 6 months to a year.

3. What do you think about that idea?
    a. Probe: do you think COCM would help you?
    b. Probe: do you think this is something you would participate in?
    c. Probe: Walk-in vs. appointments? Best appointment times?
    d. Probe: How often would you be willing to talk with the behavioral care manager? (weekly?) In person or by phone?
    e. Probe: What are some qualities of the behavioral care manager that would be important to you?
    f. Probe: Is there another way you would rather receive mental health or substance use treatment services?

4. Based on the brief description I've just provided, do you have any concerns or questions about this program? What challenges do you foresee with your participation in this program?
    a. Probe: wait-time, self-management, referral vs. centralized care at Max, travel time, socio-economic needs
    b. Probe: interaction with HIV care

5. What kinds of changes would the Max Clinic need to make in order to ensure this program is effective? What kinds of changes would you need to make to accommodate receiving mental healthcare services at the Max Clinic?

Implementation Study of Collaborative Care Management in the Max Clinic
Provider [Staff Members] Qualitative Interview Guide
Version Date: 10.20.2020

Notes:

- [Bracketed] content in probes used to direct research analyst and coders for a separate rapid analysis.
- Qualitative transcripts to be stored in REDCap during transcription/coding as audit trail in case of accidental deletion

Introduction

Thank you for participating in this interview.

***If participant was not present during research team introductions, share introduction, Otherwise proceed to following paragraph.

Let me begin by telling you a little about who I am, the purpose of this research, and how this interview will go. I'll offer a chance for you to ask any questions, and then we will get started with the discussion. I am working with the research team on adapting, piloting, and implementing an intervention to integrate mental health and substance use disorder treatment at the Max Clinic. To do that, we want to understand what Max Clinic staff members think about this idea, whether they would be interested in it, and how we can best shape the program to meet the needs of the patients and providers. During this interview, I will ask you about your past experience working with patients with mental health and substance use.

I want to make sure that I truly hear and understand what you say today. I brought a device to record our conversation so that I can go back and listen to it. The only people who will be able to hear this recording are people on my team who are directly involved with this project and someone who is paid to type up our conversation. The recording will be deleted after my team has analyzed the results from the interviews that we conduct. I might also take some notes as we talk. To help make sure that your privacy is respected, I will use only your first name. If I ask a question that you don't want to answer, please feel free to say "pass".

Ok, I'm going to start the recorder now (turn on recorders). Can you please say your first name? Do you have any questions at this point? (Wait and respond to any questions.)

1. Can you tell me about your experience working with patients in the Max Clinic who have mental illness (MH) and/or substance use disorders (SUD)?
    a. Probe: differences between MH and SUD? Specifically, depression and opioid use disorder (OUD)?
    b. Probe: how to improve care for these patients? Biggest gap with current standard of care (differentiate MH/SUD)?
    c. Probe: tell me your thoughts how we're managing depression treatment and OUD treatment for patients at the Max Clinic
    d. Probe: tell me your thoughts about the current system for referrals (differentiate MH/SUD).

Description of intervention

The collaborative care management model involves a behavioral care manager working with specialists (like a psychiatrist or addiction medicine doctor) and the primary care team to focus on improving care for specific health conditions over a defined period of time, often about 6 months. The implementation team for this project that will help facilitate the care model includes Julie Dombrowski, Lydia Chwastiak (a psychiatrist), Judith Tsui (an addiction medicine doctor), and Deepa Rao (a clinical psychologist). The collaborative care program in the Max Clinic will focus on the treatment of depression and opioid use disorder. The general vision of the team is that a behavioral care manager – likely a nurse – would work with the Max Clinic team, patients, and a specialist to support care for these two conditions. This would include assessment, counseling and adjusting medications until the treatment goal is reached. We don't know all the details yet, and we would like to gather your thoughts on how to best implement the collaborative care intervention.

Perceptions of intervention

2. What do you think about the COCM intervention? [INTERVENTION SOURCE]
    a. Probe: do you think the intervention would be effective (depression/OUD outcomes)?
    b. Probe: alternate interventions instead of COCM? [RELATIVE ADVANTAGE]
    c. Probe: appropriate/feasible for the Max Clinic?

3. How do you think the CoCM intervention would work in the Max Clinic? What barriers/challenges would you foresee in implementing COCM? [ADAPTABILITY]
    Interviewer to proceed first to either A. Patients or B. Max Clinic pending participant's response
    a. Patients
        - Probe: effectiveness at engaging pts in HIV care? engaging pts in care for their mental health/substance use disorder? [EXTERNAL] [NEEDS/RESOURCES]
        - Probe: how would it respond to patient needs (wait time, self-management, care w/out appts centralized in one location, reduced travel time)? [PT NEEDS/RESOURCES]

    b. Max Clinic
        - Probe: Role of care manager?
        - Probe: Desired attributes of the care manager?
        - Probe: Role of DIS, SW in the intervention?
        - Probe: Role of physicians?
        - Probe: 6mo time-limited vs. sustainability period?
        - Probe: affect existing relationships with other orgs/partners? [EXTERNAL]
        - Probe: leadership/culture [LEADERSHIP/CULTURE]
        - Probe: data systems? [COMPATIBILITY]
        - Probe: workflows/organization [NETWORK/COMMS]
        - Probe: policies/SOPs [COMPATIBILITY]
        - Probe: collaboration/communication within Max Clinic [NETWORK/COMMS]
        - Probe: referring out vs. managing within?

Mixed methods evaluation – Interview Guides

Implementation Study of Collaborative Care Management in the Max Clinic
Post-Implementation Patient Qualitative Interview Guide
Version Date: 03.17.2022

Notes:

- Qualitative transcripts to be stored in REDCap during transcription/coding as audit trail in case of accidental deletion

Introduction

***If participant did not participate in pre-implementation interview, share brief introduction of interviewer's role.

Let me begin by telling you a little about the purpose of this research and how this interview will go. I'll offer a chance for you to ask any questions, and then we will get started with the discussion. Now that the Collaborative Care Model program [behavioral healthcare nurse program] has been running, we want to: understand what patients think about the program so far and discuss the future of the program.

I want to make sure that I truly hear and understand what you say today. I brought a device to record our conversation so that I can go back and listen to it. The only people who will be able to hear this recording are people on my team who are directly involved with this project and someone who is paid to type up our conversation. The recording will be deleted after my team has analyzed the results from the interviews that we conduct. I might also take some notes as we talk. To help make sure that your privacy is respected, I will use only your first name only if needed. If I ask a question that you don't want to answer, please feel free to say "pass".

Do you have any questions at this point? (Wait and respond to any questions.)

Ok, I'm going to start the recorder now (turn on recorder).

Grand tour/opening:

1. Can you please share your experiences receiving care for [depression/opioid-use disorder] at the MAX clinic with the behavioral healthcare nurse?
    a. Probe: what services did you receive? Were you:
        i. Screened by a social worker or a disease research intervention specialist [non-nurse staff member] for depression and/or opioid use disorder? What did you think of the screening process?
            1. Do you remember these 9 questions [have a PHQ-9 screener]? What did you think at the time?
            2. Do you remember being asked about substance use [have a NIDA quick ASSIST]? What did you think at the time?
        ii. Referred to the behavioral healthcare nurse for an intake? What did you think of the intake process?

iii. Did you have phone calls or text conversations with the behavioral healthcare nurse about your behavioral healthcare needs? What did you think of these interactions?
iv. Did you start and/or adjust a new medication and/or receive therapy from the behavioral healthcare nurse? What did you think of this care?

b. Probe: what impressions do you have about the behavioral healthcare you have received?
c. Probe: what about the behavioral healthcare services have gone well for you? What could be improved?

2. How have your experiences with care compared with any past care you have received elsewhere for [depression/opioid-use disorder]? any thoughts, reflections, or impressions you have about how the Collaborative Care Model [behavioral healthcare nurse] has been running so far?

Interpretive evaluation:

3. Which of these parts of the program have been helpful for you? How have they been helpful to you?
    a. Probe: screening
    b. Probe: intake
    c. Probe: communication and care coordination with behavioral healthcare manager (texts, phone calls, etc)
    d. Probe: care coordination with other behavioral healthcare providers
    e. Probe: services offered by behavioral healthcare providers (medication management, therapy).

4. What factors [in your life>when at the clinic] that have influenced your ability to engage in these services?
    a. Probe: what are the things that are important to you when you arrive at the clinic?
    b. Probe: please help me understand your state of mind when you attend the clinic.
    c. Probe: how did your expectations for seeing the behavioral healthcare manager compare with what was offered to you/what you experienced?
    d. Probe [drop-out at various steps]: what were the reasons for why you attended clinic but declined to see the behavioral healthcare nurse when they were available?
    e. Probe: what has helped you stay engaged [things that the MAX clinic has done vs. outside the MAX clinic]?
    f. Probe: what has hindered your ability to stay engaged?
    g. Probe: what would help you overcome any challenges associated with staying engaged?
    h. Probe: if and how have these factors varied at each step of screening>intake>care coordination and services?
    i. Probe: what else could we be doing to improve your engagement?

5. Would you like to continue receiving care for [depression/opioid-use disorder] at the MAX clinic? Should we continue offering this program?
    a. Probe: what parts of the program would you like to keep the same and why?
    b. Probe: what parts of the program would you like to change and why?

6. Thinking of all the things in your life that you need to deal with How important for you is receiving care for [depression/opioid-use disorder] at the MAX clinic?
    a. Probe: medication vs. therapy vs. coordination.

Implementation Study of Collaborative Care Management in the Max Clinic
Post-Implementation Service Delivery Stakeholder Qualitative Interview Guide
Version Date: 03.17.2022

Notes:
- Qualitative transcripts to be stored in REDCap during transcription/coding as audit trail in case of accidental deletion

Introduction
Thank you for participating in this interview.

***If participant did not participate in pre-implementation interview, share brief introduction of interviewer's role.
Let me begin by telling you a little about the purpose of this research and how this interview will go. I'll offer a chance for you to ask any questions, and then we will get started with the discussion. Now that the Collaborative Care Model program [behavioral healthcare nurse with consulting psychiatrist] has been running, we want to: understand what Max Clinic staff members [service delivery stakeholders] think about the program so far, receive assistance in interpreting our findings, and discuss the future of the program.

I want to make sure that I truly hear and understand what you say today. I brought a device to record our conversation so that I can go back and listen to it. The only people who will be able to hear this recording are people on my team who are directly involved with this project and someone who is paid to type up our conversation. The recording will be deleted after my team has analyzed the results from the interviews that we conduct. I might also take some notes as we talk. To help make sure that your privacy is respected, I will use only your first name only if needed. If I ask a question that you don't want to answer, please feel free to say "pass".

Do you have any questions at this point? (Wait and respond to any questions.)

Ok, I'm going to start the recorder now (turn on recorder).

Grand tour/opening:
7. Can you please share any thoughts, reflections, or impressions you have about how the Collaborative Care Model has been running so far?

Interpretive evaluation:

8. Here is a care cascade showing how patients are flowing through the program from screening through intake, and various care engagement strategies. We want to understand how to increase retention and improve engagement at all steps. What do you think accounts for the drop-offs we are seeing at these various steps?

9. Some referred patients have had 1+ visits to the MAX Clinic since referral but have not enrolled in the COCM program. What are the reasons these patients have not followed-up with Ramona?
    a. Probe: what strategies should we use to address these reasons?

10. For the screening process, we initially did a targeted screening approach using the social workers before referral to the behavioral health care manager. Then we adjusted to allow the disease research intervention specialists to also screen as part of a staged universal screening. What are the reasons that some staff members declined to screen patients for the Collaborative Care Model program?
    a. Probe: differentiating between targeted social worker screening vs. disease research intervention specialist staged universal screening?
    b. Probe: reasons patients decline the initial screening?

11. How have the different components of the screening processes gone so far?
    a. Probe: what do you think about the use of the PHQ-2>PHQ-9 for depression screening?
    b. Probe: what alternatives might we employ for screening for depression or identifying patients for the Collaborative Care Model program?

12. Let's examine the care cascade comparing disease condition (depression vs. OUD). What are the reasons explaining these differences?

13. What do you think have been the successes and challenges associated with the behavioral health care manager role at the MAX clinic?
    a. Probe: integration within team structure?
    b. Probe: communication and workflows?
    c. Probe: qualifications/background nurse vs. licensed clinical social work vs. other cadres of behavioral healthcare workers (licensed counselors)

14. We want to get your opinions as to how the Collaborative Care Model is or is not working to improve patient outcomes on viral suppression. What has been the effect, if any, of the Collaborative Care Model on rates of viral suppression?
    a. Probe: how has Collaborative Care affected rates of viral suppression?
    b. Probe: which parts of Collaborative Care are important (or not) in affecting rates of viral suppression?
        i. Task-shifted care by behavioral health care manager
        ii. Services provided by behavioral health care manager (behavioral activation, care coordination, etc)
        iii. Case review/case conference with consulting psychiatrist

iv. Registry

15. We used different strategies to improve the implementation of Collaborative Care including training, conducting small group consensus meetings, and involved patients and staff members. Did these help with implementation, and if so, how?
    a. Probe: what other strategies could be helpful?
        i. Cash incentive for following-up with the behavioral healthcare nurse or other form of engagement with the behavioral healthcare nurse?
    b. Probe: in what ways could we have adjusted the strategies we used?
    c. Probe: did these improve the acceptability or feasibility of Collaborative Care? If so, how?

16. What are the other priority behavioral health conditions among patients receiving care at the MAX Clinic?
    a. Probe: how could we more effectively address these conditions?
    b. Probe: what else is needed in the community or outside the clinic to support the behavioral healthcare needs of MAX Clinic patients [COCM: depression/opioid-use disorder vs. other behavioral health needs]?

Determinants of implementation:

17. Prior to implementation, we identified potential barriers and facilitators to implementing Collaborative Care which included: openness and optimism for Collaborative Care, the MAX Clinic has a culture of solving for the patient but sometimes at the expense of detailed planning, space/room constraints, and questions about role clarity BH Care Nurse<>SW<>DRIS. What have been the barriers or facilitators to implementing Collaborative Care so far [what parts of Collaborative Care have been challenging/easy to implement?]?

CFIR Interview Guide Probes [available for use as needed]

<u>Relative Advantage:</u>

9. How does the intervention compare to other alternatives that may have been considered or that you know about [standard of care/referral to Madison Psyc./HMHS/other]?
    a. Probe: What advantages does the intervention have compared to these other programs?
    b. Probe: What disadvantages does the intervention have compared to these other programs?

<u>Patient Needs & Resources:</u>

12. How well do you think the intervention met the needs of the individuals served by the MAX Clinic?
    a. Probe: In what ways did the intervention meet their needs? E.g. in terms of access to services? Wait times? Linkage to care? Engagement in behavioral/HIV care? Self-management?
    b. Probe: How have past patient experiences receiving behavioral healthcare services affected their participation in Collaborative Care?

13. How do you think the individuals served by the MAX Clinic responded to the intervention?

Compatibility

17. How well did Collaborative Care fit with existing work processes and practices at the MAX Clinic?
    a. Probe: What issues or complications arose?

Relative Priority

18. How does the priority of implementing Collaborative Care compare with other priorities at the MAX Clinic?

Available Resources

20. Did the MAX Clinic have sufficient resources to implement and administer Collaborative Care?
    a. Probe: Were space/room constraints a factor?
    b. Probe: Were waiting room waits a factor?

Sustainability

21. Do you think we should offer Collaborative Care permanently at the MAX Clinic?

22. What adaptations or changes need to be made to facilitate offering Collaborative Care permanently?
    a. Probe: changes to the MAX Clinic
    b. Probe: changes to the Collaborative Care program

23. What additional factors would influence the sustainment of Collaborative Care permanently at the MAX clinic (as opposed to the pilot program?)
    a. Probe: what factors would influence scale-up to other low-barrier HIV settings? [specific to sub-set of service delivery stakeholders]

24. Alternatives to COCM (in addition to COCM, instead of COCM, other ways to address behavioral health needs -> best practices, ideal, practical/feasible)?

Mixed Methods Evaluation – Screening, Intake, and Clinical Assessments

Patient Health Questionnaire – 2 Item (PHQ-2): Screening

Over the last 2 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3

=PHQ-2 Score: _____

=PHQ-2 Score Free Entry: _____

Patient Health Questionnaire – 9 Item (PHQ-9): Screening, Intake, Care Delivery, Mediation Study

Over the last 2 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

=PHQ-9 Score: _____

=PHQ-9 Score Free Entry: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

Modified NIDA Quick Screen: Screening

In the past year, how often have you used the following?	Never	Once or twice	Monthly	Weekly	Daily or almost daily
Alcohol					
For men, 5 or more drinks a day					
For women, 4 or more drinks a day					
Tobacco Products					
Prescription Drugs for Non-Medical Reasons					

Illegal drugs
Opioids (heroin, Percocet, fentanyl, Vicodin,
oxycodone, etc)*
*Responses of once or twice or more frequent indicated a positive screen for OUD

Generalized Anxiety Disorder-7 Item: Intake, Care Delivery

Over the last 2 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

=GAD-7 Score: _____

=GAD-7 Score Free Entry: _____

If you checked off any problems on this questionnaire, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

Mixed Methods Evaluation – Implementation assessments

Implementation Study of Collaborative Care Management in the Max Clinic
Implementation Assessments
Version Date: 10.20.2020

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Collaborative Care meets my approval	1	2	3	4	5
2. Collaborative Care is appealing to me	1	2	3	4	5
3. I like Collaborative Care	1	2	3	4	5
4. I welcome Collaborative Care	1	2	3	4	5

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Collaborative Care seems fitting	1	2	3	4	5
2. Collaborative Care seems suitable	1	2	3	4	5
3. Collaborative Care seems applicable	1	2	3	4	5
4. Collaborative Care seems like a good match	1	2	3	4	5

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. Collaborative Care seems implementable	1	2	3	4	5
2. Collaborative Care seems possible	1	2	3	4	5
3. Collaborative care seems doable	1	2	3	4	5
4. Collaborative Care seems easy to use	1	2	3	4	5

Organizational Readiness for Implementing Change (ORIC)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. People who work here feel confident that the Max Clinic can get people invested in implementing Collaborative Care.	1	2	3	4	5
2. People who work here are committed to implementing Collaborative Care.	1	2	3	4	5
3. People who work here feel confident that they can keep track of progress in implementing Collaborative Care.	1	2	3	4	5
4. People who work here will do whatever it takes to implement Collaborative Care.	1	2	3	4	5
5. People who work here feel confident that the Max Clinic can support people as they adjust to Collaborative Care.	1	2	3	4	5
6. People who work here want to implement Collaborative Care.	1	2	3	4	5
7. People who work here feel confident that they can keep the momentum going in implementing Collaborative Care.	1	2	3	4	5
8. People who work here feel confident that they can handle the challenges that might arise in implementing Collaborative Care.	1	2	3	4	5
9. People who work here are determined to implement Collaborative Care.	1	2	3	4	5
10. People who work here feel confident that they can coordinate tasks so that implementing Collaborative Care goes smoothly.	1	2	3	4	5
11. People who work here are motivated to implement Collaborative Care.	1	2	3	4	5
12. People who work here feel confident that they can manage the politics of implementing Collaborative Care.	1	2	3	4	5

Acceptability "is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory." Acceptability of Collaborative Care can vary depending the individual's needs/preferences/expectations.(91, 123)

- Participant answers for themselves.

Appropriateness “is the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem.” Is Collaborative Care appropriate given the Max Clinic’s existing challenges/constraints/culture/working norms?(91, 123)

- Participant answers for themselves.

Feasibility “is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting.” Can Collaborative Care be implemented easily or conveniently within the Max Clinic’s existing resources/workflows/systems?(91, 123)

- Participant answers for themselves.

Organizational Readiness “organizational readiness refers to organizational members' [collective] change commitment and change efficacy to implement organizational change [willingness and ability to take action]... Change commitment is largely a function of change valence… do [the team members] collectively value the impending change?.. [Is it] needed, important, beneficial, or worthwhile [enough to commit to its implementation]?... Change efficacy is a function of organizational members’ cognitive appraisal of the task demands, resource availability, and situational factors [associated with implementation].”(124, 125)

- Participant answers for the Max Clinic as a whole.

Mediation Analysis – 4-item Self-Stigma Scale for Chronic Illness

PART – B: STIGMA SCALE FOR CHRONIC ILLNESS					
The following items ask about any stigma (shame, embarrassment) you have experienced lately as a result of your condition.					
Please indicate which condition (diabetes/sugar, depression/stress) is most stigmatizing for you	Depression ☐ Diabetes ☐ *Please consider this condition when answering the following questions.*				
	Never (1)	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Always (5)**
Because of my illness, some people avoided me	☐	☐	☐	☐	☐
Some people acted as though it was my fault I have this illness	☐	☐	☐	☐	☐
Because of my illness, I felt left out of things	☐	☐	☐	☐	☐
I felt embarrassed about my illness	☐	☐	☐	☐	☐

APPENDIX D

Mediation analysis – statistical software code

```
## This is annotated companion R code for:
## Halliday, S. (2023) Collaborative Care Models for Behavioral
##    Healthcare Services Integration. ProQuest Dissertations Publishing

## Description:
## This R code provides a complete walk through of this mediation analysis
## according to the Baron & Kenny (1986) method with bootstrapping and
## multiple imputation.
##
## Data availability:
## To obtain the datasets to reproduce this analysis, please email:
## Deepa Rao, deeparao@uw.edu. You will be asked to enter into a data
## sharing agreement with co-investigators for the INDEPENDENT study.
##
## Trial registration:
## https://clinicaltrials.gov/ct2/show/NCT02022111
##
## This R code is divided into the following sections:
##       1) Data preparation and set-up
##       2) Construct validity
##       3) Missingness exploration and multiple imputations for mediation analysis
##       4) Mediation analysis (unadjusted and adjusted models)
##       5) Longitudinal analysis of self-stigma scores (SSCI) by treatment group (data
preparation and set up; multiple imputations for longitudinal analysis; longitudinal analysis of
SSCI by treatment group)

## Session Info
## R version 4.2.2 (2022-10-31 ucrt)
## Platform: x86_64-w64-mingw32/x64 (64-bit)
## Running under: Windows 10 x64 (build 22621)

## Packages used to perform analysis (if you do not have these, they can
## be installed using the following code:
##install.packages("[insert package name"]))

##### data preparation set up for analyses #####
## packages used
library(tidyverse)
library(table1)
library(Amelia)
```

```
library(lattice)
library(mice)
library(VIM)
library(mediation)
library(nlme)
library(mitools)
library(mitml)
library(broom.mixed)
library(data.table)
library(broom)
library(psych)

## set data directory
data.dir <- "C:/Users/smhal/Documents/University of Washington/PhD 2019-
2023/Dissertation/Aim 3/"
setwd(data.dir)

## set seed for reproducible results
set.seed(1234)

## load data, ##0mo and 12mo used for analysis
INDEP_0mo <- read.csv('Complete_INDEP_NEW_0mo.csv', header=TRUE) ##for mediation +
longitudinal stigma analysis
INDEP_12mo <- read.csv('Complete_INDEP_NEW_12mo.csv', header=TRUE) ##for mediation
+ longitudinal stigma analysis
INDEP_24mo <- read.csv('Complete_INDEP_NEW_24mo.csv', header=TRUE) ##longitudinal
stigma analysis only
INDEP_36mo <- read.csv('Complete_INDEP_NEW_36mo.csv', header=TRUE,
fileEncoding="latin1") ##longitudinal stigma analysis only

## set BL model for predictors/outcomes of interest only
mod_bl <- PID ~ PType + SID  + Age + Sex + edustat + hh_inc + PHQ9_tot + A1C +
Stigma_cond + Stigma1 + Stigma2 + Stigma3 + Stigma4

## set endline model
mod_end <- PID ~ PHQ9_tot + A1C + Stigma1 + Stigma2 + Stigma3 + Stigma4

## create new dataframes with only predictors/outcomes of interest
INDEP_0mo_fin <- model.frame(mod_bl, data=INDEP_0mo, na.action = na.pass)
INDEP_12mo_fin <- model.frame(mod_end, data=INDEP_12mo, na.action = na.pass)

## create new education status (below primary, primary complete, secondary complete, post-
secondary)
INDEP_0mo_fin <- INDEP_0mo_fin %>% mutate(educ = case_when(
  INDEP_0mo_fin$edustat==7~0,
  INDEP_0mo_fin$edustat==6~1,
```

```
  INDEP_0mo_fin$edustat==5~1,
  INDEP_0mo_fin$edustat==4~2,
  INDEP_0mo_fin$edustat==3~3,
  INDEP_0mo_fin$edustat==2~4,
  INDEP_0mo_fin$edustat==1~4,
  INDEP_0mo_fin$edustat==0~4
))

## create NAs for educ == 0 (unsure)
INDEP_0mo_fin$educ[INDEP_0mo_fin$educ=="0"] <- NA

## join follow-up observations into single dataframe
INDEP <- left_join(INDEP_0mo_fin, INDEP_12mo_fin, by="PID")

## reclassify 0 values for stigma as NAs
INDEP[, 11:14][INDEP[, 11:14] == 0] <- NA
INDEP[, 18:21][INDEP[, 18:21] == 0] <- NA

## rows 405-4011 to be deleted
INDEP <- INDEP[-c(405,406,407,408,409,410,411), ]

## remove edustat variable
INDEP <- INDEP[ -c(6) ]

## create new total stigma scores
INDEP <- INDEP %>% mutate(tot_stigma.x = Stigma1.x+Stigma2.x+Stigma3.x+Stigma4.x)
INDEP <- INDEP %>% mutate(tot_stigma.y = Stigma1.y+Stigma2.y+Stigma3.y+Stigma4.y)

## create change in stigma scores as primary predictor
INDEP <- INDEP %>% mutate(stigma_change = tot_stigma.y-tot_stigma.x)

##### construct validity #####
## stigma scale variables
## use baseline measurement for cronbach alpha
stigma.vars <- c("Stigma1.x", "Stigma2.x", "Stigma3.x", "Stigma4.x")

## run Cronbahch's alpha on stigma scale variables total
stigma.alpha <- alpha(INDEP[stigma.vars])
print(stigma.alpha, digits=3)

##### descriptive characteristics for mediation analysis #####
## categorical age
INDEP <- INDEP %>% mutate(age_category = case_when(
  INDEP$Age<30 ~ 'age <30 years',
  INDEP$Age>=30 & INDEP$Age<40 ~ 'age 30-39 years',
  INDEP$Age>=40 & INDEP$Age<50 ~ 'age 40-49 years',
```

```
  INDEP$Age>=50 & INDEP$Age<60 ~ 'age 50-59 years',
  INDEP$Age>=60 ~"age>= 60 years"))

## factor variables/descriptive labels for table 1 based on imputations
INDEP$PType <-
  factor(INDEP$PType, levels=c(0,1),
        labels=c("Control",
                 "Intervention"))

label(INDEP$PType)       <- "Treatment Assignment"

## optional if interested to look at table stratified by site
INDEP$SID <-
  factor(INDEP$SID, levels=c(1,2,3,4),
        labels=c("MDRF",
                 "AIIMS",
                 "Vizag",
                 "Diacon"))

INDEP$Sex <-
  factor(INDEP$Sex, levels=c(0,1),
        labels=c("Male",
                 "Female"))

INDEP$educ <-
  factor(INDEP$educ, levels=c(1,2,3,4),
        labels=c("Less than primary school",
                 "Primary school",
                 "Secondary school",
                 "Post-secondary school"))

label(INDEP$educ)       <- "Level of educational attainment"

INDEP$hh_inc <-
  factor(INDEP$hh_inc, levels=c(1,2,3,4,5,6,7),
        labels=c("<3,000INRs",
                 "3-10,000INRs",
                 "10,000-20,000INRs",
                 "20,000-30,000INRs",
                 "30,000-40,000INRs",
                 "40,000-50,000INRs",
                 ">50,000INRs"))

label(INDEP$hh_inc)       <- "Average monthly household income (INRs)"

INDEP$Stigma_cond <-
```

```
  factor(INDEP$Stigma_cond, levels=c(1,2),
         labels=c("Depression",
                  "Diabetes"))

label(INDEP$Stigma_cond)       <- "Stigmatized condition"

label(INDEP$stigma_change)      <- "Change in Self-Stigma score (SSCI; range: -16 - +16)"
label(INDEP$PHQ9_tot.x)       <- "Depression at baseline (PHQ9; range: 0-27)"
label(INDEP$PHQ9_tot.y)       <- "Depression at endline (PHQ9; range: 0-27)"
label(INDEP$A1C.x)       <- "Diabetes at baseline (A1c)"
label(INDEP$A1C.y)       <- "Diabetes at endline (A1c)"
label(INDEP$tot_stigma.x) <- "Self-Stigma score at baseline (SSCI; range: 4-20)"
label(INDEP$age_category) <- "Categorical Age"

## table 1 pre-imputation
table1_pre_imp <- table1(~ Sex + age_category + educ + hh_inc + as.factor(Stigma_cond) +
tot_stigma.x + stigma_change + PHQ9_tot.x + PHQ9_tot.y + A1C.x + A1C.y | PType,
data=INDEP)
table1_pre_imp

## table 1 pre-imputation, stratified by site, not used
table1_pre_imp_site <- table1(~ Sex + Age + educ + hh_inc + as.factor(Stigma_cond) +
tot_stigma.x + stigma_change + PHQ9_tot.x + PHQ9_tot.y + A1C.x + A1C.y | factor(SID) +
PType, data=INDEP)
table1_pre_imp_site

##### missingness exploration and multiple imputations for mediation analysis #####

## exploratory analysis for missingness
INDEP_miss = aggr(INDEP, col=mdc(1:2), numbers=TRUE, sortVars=TRUE,
labels=names(INDEP), cex.axis=.5, gap=2, ylab=c("Proportion of missingness","Missingness
Pattern"))

## drop individual stigma scores and total stigma score to avoid collinearity with stigma
outcomes
INDEP <- INDEP[ -c(10:13) ] ##baseline stigma scores
INDEP <- INDEP[ -c(13:18) ] ##endline stigma scores and total stigma scores

## create bounds for PHQ9 imputations (restrict to values of 0-27)
bds <- matrix(c(11,0,27), nrow=1, ncol=3)
bds ##check that it worked

## use AMELIA for 30 multiple imputations
set.seed(1234)
m = 30
INDEP_imp <- amelia(INDEP, m=m, p2s = 1,
```

```
                idvars=c("PID","PType","SID","age_category"),
                noms=c("Stigma_cond"),
                ords=c("educ", "Sex", "hh_inc"),
                max.resample = 1000)
INDEP_imp
plot(INDEP_imp) ## assess convergence ## education variable has multiple peaks indicating
overdispersion
write.amelia(obj=INDEP_imp, file.stem="INDEP_imp")

## set up imputed datasets for mediation analysis, store as list-like object
setwd(data.dir)

ll.imp_sets <-
  lapply(1:m, function(i){
    INDEP_imp.i <- read.csv(paste0('indep_imp', i, '.csv'), header=TRUE) ## load m=30 imputed
datasets

    INDEP_imp.i$PHQ9_tot.y <-round(INDEP_imp.i$PHQ9_tot.y) ## round imputed PHQ9
values to nearest whole numbers (no missingness at baseline)

    INDEP_imp.i$stigma_change <- round(INDEP_imp.i$stigma_change) ## round imputed
stigma change values to nearest whole number

    INDEP_imp.i$A1C.y <- round(INDEP_imp.i$A1C.y, digits = 1) ## round imputed A1c
values to 1 decimal place (no missingness at baseline)

    return(INDEP_imp.i)
  })

## check an imputed dataset
INDEP_imp1 <- ll.imp_sets[[1]]

##### evaluate data distributions for mediation analysis #####

## density plot depression (use imputed dataset 1 for reference)
## call dev.off if invalid graphics state error persists
dens_dep_12mo <- ggplot(INDEP_imp1,
                aes(x=PHQ9_tot.y)) +
  geom_density(fill="#69b3a2", color="#e9ecef", alpha=0.8) +
  theme_light() +
  labs(
    title = "Distribution of depression at endline",
    x = "Depression at endline (PHQ9 scores, range: 0-27)",
    y = "Distribution of depression at endline")
dens_dep_12mo
```

```
dens_dep_0mo <- ggplot(INDEP_imp1,
                       aes(x=PHQ9_tot.x)) +
  geom_density(fill="#69b3a2", color="#e9ecef", alpha=0.8) +
  theme_light() +
  labs(
    title = "Distribution of depression at baseline",
    x = "Depression at endline (PHQ9 scores, range: 0-27)",
    y = "Distribution of depression at baseline")
dens_dep_0mo

## density plot diabetes endline
dens_diab_12mo <- ggplot(INDEP_imp1,
                    aes(x=A1C.y)) +
  geom_density(fill="#69b3a2", color="#e9ecef", alpha=0.8) +
  theme_light() +
  labs(
    title = "Distribution of diabetes at endline",
    x = "Diabetes at endline (glycated hemoglobin A1c scores,0-100%",
    y = "Distribution of diabetes at endline")
dens_diab_12mo

dens_diab_0mo <- ggplot(INDEP_imp1,
                        aes(x=A1C.x)) +
  geom_density(fill="#69b3a2", color="#e9ecef", alpha=0.8) +
  theme_light() +
  labs(
    title = "Distribution of diabetes at baseline",
    x = "Diabetes at baseline (glycated hemoglobin A1c scores,0-100%",
    y = "Distribution of diabetes at baseline")
dens_diab_0mo

## convert multiple imputed datsets to mids object
INDEP_mids <- miceadds::datalist2mids(INDEP_imp$imputations)

##### mediation analysis #####
### unadjusted analysis ###
## change in stigma = predictor, diabetes = outcome, no mediator
mod.0_imp <- A1C.y ~ stigma_change + A1C.x

## change in stigma = predictor, depression = mediator, no outcome
mod.1_imp <- PHQ9_tot.y ~ stigma_change + PHQ9_tot.x

## change in stigma = predictor, depression = mediator, diabetes = outcome, full model
mod.2_imp <- A1C.y ~ stigma_change + A1C.x + PHQ9_tot.x + PHQ9_tot.y

## bootstrapped mediation results, save as list-like object
```

```
ll.results <-
  lapply(1:m, function(i) {
    mod.0_outp_imp <- lm(mod.0_imp, data = ll.imp_sets[[i]]) ## change in stigma = predictor,
diabetes = outcome, no mediator

    mod.1_outp_imp <- lm(mod.1_imp, data = ll.imp_sets[[i]]) ## change in stigma = predictor,
depression = mediator, no outcome

    mod.2_outp_imp <- lm(mod.2_imp, data = ll.imp_sets[[i]]) ## change in stigma = predictor,
depression = mediator, diabetes = outcome, full model

    results_med <- mediation::mediate(mod.1_outp_imp,
                        mod.2_outp_imp, treat = 'stigma_change', mediator = 'PHQ9_tot.y', boot =
TRUE, sims = 1000)     ## bootstrap CI with 1000 simulations

    list("mod.0_outp_imp" = mod.0_outp_imp,
         "mod.1_outp_imp" = mod.1_outp_imp,
         "mod.2_outp_imp" = mod.2_outp_imp,
         "results_med" = results_med)

  })

save(list = c("ll.imp_sets", "ll.results"), file = "imputed_datasets_results.image")
load("imputed_datasets_results.image")

## pooled mediation results
## bootstrapped p-values function, adapted from boot.pval::boot.pval[]
modified.boot.pval <- function(sims, theta_null = 0) {
  pval_precision = 1/length(sims)

  alpha_seq <- seq(1e-16, 1 - 1e-16, pval_precision)

  ci <- lapply(alpha_seq, function(xalpha) {rbind(quantile(sims, c(xalpha/2, 1 - xalpha/2)))})
  bounds <- do.call(rbind, ci)

  alpha <- alpha_seq[which.min(theta_null >= bounds[,1] & theta_null <= bounds[,2])]
  return(alpha)
}

## p values function from mediation package
p.val <- function (x, xhat){
  if (xhat == 0)
    out <- 1
  else {
    out <- 2 * min(sum(x > 0), sum(x < 0))/length(x)
  }
```

```
  return(min(out, 1))
}

## ACME
## Pooled ACME point estimate
ll.med.results <- lapply(1:m, function(i){ll.results[[i]]$results_med})

pool.ACME <-
  (ll.m <-
     lapply(ll.med.results,
            function(l){
              l$d0
            }) %>% unlist()) %>% mean()
pool.ACME

## Pooled ACME CI
pool.ACME.CI <-
  (ll.ACME <-
     lapply(lapply(1:m, function(i){ll.results[[i]]$results_med}),
            function(l) {
              l$d0.sims
            }) %>% unlist()) %>% quantile(., c(2.5, 97.5)/100)
pool.ACME.CI

## Pooled ACME p value
plot(density(ll.ACME[1:1000]))
plot(density(ll.ACME[1:1000 + 1000]))
plot(density(ll.ACME[1:1000 + 2*1000]))
plot(density(ll.ACME[1:1000 + 20*1000]))
plot(density(ll.ACME[1:1000 + 29*1000]))

pool.ACME.pval <- p.val(ll.ACME, xhat = pool.ACME)
pool.ACME.pval

pool.ACME.pval.al <- modified.boot.pval(ll.ACME)
pool.ACME.pval.al

## ADE
## Pooled ADE point estimate
pool.ADE <-
  lapply(lapply(1:m, function(i){ll.results[[i]]$results_med}),
         function(l) {l$z0}) %>% unlist() %>% mean()
pool.ADE

## Pooled ADE CI
pool.ADE.CI <-
```

```
  (ll.ADE <-
     lapply(lapply(1:m, function(i){ll.results[[i]]$results_med}),
            function(l) {
              l$z0.sims
            }) %>% unlist()
  ) %>% quantile(., c(2.5, 97.5)/100)
pool.ADE.CI

## Pooled ADE p value
pool.ADE.pval <- p.val(ll.ADE, xhat = pool.ADE)
pool.ADE.pval

pool.ADE.pval.al <- modified.boot.pval(ll.ADE)
pool.ADE.pval.al

## Pooled total effect
pool.Tot <-
  lapply(lapply(1:m, function(i){ll.results[[i]]$results_med}),
         function(l) {l$tau.coef}) %>% unlist() %>% mean()
pool.Tot

## Pooled total effect CI
pool.Tot.CI <-
  (ll.Tot <-
     lapply(lapply(1:m, function(i){ll.results[[i]]$results_med}),
            function(l) {
              l$tau.sims
            }) %>% unlist()) %>% quantile(., c(2.5, 97.5)/100)
pool.Tot.CI

## Pooled total effect p value
pool.Tot.pval <- p.val(ll.Tot, xhat = pool.Tot)
pool.Tot.pval

pool.Tot.pval.al <- modified.boot.pval(ll.Tot)
pool.Tot.pval.al

## Prop. Mediated
## Prop. Mediated point estimate
pool.Prop.Med <-
  lapply(lapply(1:m, function(i){ll.results[[i]]$results_med}),
         function(l) {l$n0}) %>% unlist() %>% mean()
pool.Prop.Med

## Prop. Mediated CI
pool.Prop.Med.CI <-
```

```
  (ll.Med <-
     lapply(lapply(1:m, function(i){ll.results[[i]]$results_med}),
            function(l) {
              l$n0.sims
            }) %>% unlist()) %>% quantile(., c(2.5, 97.5)/100)
pool.Prop.Med.CI

## Prop. Mediate p value
pool.Prop.Med.pval <- p.val(ll.Med, xhat = pool.Prop.Med)
pool.Prop.Med.pval

pool.Prop.Med.pval.al <- modified.boot.pval(ll.Med)
pool.Prop.Med.pval.al

## Store results in tibble
TAB <- ## With p.val() p-values
  tribble(
    ~indicator, ~Estimate, ~LB, ~UB, ~pval,
    "ACME", pool.ACME, pool.ACME.CI[1], pool.ACME.CI[2], pool.ACME.pval,
    "ADE",  pool.ADE, pool.ADE.CI[1], pool.ADE.CI[2], pool.ADE.pval,
    "Total Effect", pool.Tot, pool.Tot.CI[1], pool.Tot.CI[2], pool.Tot.pval,
    "Prop. Mediated", pool.Prop.Med, pool.Prop.Med.CI[1], pool.Prop.Med.CI[2],
pool.Prop.Med.pval
  )
TAB

TAB1 <- ## With p.val() and boot.pval() p-values
  tribble(
    ~indicator, ~Estimate, ~LB, ~UB, ~pval, ~pval.al,
    "ACME", pool.ACME, pool.ACME.CI[1], pool.ACME.CI[2], pool.ACME.pval,
pool.ACME.pval.al,
    "ADE",  pool.ADE, pool.ADE.CI[1], pool.ADE.CI[2], pool.ADE.pval, pool.ADE.pval.al,
    "Total Effect", pool.Tot, pool.Tot.CI[1], pool.Tot.CI[2], pool.Tot.pval, pool.Tot.pval.al,
    "Prop. Mediated", pool.Prop.Med, pool.Prop.Med.CI[1], pool.Prop.Med.CI[2],
pool.Prop.Med.pval, pool.Prop.Med.pval
  )
TAB1
summary(TAB1)

### adjusted analysis ###
## model formulas
## change in stigma = predictor, diabetes = outcome, no mediator
mod.0_imp_adj <- A1C.y ~ stigma_change + A1C.x + Age + Sex + hh_inc + educ + PType

## change in stigma = predictor, depression = mediator, no outcome
```

```
mod.1_imp_adj <- PHQ9_tot.y ~ stigma_change + PHQ9_tot.x + Age + Sex + hh_inc + educ +
PType

## change in stigma = predictor, depression = mediator, diabetes = outcome, full model
mod.2_imp_adj <- A1C.y ~ stigma_change + A1C.x + PHQ9_tot.x + PHQ9_tot.y + Age + Sex +
hh_inc + educ + PType

## bootstrapped mediation (adjusted) results, save as list-like object
ll.results_adj <-
  lapply(1:m, function(i) {
    mod.0_outp_imp_adj <- lm(mod.0_imp_adj, data = ll.imp_sets[[i]]) ## change in stigma =
predictor, diabetes = outcome, no mediator

    mod.1_outp_imp_adj <- lm(mod.1_imp_adj, data = ll.imp_sets[[i]]) ## change in stigma =
predictor, depression = mediator, no outcome

    mod.2_outp_imp_adj <- lm(mod.2_imp_adj, data = ll.imp_sets[[i]]) ## change in stigma =
predictor, depression = mediator, diabetes = outcome, full model

    results_med_adj <- mediation::mediate(mod.1_outp_imp_adj,
                        mod.2_outp_imp_adj, treat = 'stigma_change', mediator = 'PHQ9_tot.y', boot =
TRUE, sims = 1000)     ## bootstrap CI with 1000 simulations

    list("mod.0_outp_imp_adj" = mod.0_outp_imp_adj,
         "mod.1_outp_imp_adj" = mod.1_outp_imp_adj,
         "mod.2_outp_imp_adj" = mod.2_outp_imp_adj,
         "results_med_adj" = results_med_adj)

  })

save(list = c("ll.imp_sets", "ll.results_adj"), file = "imputed_datasets_results_adj.image")
load("imputed_datasets_results_adj.image")

## pooled mediation results, adjusted analysis
## bootstrapped p-values function, adapted from boot.pval::boot.pval[]
modified.boot.pval <- function(sims, theta_null = 0) {
  pval_precision = 1/length(sims)

  alpha_seq <- seq(1e-16, 1 - 1e-16, pval_precision)

  ci <- lapply(alpha_seq, function(xalpha) {rbind(quantile(sims, c(xalpha/2, 1 - xalpha/2)))})
  bounds <- do.call(rbind, ci)

  alpha <- alpha_seq[which.min(theta_null >= bounds[,1] & theta_null <= bounds[,2])]
  return(alpha)
}
```

```
## p values function from mediation package
p.val <- function (x, xhat){
  if (xhat == 0)
    out <- 1
  else {
    out <- 2 * min(sum(x > 0), sum(x < 0))/length(x)
  }
  return(min(out, 1))
}

## ACME
## Pooled ACME point estimate
ll.med.results_adj <- lapply(1:m, function(i){ll.results_adj[[i]]$results_med_adj})

pool.ACME_adj <-
  (ll.m_adj <-
     lapply(ll.med.results_adj,
            function(l){
              l$d0
            }) %>% unlist()) %>% mean()
pool.ACME_adj

## Pooled ACME CI
pool.ACME.CI_adj <-
  (ll.ACME_adj <-
     lapply(lapply(1:m, function(i){ll.results_adj[[i]]$results_med_adj}),
            function(l) {
              l$d0.sims
            }) %>% unlist()) %>% quantile(., c(2.5, 97.5)/100)
pool.ACME.CI_adj

## Pooled ACME p value
plot(density(ll.ACME_adj[1:1000]))
plot(density(ll.ACME_adj[1:1000 + 1000]))
plot(density(ll.ACME_adj[1:1000 + 2*1000]))
plot(density(ll.ACME_adj[1:1000 + 20*1000]))
plot(density(ll.ACME_adj[1:1000 + 29*1000]))

pool.ACME.pval_adj <- p.val(ll.ACME_adj, xhat = pool.ACME_adj)
pool.ACME.pval_adj

pool.ACME.pval.al_adj <- modified.boot.pval(ll.ACME_adj)
pool.ACME.pval.al_adj

## ADE
```

```
## Pooled ADE point estimate
pool.ADE_adj <-
  lapply(lapply(1:m, function(i){ll.results_adj[[i]]$results_med_adj}),
         function(l) {l$z0}) %>% unlist() %>% mean()
pool.ADE_adj

## Pooled ADE CI
pool.ADE.CI_adj <-
  (ll.ADE_adj <-
     lapply(lapply(1:m, function(i){ll.results_adj[[i]]$results_med_adj}),
            function(l) {
              l$z0.sims
            }) %>% unlist()
  ) %>% quantile(., c(2.5, 97.5)/100)
pool.ADE.CI_adj

## Pooled ADE p value
pool.ADE.pval_adj <- p.val(ll.ADE, xhat = pool.ADE_adj)
pool.ADE.pval_adj

pool.ADE.pval.al_adj <- modified.boot.pval(ll.ADE_adj)
pool.ADE.pval.al_adj

## Pooled total effect
pool.Tot_adj <-
  lapply(lapply(1:m, function(i){ll.results_adj[[i]]$results_med_adj}),
         function(l) {l$tau.coef}) %>% unlist() %>% mean()
pool.Tot_adj

## Pooled total effect CI
pool.Tot.CI_adj <-
  (ll.Tot_adj <-
     lapply(lapply(1:m, function(i){ll.results_adj[[i]]$results_med_adj}),
            function(l) {
              l$tau.sims
            }) %>% unlist()) %>% quantile(., c(2.5, 97.5)/100)
pool.Tot.CI_adj

## Pooled total effect p value
pool.Tot.pval_adj <- p.val(ll.Tot, xhat = pool.Tot_adj)
pool.Tot.pval_adj

pool.Tot.pval.al_adj <- modified.boot.pval(ll.Tot_adj)
pool.Tot.pval.al_adj

## Prop. Mediated
```

```
## Prop. Mediated point estimate
pool.Prop.Med_adj <-
  lapply(lapply(1:m, function(i){ll.results_adj[[i]]$results_med_adj}),
         function(l) {l$n0}) %>% unlist() %>% mean()
pool.Prop.Med_adj

## Prop. Mediated CI
pool.Prop.Med.CI_adj <-
  (ll.Med_adj <-
     lapply(lapply(1:m, function(i){ll.results_adj[[i]]$results_med_adj}),
            function(l) {
              l$n0.sims
            }) %>% unlist()) %>% quantile(., c(2.5, 97.5)/100)
pool.Prop.Med.CI_adj

## Prop. Mediate p value
pool.Prop.Med.pval_adj <- p.val(ll.Med, xhat = pool.Prop.Med_adj)
pool.Prop.Med.pval_adj

pool.Prop.Med.pval.al_adj <- modified.boot.pval(ll.Med_adj)
pool.Prop.Med.pval.al_adj

## Store results in tibble
TAB_adj <- ## With p.val() p-values
  tribble(
    ~indicator, ~Estimate, ~LB, ~UB, ~pval,
    "ACME", pool.ACME_adj, pool.ACME.CI_adj[1], pool.ACME.CI_adj[2],
pool.ACME.pval_adj,
    "ADE",  pool.ADE_adj, pool.ADE.CI_adj[1], pool.ADE.CI_adj[2], pool.ADE.pval_adj,
    "Total Effect", pool.Tot_adj, pool.Tot.CI_adj[1], pool.Tot.CI_adj[2], pool.Tot.pval_adj,
    "Prop. Mediated", pool.Prop.Med_adj, pool.Prop.Med.CI_adj[1], pool.Prop.Med.CI_adj[2],
pool.Prop.Med.pval_adj
  )
TAB_adj

TAB1_adj <- ## With p.val() and boot.pval() p-values
  tribble(
    ~indicator, ~Estimate, ~LB, ~UB, ~pval, ~pval.al,
    "ACME", pool.ACME_adj, pool.ACME.CI_adj[1], pool.ACME.CI_adj[2],
pool.ACME.pval_adj, pool.ACME.pval.al_adj,
    "ADE",  pool.ADE_adj, pool.ADE.CI_adj[1], pool.ADE.CI_adj[2], pool.ADE.pval_adj,
pool.ADE.pval.al_adj,
    "Total Effect", pool.Tot_adj, pool.Tot.CI_adj[1], pool.Tot.CI_adj[2], pool.Tot.pval_adj,
pool.Tot.pval.al_adj,
    "Prop. Mediated", pool.Prop.Med_adj, pool.Prop.Med.CI_adj[1], pool.Prop.Med.CI_adj[2],
pool.Prop.Med.pval_adj, pool.Prop.Med.pval_adj
```

```
 )
TAB1_adj

##### longitudinal analysis of SSCI by treatment group #####
### data preparation and set up ###
## set longitudinal model
mod_long <- PID ~ Stigma1 + Stigma2 + Stigma3 + Stigma4

## create data frames with only model
INDEP_24mo_fin <- model.frame(mod_long, data=INDEP_24mo, na.action = na.pass)
INDEP_36mo_fin <- model.frame(mod_long, data=INDEP_36mo, na.action = na.pass)

## reclassify 0 values for stigma as NAs
INDEP_24mo_fin[, 2:5][INDEP_24mo_fin[, 2:5] == 0] <- NA
INDEP_36mo_fin[, 2:5][INDEP_36mo_fin[, 2:5] == 0] <- NA

## mutate new total stigma scores in longitudinal data frames
INDEP_24mo_fin <- INDEP_24mo_fin %>% mutate(tot_stigma.24mo =
Stigma1+Stigma2+Stigma3+Stigma4)
INDEP_36mo_fin <- INDEP_36mo_fin %>% mutate(tot_stigma.36mo =
Stigma1+Stigma2+Stigma3+Stigma4)

## join dataframes
INDEP_long <- left_join(INDEP_0mo_fin, INDEP_12mo_fin, by="PID")

## rows 405-4011 to be deleted
INDEP_long <- INDEP_long[-c(405,406,407,408,409,410,411), ]

## join dataframes
INDEP_long <- left_join(INDEP_long, INDEP_24mo_fin, by="PID")
INDEP_long <- left_join(INDEP_long, INDEP_36mo_fin, by="PID")

## mutate new total stigma scores from baseline/12mo
INDEP_long <- INDEP_long %>% mutate(tot_stigma.0mo =
Stigma1.x+Stigma2.x+Stigma3.x+Stigma4.x)
INDEP_long <- INDEP_long %>% mutate(tot_stigma.12mo =
Stigma1.y+Stigma2.y+Stigma3.y+Stigma4.y)

## drop unused variables for longitudinal analysis
INDEP_long <- INDEP_long[ -c(11:14) ]
INDEP_long <- INDEP_long[ -c(14:21) ]
INDEP_long <- INDEP_long[ -c(15:18) ]

## convert to long format for repeated measures indexed by time
INDEP_long <- INDEP_long %>%
```

```
            gather(key = "time", value = "SSCI", tot_stigma.0mo, tot_stigma.12mo,
tot_stigma.24mo, tot_stigma.36mo)

## relabel time values
INDEP_long$time <-
  factor(INDEP_long$time,
levels=c("tot_stigma.0mo","tot_stigma.12mo","tot_stigma.24mo","tot_stigma.36mo"),
        labels=c("0",
                 "12",
                 "24",
                 "36"))

### multiple imputations for longitudinal analysis ###
## use AMELIA for 30 multiple imputations
set.seed(1234)
m = 30
INDEP_long_imp <- amelia(INDEP_long, m=m, p2s = 1,
                   idvars=c("PID","PType","SID"),
                   noms=c("Stigma_cond","time"),
                   ords=c("educ", "Sex", "hh_inc"),
                   max.resample = 1000)
INDEP_long_imp
plot(INDEP_long_imp) ## assess convergence ## education variable has multiple peaks
indicating overdispersion
write.amelia(obj=INDEP_long_imp, file.stem="INDEP_long_imp")

## set up imputed datasets for longitudinal analysis, store as list-like object
ll.long.imp_sets <-
  lapply(1:m, function(i){
    INDEP_long_imp.i <- read.csv(paste0('indep_long_imp', i, '.csv'), header=TRUE) ## load
m=30 imputed datasets

    INDEP_long_imp.i$PHQ9_tot.y <-round(INDEP_long_imp.i$PHQ9_tot.y) ## round imputed
PHQ9 values to nearest whole numbers (no missingness at baseline)

    INDEP_long_imp.i$SSCI <- round(INDEP_long_imp.i$SSCI) ## round imputed SSCI values
to nearest whole number

    INDEP_long_imp.i$A1C.y <- round(INDEP_long_imp.i$A1C.y, digits = 1) ## round imputed
A1c values to 1 decimal place (no missingness at baseline)

    return(INDEP_long_imp.i)
  })

## check an imputed dataset
INDEP_long_imp1 <- ll.long.imp_sets[[1]]
```

```
### longitudinal analysis of SSCI by treatment group ###
## model formula
## intervention assignment = predictor, total self-stigma score as outcome
mod_long <- SSCI ~ PType + as.numeric(time) + PType*as.numeric(time) + Age + Sex +
as.factor(hh_inc) + as.factor(educ) + PHQ9_tot.x + A1C.x

## mixed effects model, intervention*time interaction, random intercept for individuals with
different SSCI values, exchangeable correlation structure, no random slopes
ll.long.mod <-
  lapply(1:m, function(i) {
    mod.long.outp <- lme(mod_long,
                         random = ~ 1 | PID,
                         correlation = corCompSymm(form = ~1 | PID),
                         method = "ML",
                         data = ll.long.imp_sets[[i]])

  })
ll.long.mod

## pool results together
long.fit <- pool(ll.long.mod)

## point estimates, robust CI, p values
summary(long.fit, conf.int=TRUE)

## random effects model parameters
testEstimates(ll.long.mod, var.comp=TRUE, extra.pars = TRUE)
```

VITA

Scott Halliday has 13 years of experience in global health delivery, healthcare systems strengthening, and implementation science. His research interests include scaling up access to evidence-based behavioral healthcare services and strengthening community healthcare systems using mixed methods, quasi-experimental designs, and routine health information systems. He currently works as an Implementation Science Researcher with the Washington State Department of Children, Youth, & Families where he oversees an active-learning implementation school to support programs in child welfare, early learning, and juvenile rehabilitation. Scott serves as an Advisor to Possible, a non-profit that conducts and leverages research for implementing innovating healthcare solutions in Nepal. He previously worked with the Arnhold Institute for Global Health at Mount Sinai, Brigham and Women's Hospital Department of Global Health Equity, and Dhulikhel Hospital-Kathmandu University Hospital. He received a BA in International Studies from the University of Washington and an MS in Medical Sciences from Boston University.