OREGON'S ALTERNATE MEDICAL HOME

EVALUATING SUCCESSES AND CHALLENGES OF CREATING AN INTEGRATED CARE SETTING IN OREGON'S CERTIFIED COMMUNITY BEHAVIORAL HEALTH CLINICS

By

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CERTIFICATE OF APPROVAL

This is to certify that the Master's Capstone Project of

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Oregon's Alternative Medical Home

Evaluating successes and challenges of creating an integrated care setting in Oregon's Certified Community Behavioral Health Clinics

Has been approved

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INTRODUCTION

Based on the 2018 National Survey on Drug Use and Healthⁱ, approximately 47.6 million adults (18 and older) had a mental illness in the past year, with an estimated 11.4 million adults having a serious mental illness (SMI). There is also an increasing percentage of those with mental health issues who also have a substance use disorder (SUD); approximately 9.2 million adults had both mental illness and a SUD in the last year.

Substance use and mental illnesses impact millions of people in the United States and puts a strain on the nations behavioral health services and correction system, and based on this national surveyⁱⁱ, continues to grow. Of this significant population, about half of these adults either received treatment for their mental illness or substance use disorder, and the other half did not receive either type of treatment. The need to provide comprehensive care to this population to treat their mental and substance abuse needs is critical.

In 2013, the federal government started down the path of defining an integrated care model for behavioral health called certified community behavioral health clinics, or CCBHCs. The term "behavioral health" is inclusive of both mental and substance abuse disorders. CCBHCs provide a wide array of behavioral health services including crisis support and integrated primary care screening and monitoring services. The goal of these CCBHCs is to provide treatment promptly and with the right resources to improve outcomes of this growing population.

The majority of the focus of research over the last ten years has been on integrating all services under one roof, which has predominantly taken shape as physical health settings integrate elements of behavioral health delivery and care coordination, i.e. the medical home model. The CCBHC program is an alternative version of this model, where the focus is primarily on behavioral health, and providing whole-person care with the integration of primary care services and focus on open access to services.

Patients with a behavioral health disorder have a higher rate of a physical illness (e.g. diabetes)ⁱⁱⁱ and 68% of adults with a mental illness have at least one chronic physical condition^{iv}. Integrating behavioral health services and screenings at primary care clinics (e.g. medical home model) has been proven to improve the treatment and outcomes of individuals with depression and anxiety disorders. However, the treatment of individuals with severe mental illness (SMI) require a more integrated approach and CCBHCs may be the answer. A systematic review of "health homes" or integrated models showed that integration reduced costs and decreased health care utilization for adults with SMI^v.

Oregon participated in a federal program to demonstrate the value of the CCBHC model over a two-year period from March 2017 to June 2019. The demonstration was short, but impactful to how behavioral health is delivered to Oregonians. Twelve organizations participated, which included 21 individual locations or sites. Overall, the organizations reported improved outcomes with reduced emergency department utilization and improved access.

In an effort to evaluate the challenges the providers experienced in implementing the CCBHC model, a survey tool was built to gather quantitative and qualitative information about the demonstration project. While staffing level and services provided are key indicators of change due to the demonstration; the qualitative data received from the survey provided insight into the barriers and challenges Oregon and the nation may face with implementing comprehensive care models in behavioral health settings. The constant comparison method was used as the qualitative method of analysis.

The survey had an informatics focus and explored topics related to the technology supporting the demonstration both from the perspective of behavioral and physical health services; and challenges experienced by adding additional screenings and data gathering techniques in order to evaluate and track outcomes.

This survey aims to identify the challenges and successes experienced by the Oregon CCBHCs during the two-year demonstration and provide a starting point for further research to identify suggested pathways towards creating solutions to support these behavioral health models of integrated care.

BACKGROUND

During the 113th congress (2013-2014), the federal government signed into law two pieces of legislation that established the certified community behavioral health clinics (CCBHCs). First, the Excellence in Mental Health and Addition Act^{vi} defined the criteria of becoming a CCBHC. Second, the Protecting Access to Medicare Act (PAMA) established a two-year, eight state CCBHC demonstration providing enhanced federal funding through Medicaid to fund this higher level of behavioral health care. Oregon was chosen as one of the eight states to participate in the two-year demonstration.

The Excellence Act defined CCBHCs and created a pathway for these organizations to receive an enhanced Medicaid reimbursement rate based on their anticipated costs of being a CCBHC using a Prospective Payment methodology. The pathway was essential to the CCBHC model; however, it did not incentivize states to start the program with additional funding. The Excellence Act specifies that CCBHCs must provide directly or through contracting organizations the following types of services^{vii}:

- 1. Crisis mental health services
- 2. Screening, assessment and diagnosis, including risk assessment
- 3. Patient-centered treatment planning
- 4. Outpatient mental health and substance use services
- 5. Primary care screening and monitoring of key health indicators/health risk
- 6. Targeted case management
- 7. Psychiatric rehabilitation services

- 8. Peer support and family supports
- Intensive, community-based mental health care for members of the armed forces and veterans

It was not until PAMA^{viii} (section 223) was signed that federal funding was put behind the CCBHC definition and a demonstration program was created. The demonstration offered eight states the opportunity to receive enhanced federal funding to provide community-based mental and substance abuse treatment through the CCBHC model with an emphasis on whole-person care. Implementation of Section 223 began by authorizing planning grants and awards to 24 states. Of the 24, 19 states submitted applications to participate in the demonstration program and only eight states were selected to participate in the demonstration, they included: Minnesota, Missouri, Nevada, New Jersey, New York, Oklahoma, Oregon and Pennsylvania.^{ix}

Section 223 also required Substance Abuse and Mental Health Services administration (SAMSHA) to develop federal criteria for CCBHCs. SAMSHA used public input and the statutory guidance from the federal legislation to develop criteria; see excerpt from the SAMSHA CCBHC report below^x:

| CCBHC CRITERIA AREAS | | |
|----------------------|---|--|
| Staffing | Staff have diverse disciplinary backgrounds, have necessary state-required license and accreditation, and are culturally and linguistically trained to serve the needs of the clinic's patient population. | |

| Availability & accessibility of services | The clinic provides 24-hour crisis management services, a sliding scale for payment, and does not reject or limit services by the patient's ability to pay or place of residence. |
|--|--|
| Care coordination | Coordinated care across settings and providers ensures seamless transitions for patients across the full spectrum of health services, including physical and behavioral health needs. The clinics maintain partnerships or formal contracts with the following: FQHCs and rural health clinics (as applicable) Inpatient psychiatric facilities and substance use detoxification, post-detoxification Step-down services, and residential programs Schools, child welfare agencies, and juvenile and criminal justice agencies and facilities, Indian Health Service youth regional treatment centers, state-licensed and nationally accredited child-placing agencies for therapeutic foster care service, and other social and human services U.S. Department of Veterans Affairs medical centers, independent outpatient clinics, and drop-in centers3 Inpatient acute care hospitals and hospital outpatient clinics |
| Scope of services— delivered directly by CCBHCs only | Crisis mental health services, including 24-hour mobile crisis teams, emergency crisis intervention services, and crisis stabilization4 Screening, assessment, and diagnosis, including risk assessment Patient-centered treatment planning or similar processes, including risk assessment and crisis planning Outpatient mental health and substance use services |
| Scope of services— delivered directly by CCBHCs or | Outpatient clinic primary care screening and monitoring of key health indicators and health risk Targeted case management Psychiatric rehabilitation services |

| through referral with DCOs | Peer support and counselor services and family supports Intensive, community-based mental health care for members of the armed forces and veterans, particularly those members and veterans located in rural areas |
|-------------------------------|--|
| Quality and other reporting | The clinic reports encounter data, clinical outcomes data, quality data, and such other data as the Secretary requires. |
| Organizational authority | The clinic is a nonprofit or part of a local government behavioral health authority or operated under the authority of the Indian Health Service, an Indian tribe, or a tribal organization pursuant to a contract, grant, cooperative agreement, or compact with the Indian Health Service pursuant to the Indian Self- Determination Act or an urban Indian organization pursuant to a grant or contract with the Indian Health Service. |

The seven federal criteria areas provided the basis for the CCBHC definition that is consistent across the demonstration states. However, states were also allowed to expand and add to the criteria for their individual programs. Oregon choose to add additional requirements, which is detailed in a subsequent section. A key aspect of the federal criteria is the focus on evaluating outcomes through improving reporting and tracking of clinical information as this integrated model takes shape. This made the processing of information and supporting technology key components to the transformation of these organizations to meet the CCBHC definition.

SAMSHA was also charged with creating a standard for how the enhanced funding would be developed and rolling out the grant programs to the states.

ENHANCED FUNDING AND PAYMENT METHODOLOGY

The Excellence Act allows CCBHCs to receive a Medicaid payment based on their anticipated costs of offering CCBHC services to their community called a prospective payment system, or PPS rate^{xi}. PAMA directed SAMSHA to develop standards for how this payment system would be developed for CCBHCs. Generally, a PPS flat payment is paid to a clinic for each allowable Medicaid service and the payment is built including the costs of providing this level of care to the community.

The PPS methodology uses a cost report to identify the allowable costs of running the CCBHC based on SAMSHA's guidance and anticipated eligible services a CCBHC will offer. The costs become the numerator and the services the denominator to arrive at a perservice rate, or the PPS rate. This PPS is then paid to the CCBHC when a service is provided to a Medicaid patient. This rate is flat and does not vary based on the services provided. The PPS methodology provides a predictable form of payment to support the clinic in providing services to the community, including individuals who do not have insurance.

Federal Qualified Health Centers, or FQHCs, have received PPS payments for decades. FQHCs are considered a critical part of what is called the "safety net" for health services, and a key part of their operation is availability of services to any individual no matter their insured status or ability to pay. CCBHCs also share this key requirement of not turning a person away based on their income or insured status, and essentially becomes part of a critical component of the mental and substance abuse safety net.

Medicaid funding is a mix of both state and federal dollars. During the demonstration, the federal share of funding this program was higher and included enhanced services not typically covered in a state Medicaid plan. After the demonstration, the federal match will decrease to the standard federal share and will increase the state portion of the payment if the state decides to continues the PPS program for CCBHCs.

Generally, the CCBHC model is more expensive for the state upfront due to enhanced payments that includes additional services than what was previously offered and would require additional state funds. Depending on the budgetary constraints, the state may continue or discontinue the enhanced payment. As of November 2019, the state has discontinued the enhanced payment and is evaluating the demonstration results. However, many of the CCBHCs have qualified for new grants due to the expansions they made during the CCBHC demonstration.

OREGON'S CERTIFIED COMMUNITY BEHAVIORAL HEALTH CLINICS CRITERIA

The Oregon Health Authority (OHA) applied and was awarded a two-year demonstration grant with Substance Abuse and Mental Health Services administration (SAMSHA) to received enhanced federal matching funds to support and fund clinics who become Certified Community Behavioral Health Clinics (CCBHCs). The demonstration in Oregon was from March 1, 2017 to June 30, 2019. In addition to the federal standards of a CCBHC cited earlier, Oregon required nine additional standards to become a CCBHC under the two-year demonstration. The nine standards are as follows (excerpt from the Oregon Health Authority website^{xii}):

- Telephone and Electronic Access CCBHC provides continuous access to behavioral health advice by telephone.
- Performance and Clinical Quality CCBHC tracks one quality metric from the core or menu set of PCPCH Quality Measures. See appendix for list of measures.
- 3. Provision of Services CCBHC reports that it routinely offers all of the following categories of BH services: screening, assessment and diagnosis including risk assessment, person-centered treatment planning, outpatient mental health services, targeted case management services and psychiatric rehabilitation.
- Coordination and Integration with Primary Care CCBHC has primary care services onsite at least 20 hours a week and has a process to ensure patients can access primary care services during the hours onsite primary care is not available.
- 5. Organization of CCBHC Information CCBHC maintains a health record for each consumer that contains at least the following elements: problem list, medication list, medication list, allergies, basic demographic information, preferred language, and updates this record as needed at each visit.

- 6. **Specialized Care Setting Transitions** CCBHC has a written agreement with its usual hospital providers or directly provides routine hospital care.
- 7. Care Coordination CCBHC demonstrates that members of the health care team have defined roles in care coordination for consumers and tell each consumer or family the name(s) of the team member(s) responsible for coordinating his or her care.
- End of Life Planning CCBHC has a process to offer or coordinate hospice and palliative care and counseling for consumers and families who may benefit from them.
- 9. Language and Cultural Interpretation CCBHC offers and/or uses either providers who speak a consumer's and family's language at time of service inperson or telephonic trained interpreters to communicate with consumers and families in their language of choice.

THE PRIMARY CARE MEDICAL HOME MODEL

The CCBHC model is centered around a concept of whole-person care, which is similar to the medical home model promoted in primary care clinics across the nation, and in Oregon. While primary care is encouraged to integrate behavioral health services, CCBHCs are required to integrate physical health services either directly or through a contracted partner. Both are meant to meet the patient's needs where they receive treatment and improve outcomes when co-morbidities exist across physical and behavioral disorders that can result in high costs and poor outcomes^{xiii}. Primary care is further in the transformation towards integration and team-based care, and provides a useful place to establish standards for behavioral health clinics.

The medical home model as defined by the Patient-Centered Primary Care Collaborative (PCPCC) is as follows:

"The medical home is best described as a model or philosophy of primary care that is patient-centered, comprehensive, team-based, coordinated, accessible, and focused on quality and safety. It has become a widely accepted model for how primary care should be organized and delivered throughout the health care system, and is a philosophy of health care delivery that encourages providers and care teams to meet patients where they are, from the most simple to the most complex conditions. It is a place where patients are treated with respect, dignity, and compassion, and enable strong and trusting relationships with providers and staff. Above all, the medical home is not a final destination instead, it is a model for achieving primary care excellence so that care is received in the right place, at the right time, and in the manner that best suits a patient's needs."^{xiv}

Over the past ten years, Oregon and many other states across the US have developed programs geared towards recognizing primary-care clinics using a menu of measures and standards that include integrating behavioral health services and screenings. The program in Oregon is called the Patient-Centered Primary Care Home (PCPCH) has been

successful in being a foundation of health care transformation in Oregon and been incorporated in a variety of funding models across payers. For example, Oregon's Medicaid plans (i.e. Coordinated Care Organizations) starting in 2020 are required to vary service payment to clinics based on their PCPCH tier level to represent their commitment to clinics achieving and maintaining a high standard of care^{xv}.

Funding continues to be key for the primary care clinics to be successful and for the recognition of the PCPCH standards to be implemented across Oregon. As of 2019, there were 630 recognized clinics in Oregon at varied tier levels. Many of the 630 recognized clinics are Federally Qualified Health Centers that also receive a PPS reimbursement structure, which provides more stable funding for their efforts of integrated care. Physical health has been the focus of the medical home model due to a long history that includes federal acts and funding priorities, similar to the CCBHC history.

According to the history outlined by the PCPCC^{xvi}, the primary care medical home model really started with the support received by the Affordable Care Act (ACA) signed into law by President Barack Obama in 2010 that included specific funding options and bonuses for primary care clinics. The medical home model federal funding support started in 2010, seven years earlier than the two-year CCBHC demonstration.

HITECH ACT

A key to the success of the medical home model has been technology. In Oregon, the Electronic Health Records (EHR) Meaningful Use Incentive Program measures are included in the menu to achieve the recognition of a PCPCH at every tier level. The EHR Incentive Program was started with the passing of the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted in 2009 as part of the American Recovery and Reinvestment Act^{xvii}. This legislation spurred the adoption of EHRs across a variety of clinics and hospitals who wanted to receive this monetary incentive and included measures of "Meaningful Use" that ensure technology is positively contributing to health care delivery. Most behavioral health providers were not eligible^{xviii} to participate in this incentive program, which has resulted in a fragmentation between physical health and behavioral health.

Technology and data barriers exist for behavioral health due to the slower adoption of EHRs^{xix} and lack of financial incentives, compared to the physical health clinics and hospitals. In addition, privacy and security concerns for behavioral health are heightened due to 42 CFR Part 2^{xx} related to protecting substance abuse records separately from standard medical records. This protection has been a challenge for the medical home model to integrate data with behavioral health providers.

In an article published in 2015^{xxi}, four workarounds were cited when behavioral health was integrated in a primary care setting:

- 1. Double documentation and duplicate data entry
- 2. Scanning and transporting documents
- 3. Reliance on patient or clinician recall for inaccessible clinical information
- 4. Use of freestanding tracking systems

These workarounds provide a view into the potential barriers or additional process that might occur when integrating services of any types in the health care setting, including CCBHCs.

Integrating behavioral health services into primary care clinics through the medical home model has shed some light into these barriers of data sharing and interoperability; however, the CCBHC model allows us another view into technology and integrated care – one where behavioral health is the primary setting.

METHODS

The CCBHC demonstration will be evaluated by the Oregon Health Authority (OHA) using a variety of data gathering techniques beyond the survey detailed in this report and will include metrics evaluation, claims data review and additional surveys. This specific study utilized a survey instrument to evaluate the demonstration with a focus on challenges and successes of integrating physical health and the Electronic Health Record technology used to support the participating organizations. The comments from the survey respondents, and all other qualitative data provided by the survey respondents, was analyzed using the constant comparison method and is detailed in the discussion section.

SURVEY BACKGROUND

The CCBHC demonstration survey was built in collaboration with the OHA and Oregon Health & Science University's (OHSU) informatics department. The survey was built to gather information related to the health information technology used during the demonstration, such as the EHR information and data gathering methods, but also included general information about the level of services provided by the organizations.

The project is a survey-based study of CCBHCs to understand their successes and challenges during the two-year demonstration. The goal is to identify themes and use them to start creating potential solutions that might improve the efforts to bring integrated care to behavioral health clinics.

The survey was released in August 2019 and 8 of the 12 organizations responded.

IRB PROCESS AND STUDY PROTOCOL

The survey and process of analyzing the survey data was approved through OHSU's Institutional Review Board (IRB). The IRB process included a review of the study's protocol, which included the following information:

Study Subjects: The survey will be distributed to clinics who are CCBHCs during the two-year demonstration. This is 12 organizations representing 21 physical locations/sites.

Inclusion and Exclusion Criteria: Eligibility will be if the clinics is a CCBHC in Oregon.

Vulnerable Populations: The study will not be collecting information that identifies a subject as a certain member of the vulnerable population.

Setting: The survey will be conducted by an OHSU student in collaboration with the Oregon Health Authority.

Recruitment Methods: CCBHCs will be sent the survey information via email by the Oregon Health Authority and the survey will be available for approximately three weeks. The survey tool used to collect answers from the participants was Survey Monkey.

Consent Process: CCBHCs can choose to not take the survey and a consent information sheet is attached to the IRB submission separately. The consent sheet will be provided within the survey tool and the survey will ask the clinic if they would like to participate in the study. (see appendix A for the survey)

Data Analysis: The survey will be reviewed and summarized for evaluation purposes. This will include some minor percent calculations to determine compliance and also a detailed review of the narrative responses related to challenges, etc.

Privacy, Confidentiality and Data Security: The survey respondent names will be blinded and the data will be aggregated when published. The respondent information will only be used for follow-up and internal review. The survey will also ask that respondents not provide any details of their patients, including PHI, in the survey responses. Data will be stored at the Oregon Health Authority (OHA) and in the Survey Monkey tool itself. Data will be shared with the OHSU

student through their existing access at OHA and raw data will not be saved in another place. Access will be restricted to the OHA staff involved in the survey, the principal investigator, and the co-investigator (OHSU student). The raw data will not be stored on any OHSU server. The data will not be stored for future OHSU research.

Risks to Subjects: There is a minimal risk of breach of confidentiality.

Potential Benefits to Subjects: The subjects will benefit from collective solutions to improving the integration of physical health services into behavioral health settings.

Based on the information above provided to the IRB, approval was given to conduct the survey. The IRB approval letter for the study is included as Appendix B.

METHODOLOGY OF ANALYSIS

The constant comparative method was used to analyze the survey data to identify themes and categories among the participants' comments related to the demonstration. This method is used to evaluate human experience and understand the way the problems and events of the demonstration impacted the participants. As stated by Corbin & Strauss^{xxii}, the original authors of this method:

"The most important is the desire to step beyond the known and enter in to the world of participants, to see the world from their perspective and in

doing so make discoveries that will contribute to the development of empirical knowledge." (Corbin & Strauss 2008)

The constant comparative method uses the following general steps of evaluation^{xxiii}:

- 1. Read the data thoroughly
- 2. Beginning coding the data by identifying categories within the data
- 3. Review the prevalence of specific categories to develop themes from the coding
- 4. Review additional data if available to help with interpretation (triangulation)

The categories are reviewed and variation among the participants within a category is evaluated. The themes found through the coding process helps to dissect the complex experience of implementing the CCBHC model in Oregon. The main source of the analysis is the open-ended questions presented in the survey regarding challenges and successes the participants experienced; however, the basic information related to EHR platform and level of physical health services were also reviewed to enhance the analysis.

The survey focused on the informatics components of the demonstration, which include the technology supporting this new model of care and also the data-driven focus of the CCBHCs to evaluate outcomes. The information collected in the survey asks the CCBHCs what data elements were collected during physical health services, along with the EHR used at the various locations. The collection of this information provides a view into the processes created at the different CCBHCs to integrate physical health screening and the technology collection method that supported the CCBHCs' workflow. A variety of other information was also collected to understand the technology and its limitations.

While technology and data were the focuses, other themes emerged in the open-ended responses that are included and may be valuable to the future of the model.

SURVEY RESULTS

The following section will highlight summarized results from the survey. The majority of the answers are presented in this section; however, a few questions are not included if they were primarily open-ended. Open-ended questions are reviewed in the subsequent discussion section. In addition, all the survey questions are included as Appendix A for reference. The survey results presented are split up in the following sections:

- Demographic & Electronic Health Records (EHR) information
- High-level demonstration metrics
- Current level of service delivery
- Physical health integration & Information on health screening process

DEMOGRAPHIC & EHR INFORMATION

Each survey respondent was asked to provide basic demographic information about themselves and also the organization they represent. This information requested included such things as their job title, organization name, EHR used and sites.

The following CCBHC organizations participated in the survey:

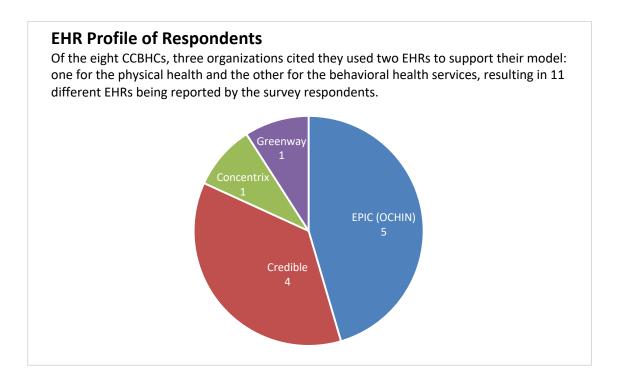
- 1. Wallowa Valley Center for Wellness
- 2. Cascadia BHC
- 3. Options for Southern Oregon
- 4. Symmetry Care, INC.
- 5. PeaceHealth in Oregon
- 6. Deschutes County Health Services Behavioral Health Division
- 7. Community Counseling Solutions John Day, Oregon
- 8. Columbia Community Mental Health

The respondents from the various CCBHC organizations included Chief Operations

Officers, Directors, Compliance Officers, Program Managers, and Information Analysts.

Of the eight organizations that responded, 15 of the 21 sites were represented in the

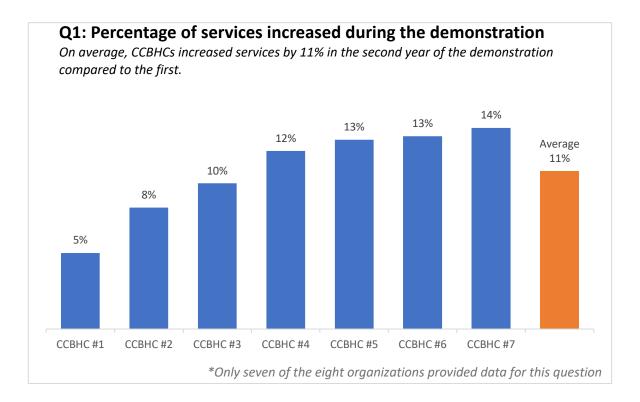
responses. The EHRs used to support the respondents include the following:

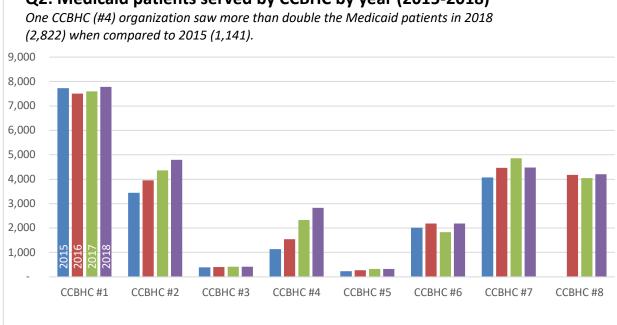


Of the EHRs used, all respondents reported that their EHR meets the Meaningful Use Stage 2 requirements in HITECH and all sites use appropriate consent regarding sharing of substance abuse data as defined by 42 CFR Part 2. Finally, all eight organizations consented to have their responses be presented in this evaluation report. The consent sheet is included in Appendix A on page 3-4 of the survey tool.

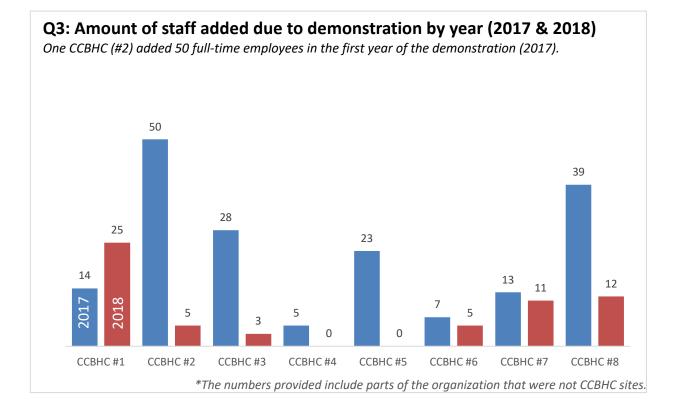
HIGH-LEVEL DEMONSTRATION METRICS

Three questions were asked to understand the increases that occurred in services, staffing and Medicaid patients served under the demonstration model. The questions provide a snapshot of the increases in staff and services that occurred during the two demonstration years (Question #1 and #3) and also over a longer time period with the demonstration years included (Question #2). The following are the results:



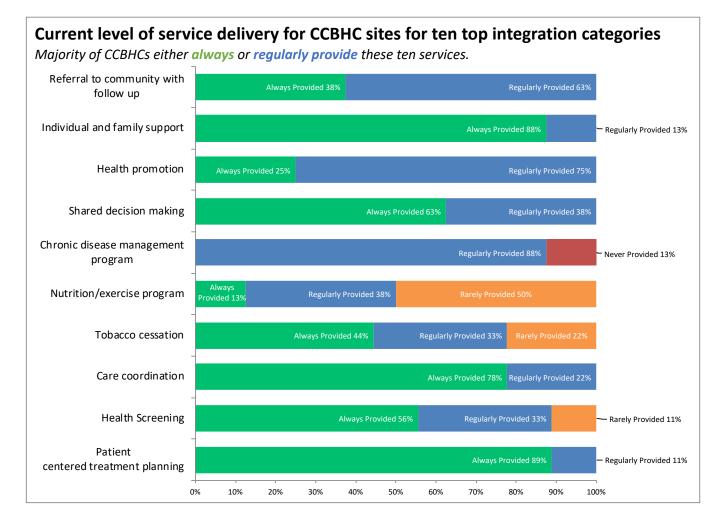


Q2: Medicaid patients served by CCBHC by year (2015-2018)



CURRENT LEVEL OF SERVICE DELIVERY

The CCBHCs were asked to rate their current level of service delivery (from always provided to never provided) for ten key CCBHC integration categories. These ten categories are critical services for the Oregon CCBHC program. The "green" bar below shows that these services were always provided and the "blue" show that they were regularly provided to the patients receiving services at the CCBHC sites. The "orange" means the service was rarely provided and "red" means it was never provided. The graphic gives you a glimpse into the expanded services offerings available to patients at the CCBHCs. The following summaries the responses:

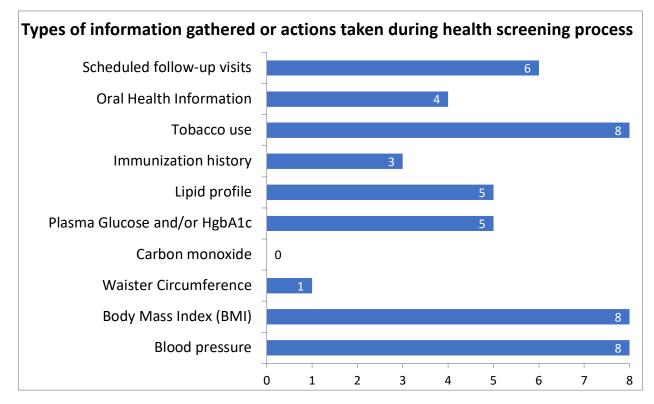


PHYSICAL HEALTH INTEGRATION & INFORMATION ON HEALTH SCREENING PROCESS

The CCBHCs were asked if they have an onsite physical health provider offering services,

and 100% indicated they did. In addition, they were asked what type of data was

collected during the health screening for physical health at their locations:



In addition to collecting and performing these actions, CCBHCs also gathered information about chronic conditions, medications, and some also provide dental services onsite. The rest of the survey included open-ended responses that were evaluated in the next section.

DISCUSSION

The survey collected quantitative data, such as services provided, and also qualitative data related to the successes and challenges of the CCBHC model, specifically related to technology. As discussed in the methods section, the comments and information provided by the CCBHC organizations were coded using the constant comparative method and five distinct themes emerged among the responses. Two of the themes directly related to technology and the electronic health records supporting the integrated model of care.

The following details the themes describing successes and challenges that emerged during the analysis.

THEME #1: STAFFING AND PARTNERSHIPS

The first category that emerged from the data received from the CCBHCs was related to staffing and partnerships. The following highlights the successes in the CCBHC model and the challenges related to this theme.

SUCCESSES

The CCBHCs found that the funding received through the demonstration helped with recruitment efforts for higher-educated providers, specifically Masters level. Some CCBHCs also improved their ability to administer medicated assisted treatment (MAT) by recruiting and retaining providers with Buprenorphine waivers. Buprenorphine is a specific medication that helps treat opioid addiction and requires a provider to get a specific waiver to be able to prescribe. The following are two quotations from different survey respondents related to staffing and recruitment successes:

> "We added case managers, peers and physical health integration at all of our other sites with enormous success in terms of improving interdisciplinary team approaches and care coordination."

"Living in a national health provider shortage area, this [CCBHC model] has been integral in helping meet the needs of our area. We have been able to increase recruiting practices and expand programming."

While some organizations hired physical health providers to deliver services on-site, many others contracted with other organizations to meet the physical health screening requirements of the CCBHC model. Generally, the collaboration with other clinics and the community to support the CCBHC model and meet the criteria was cited as a success. According to one respondent, the partnerships improved the awareness of behavioral health issues:

> "Community stakeholders are more involved, more actively engaged in BH [behavioral health] issues, and more supportive of the role that BH plays in creating a healthier population."

CHALLENGES

While there were successes in staffing, some CCBHCs found retention and recruitment difficult. Oregon has experienced a shortage in behavioral health providers^{xxiv}, and this was also mentioned and experienced by the CCBHCs, especially in rural areas. According to one organization, they experienced challenges with hiring specific clinicians:

"[Challenged with] hiring master's level clinicians, hiring LCSW's and psychologists to bill Medicare."

Additionally, since the demonstration was only for two years and future funding was uncertain, CCBHCs had difficulty with retention of staff:

> "Large amount of transformation in a short amount of time. Onboarding staff, acquiring space, implementing billing requirements as a large health system was extremely challenging and had to happen all at once."

The respondents also cited that introducing peer support services and staff was challenging, along with care coordinators lacking clinical knowledge:

"Care coordinators were hired at the QMHA level, but in retrospect perhaps the QMHP level was needed to advocate more clinically and evaluate appropriate interventions based on hospitalization/higher level of care trends. Care coordinators acted in more of a 'case manager' fashion because they lacked higher level clinical guidance."

THEME #2: EXPANDED SERVICES TO MORE IN NEED

The second category that emerged from the data received from the CCBHCs was related to offering robust services to a broader population no matter the patient's income or insurance. The following highlights the successes in the CCBHC model related to this theme. CCBHC respondents did not cite challenges related to this theme.

SUCCESSES

The CCBHC model requires specific services to be offered, such as crisis services, screenings and primary care monitoring, but a key part of the model is offering these services to anyone in need no matter their ability to pay. Many CCBHCs cited that they increased service offerings to their existing population; however, most CCBHCs highlighted that the main success was that they increased services to populations they did not serve much before the demonstration, including veterans, Medicaid and uninsured individuals. The following are two survey respondents' comments related to expanding services:

"Our agency already had many of the required services/programs of CCBHC in place, programs such as 24/7 Crisis, forensic diversion, ACT and other intensive case management programs, one fully integrated site, etc. As a result, the significant successes of our CCBHC were demonstrated in enhancing services to our most vulnerable populations. We added case managers, peers and physical

health integration at all of our other sites with enormous success in terms of improving interdisciplinary team approaches and care coordination. We increased services to veterans threefold, from 120 veterans served to over 400. We increased the number of services provided to individuals and we increased services to uninsured and underinsured individuals."

"We have been able to expand services to all Oregonians in need of mental health care regardless of income. Living in a national health provider shortage area, this has been integral in helping meet the needs of our area."

Furthermore, the expanded population receiving care were served by CCBHCs in a variety of settings, such as with after school programs, as detailed by one respondent:

"After school behavioral health programs have been created to help kids avoid residential and day treatment and to stay in their natural school environment. We have embedded more treatment providers in areas around [our community], where folks are at. We have been able to be creative to get folks into treatment that do not want to come into the clinic."

The enhanced service offering did not stop at the required CCBHC criteria. Organizations choose to also implement additional services based on the need in their community during this demonstration that included such things as: a pain management pilot program, jail diversion programs, mobile crisis access, increased school services, and telemedicine. According to one respondent, this was a huge success:

"Truly, the impact of the CCBHC has been tremendous. Services have increased, more individual have received needed services. Our service array has greatly increased. Increased crisis services have reduced emergency department utilization and diverted many SMI [severely mental ill] individuals from jail."

The flexibility in the demonstration and with the PPS rate methodology allowed for creativity in the way services were delivered and was cited as a significant success in the model. Being funded holistically using the PPS rate methodology allowed CCBHCs to anticipate the costs of these wraparound services and not be driven to only generate "billable visits". The PPS rate is built on the anticipated costs of the model. This gave CCBHCs funding that supported their business as a whole and was not dependent on what type of insurance a person has that walks through the door. This reimbursement methodology has been successful in supporting the physical health safety net (e.g. FQHCs, etc.), which has historically cared for our uninsured population.

Essentially, this theme of having an "open door" to the community demonstrates CCBHCs are key to building a behavioral health safety net in Oregon.

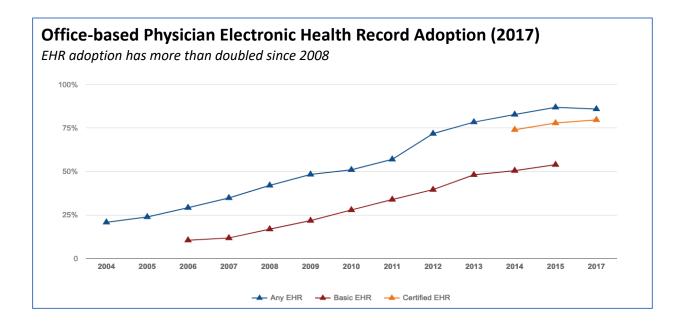
THEME #3: ELECTRONIC HEALTH RECORD

The third category that emerged from the data received from the CCBHCs was related to the health IT and the electronic health record (EHR) used to support the model, specifically the complexities of interoperability. The following highlights the successes and challenges in the CCBHC model related to this theme.

SUCCESSES

While there were mainly challenges expressed related to the use of health IT and EHRs, there were some overall successes. The first being that each CCBHC used at least one EHR to support the model and many leveraged their EHR's analytic engine to develop the needed CCBHC reports to monitor the effectiveness of the model. Also, all the EHRs used by the CCBHCs are certified and meet the Meaningful Use Stage 2 criteria^{xxv}. Stage 2 certification is the federal criteria to show that the EHR is capable of meeting a level of minimum functions, and may be useful for future grant and funding opportunities at the federal level.

Each CCBHC had a slightly different answer for how they gathered data from patients during the demonstration, but all used their EHR in some capacity, which is positive. Moving away from paper might seem obvious as a business; however, the health care industry has been late to adopt technology, and behavioral health providers have lagged behind even more due to the lack of federal financial incentives.^{xxvi} The following chart provided by the Office of the National Coordinator for Health Information Technology (ONC) shows the EHR adoption in 2017 compared to 2008 has more than doubled for office based physicians (mostly physical health providers):



The other success was that CCBHCs used their EHR to create intake forms, identify data points, added medical profiles and implemented processes to house data in the appropriate file for reporting. These processes are essential to move towards datadriven outcomes and in the future provided important information to streamline the process for other organizations to implement the CCBHC model, as detailed by one survey respondent below:

"Data points are identified on specific forms within EHR and mapped appropriately. [Our EHR] has Business Intelligence functions to produce reports."

CHALLENGES

A key component of the CCBHC model is the integration of physical health services (e.g. screenings and monitoring) into the behavioral health setting. In this integrated care

environment, technology needs to be flexible and operate in synergy to support the diverse providers needing the information about their patients. In the CCBHC demonstration, a key challenge cited multiple times by the survey respondents was the interoperability between electronic health records (EHR) and other health information technology. The CCBHCs had difficulty having the technology share essential data, extracting precise data and building helpful screening or assessment modules within the EHR. According to one respondent, they experienced challenges with *"Pulling accurate data from EHR"*. Another organization also mentioned they implemented a new EHR during the demonstration, which came with its own challenges.

Of the eight respondents, three organizations operated the CCBHC model with two different EHRs, one for physical health and one for behavioral health. Working with two EHRs, or for some organizations an EHR and paper, presented issues with sharing data among providers even at the same clinic. Some sharing occurred by printing out chart notes from one EHR, or having two separate logins to see the information. The CCBHCs cited many duplicative process and challenges working to integrate new processes in their existing technology.

Interoperability between EHRs has been a challenge throughout the health system, and even more for behavioral health providers who have lagged in adoption due to the lack of federal monetary incentives. According to one respondent, a significant challenge was *"Interoperability/working with multiple EHRs"*, which was shared by many others.

Additionally, billing requirements were also a challenge from a technology perspective. One respondent commented that *"Billing requirements were challenging"* and another elaborated on that challenge linking it to their EHR:

"Took a lot of coordination with the EMR [EHR], billing and accounting to successfully submit billing for one site."

THEME #4: INTEGRATED MODEL

The fourth category that emerged from the data received from the CCBHCs was related to the integrated care model and the required cultural change within the organization. The following highlights the successes and challenges in the CCBHC model related to this theme.

SUCCESSES

Overall, the CCBHC respondents saw the move to integrated care as a success with some growing pains. The integration of physical health and the broad suite of services changed the culture from behavioral health only to "whole person" health. The organizations focused on cultural competency, team-based care and ensuring the appropriate policies were in place for all providers involved, including trauma-informed care policies. This quickly improved care for individuals with a physical health comorbidity (e.g. diabetes) and providing screening and monitoring was shown as a success by the respondents and is a promising way to decrease costs^{xxvii}. One respondent provided an example of how the health screenings prevented a worse situation:

"In conducting wellness screenings, found patients with high blood pressure and immediately directed them to appropriate medical care that without referral could have been life threatening."

Integration for the CCBHCs did not just mean primary care services; it also meant adding improved crisis support, adding substance abuse program onsite and providing the full continuum of services to their patients, as detailed by one survey respondent:

"Being a CCBHC drove us to implement a SUD program. We have the full continuum of services, including ED Crisis, an inpatient psychiatric unit. This project has supported us in bringing down the silos between services and programs allowing us to meet the patient where they are and support them through transitions of care. We have reduced the use of the ED and the rate of 30 day readmissions to our inpatient psych unit for those we serve in our CCBHC."

CHALLENGES

Change always brings challenges. Moving towards an integrated model brought about staffing and cultural changes that stretched the CCBHCs during the demonstration. The survey respondents cited the difference between how physical health and behavioral health operate as an obstacle to overcome. Also, training and helping staff and their

patients understand why integration is important was cited as a challenge by multiple respondents. One CCBHC detailed this challenge in the following comment:

"Helping staff to learn about the importance of physical health and mental health services. Training behavioral health staff on integrated model of care [and] educating patients on the importance of integrated care."

CCBHCs also specifically cited that the health screening process created some issues:

"Scheduling wellness screenings was a challenge with a population that is being asked a lot of questions, "is this for you, or are you trying to help me?". Patients were reluctant to get into medical information stating, "I do this at my doctor, why do you need my weight and height?" Often nurses would have duty of conducting alcohol, tobacco and drug screenings, which was seen as a burden."

The amount of screenings added due to the CCBHC integrated model impacted staff's interaction with the EHR, as detailed by one respondent:

"Other challenges had to do with the sheer volume of new screening and assessment practices that had to be on-boarded into the EHR, and in which staff had to be trained and supported in adopting."

Generally, the CCBHCs struggled with the uncertainty of the model after the two-year demonstration and investing in these large changes without an aligned vision. The changes were difficult and without understanding the future; CCBHCs had trouble getting things up and running, as detailed by the following comment: "The uncertainty of a 'two year only' program created limited investment for the sake of not "putting all eggs in one basket" when it comes to complete organizational re-design and culture change."

The timing seemed to be too short for the respondents, but long enough to show this is a promising model that is worth continuing. Survey respondents also wished the demonstration could have been leveraged as a larger opportunity to shift the culture, as one respondent commented:

"Barrier: Lack of a state champion, lack of an aligned vision, inconsistent staffing during year 2; this was not used as an opportunity to change the system."

THEME #5: DATA-DRIVEN FOCUS AND IMPROVED OUTCOMES

The fourth category that emerged from the data received from the CCBHCs was related to the data-driven focus that provided information about improved outcomes. The following highlights the successes and challenges in the CCBHC model related to this theme.

SUCCESSES

CCBHC criteria focused on data-driven outcome measurement. The move towards this type of focus in the CCBHC model was seen as a challenge, but mostly a success. Proving this model works is a key goal of the demonstration, and having real data and analytics supporting improved outcomes is a key success. CCBHCs observed that even though the data gathering was laborious, the ability to track outcomes and measure improvement was seen as a success.

Multiple respondents cited the following improvements in their population's outcomes:

- Reduced emergency department utilization due to mental health
- Reduced inpatient hospitalization due to mental health
- Improved waiting time for referrals to first visit
- Improved access to services
- Diverted patients with serious mental illness from jail

These observations of improved outcomes support the model and are worth a future claims study to review the entire patient population served by the CCBHCs during the demonstration. The following comment from one CCBHC provides a glimpse into the impact of the improved data gathering that occurred during the demonstration:

"CCBHC programs have been an ambitious demonstration project that Oregon can be proud of. For the first time, real data about the effectiveness and cost savings of an integrated behavioral healthcare approach is available and being utilized to improve existing programs. The results summarized here are encouraging but likely do not capture the full benefit of what has been achieved. There is certainly enough to promote that this project has succeeded and warrants continuation." In addition, one respondent also provided quantitative outcome data in their comment to provide context at how successful the program was for one community:

"Reduction in ED utilization - 18 percent. Reduction in inpatient medical admissions - 23 percent."

CHALLENGES

While moving to a data-driven, outcome focused model was a success, it also was challenging to pull accurate data from the EHR, and in some cases from multiple EHRs. The model also created billing challenges that were more complex in an integrated model across multiple systems. CCBHCs expressed concern over the administratively burdensome processes required by the CCBHC model, which included 90-day updates on the patients and providing detailed assessments at each service, such as PHQ9. PHQ9 is a screening tool to identify depression.

"Being required to perform the PHQ9 for every service became an extreme administrative burden and impacted clinical practice. The frequency required by CCBHC (as opposed to intended use re the guidelines of CMS) diluted the intention/effectiveness of the tool (specifically for clients receiving daily services)."

The data allowed for improved reporting on the model, but it needs to be weighed against the challenges and burden it may have on clinical practice. The CCBHC organizations were also concerned that their investment in primary care integration would show cost savings and improved outcomes on the physical health side, or very far down the road. There was a consistent theme throughout the comments from CCBHCs that they were concerned about funding, as the following respondent highlights:

"The cost savings in preventative care will not be seen within the behavioral health services rather in medical services. Further, preventative care savings are not seen for years down the road."

CONCLUSION & FURTHER RESEARCH

The organizations who participated in the CCBHC demonstration in Oregon and who responded to this survey illustrate a model worth a deeper review and evaluation. The successes are vast and the challenges are equally important that emerged from the voices of these organizations.

To summarize, the five themes detailed in this report include:

- 1. **Staffing and Partnerships**: CCBHCs cited increased staffing and partnerships as a success, while the staffing shortage of behavioral health providers continues.
- 2. Expanded Services to More in Need: CCBHCs expanded their population and served more patients in needed, including Medicaid and uninsured individuals.

- 3. Electronic Health Records (EHRs): CCBHCs used certified EHRs to support the model, but had difficulty with interoperability and customizing the EHR to support their needs.
- 4. **Integrated Model**: CCBHCs found the integration of physical health and other services as a success, but also a challenge to train staff and inform patients on the value.
- 5. Data-driven Focus and Improved Outcomes: CCBHCs used data to evaluate the effectiveness of the model and cited improvement in outcomes, but also found challenges with the administrative burden of collecting it at the intervals required.

The CCBHC demonstration warrants further research and a detailed interview process of these organizations. Based on the results of the survey, the five themes identified provide a good starting point for the interview questions. Understanding the successes and challenges is just the beginning, and more details are needed to identify and create solutions that can be applied.

APPENDIX A: SURVEY

Health

CCBHC Demonstration Survey 2019

Survey Overview & General Questions

The 2019 CCBHC survey will help to evaluate the two-year demonstration that has occurred in Oregon as required by the federal government and help the Oregon Health Authority (OHA) plan for the future of CCBHCs and physical health integration in behavioral health settings. Results may be used for a variety of internal and external research on the topic. Public results will be provided at an aggregate level without the specific CCBHC name included. This survey was built with a collaboration with the Oregon Health & Science University's (OHSU) informatics department.

Multiple sites: If you have very unique sites that perhaps experience different challenges, please submit separate survey responses for each site or group of sites. If you have sites that are all the same, feel free to submit one survey response for that group and itemize the sites below.

Survey Goal: Provide OHA with an understanding of the challenges and benefits of physical health integration and EHRs as part of the CCBHC program, and plan for the future of behavioral health service delivery.

Disclaimer: The results of this survey will be shared with OHSU for research purposes. Please do not provide details of your patients in this survey, such as Personal Health Information. The survey should take approximately 20 minutes to complete.

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| for in | umber of sites/ph n this survey) | sical locations within your organization (only lis | t CCBHC sites you will be responding |
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| Site # | | | |
| Site # | ŧ2: | | |
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| Site # | ‡3: | | |
| Other | Sites (please list): | | |
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| | | alth Record (EHR) do you current use at your C tify which site uses which EHR. | CBHC sites? If there are multiple, |
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| 8. Dr | o the EHR(s) sup | orting each CCBHC site meet Meaningful Use | Stage 2 requirements? click here to |
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Health

CCBHC Demonstration Survey 2019

Consent

Consent Information Sheet

TITLE: Certified Community Behavioral Health Clinic (CCBHC) Evaluation Survey IRB#STUDY00019763 PRINCIPAL INVESTIGATOR: Vishnu Mohan CO-INVESTIGATOR: Chelsea Guest

WHY IS THIS STUDY BEING DONE ?:

You have been invited to be in this research study due to your organization's involvement in the CCBHC demonstration project with the Oregon Health Authority. The purpose of this study is to evaluate the first two years of the CCHBC program, and specifically understand the technological support needed to ensure this type of advanced care model can be successful. Data collected from you in this study will not be used for future research.

WHAT PROCEDURES ARE INVOLVED IN THIS STUDY ?:

If you choose to participate, you will be asked to complete a brief survey about your CCBHC demonstration experience, what electronic health record you utilize, and successes and challenges you face or continue to face as it related to integrated patient care. The survey should take about 30 minutes to complete. If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact Chelsea Guest (503-888-8320).

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY ?:

Although we have made every effort to protect you and your organizations' identity, there is a minimal risk of loss of confidentiality.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY ?:

You may or may not benefit from being in this study. However, by serving as a subject, you may help us learn how to improve the behavioral health network and advance the CCBHC program.

WILL I RECEIVE RESULTS FROM THIS STUDY?

Aggregated results from this study will be available to all CCBHCs, along with the final evaluation report.

WHO WILL SEE MY PERSONAL INFORMATION ?:

In this study we are not receiving any identifiable information about you so there is little chance of breach of confidentiality.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?

Information about obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information.

WHERE CAN I GET MORE INFORMATION ?:

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

| | L0. Please review the consent information sheet below about how the survey responses will be used and select "I agree" or "I do not agree" |
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| CCBHC Demonst | ration Survey 2019 |
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| emonstration Metric | xs |
| 11. Provide the appr demonstration. | oximate number of CCBHC demonstration services offered in year 1 and year 2 of the |
| Year 1 | |
| Year 2 | |
| | ber of Medicaid patients served by your CCBHC sites in total for each year below: |
| 2015 | |
| 2016 | |
| 2017 2018 | |
| clinic/organization. | r of staff added in each demonstration calendar year as a result of being a CCBHC |
| 2018 | |
| | ner areas where you have expanded existing services due to the CCBHC |
| 14. Are there any oth demonstration? Yes No | her areas where you have expanded existing services due to the CCBHC |
| 14. Are there any oth demonstration? | her areas where you have expanded existing services due to the CCBHC |
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Health

CCBHC Demonstration Survey 2019

Service Delivery

15. Please select the current level of service delivery below for your CCBHC sites for each personcentered, integrated item listed?

| | Always Provided | Regularly Provided | Rarely Provided | Never Provided |
|--|-----------------|--------------------|-----------------|----------------|
| Patient centered treatment planning | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Health Screening | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Care coordination including care management and transitional care | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Tobacco cessation | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Nutrition and exercise program | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Chronic disease self management program | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Shared decision making | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Health promotion | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Individual and family support | \bigcirc | \bigcirc | \bigcirc | \bigcirc |
| Referral to community and social support services with follow up | \bigcirc | \bigcirc | \bigcirc | \bigcirc |

16. If "rarely provided" or "never provided" are selected above for any item, please describe if you plan on implementing this service in the future and the timeline:

17. How do you gather data for the services listed above? If there are multiple methods, please Include information of why the data gathering method is different.

| | e CCBHC sites trained in trauma-informed care and culturally- |
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| responsive practices? | |
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| CCBHC D | emonstration Survey 2019 | |
| nysical Hea | Ith Integration | |
| 19. Do you | have an onsite physical health provider offering services at your CCBHC site(s)? | |
| O No | | |
| O Yes | | |
| | o not have a physical health provider onsite, what is your process for providing members P Please also provide details on how you store the data gathered and follow-up. | he |
| | ave deferred your physical health integration, please describe your plan on integration this | s |
| service at y | our sites? | |
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| CCBHC Demonstration Survey 201 | 9 |
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| alth Screening Questions | |
| 22. Please select the information gather process: | ed or actions taken by your clinic(s) during the health screening |
| Blood pressure | Lipid profile |
| Body Mass Index (BMI) | Immunization history |
| Waister Circumference | Tobacco use |
| Carbon monoxide | Oral Health Information |
| Plasma Glucose and/or HgbA1c | Scheduled follow-up physical health wellness visits and/ examinations |
| Other (please specify) | |
| 23. How did you gather and store data fi | rom the health screening? |
| 23. How did you gather and store data fi 24. What was your process for following | |
| 24. What was your process for following | up on the health screening results? |
| | up on the health screening results? |
| 24. What was your process for following 25. What does your physical health prov | up on the health screening results? |
| 24. What was your process for following 25. What does your physical health prov 26. Do the behavioral health providers h | up on the health screening results? |

| responsive practices? | | | |
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| ccesses & (| Challenges |
| | e Oregon CCBHC story by providing your successes and challenges. |
| encouraging that have oc | rovide a short snapshot of your successes due to the CCBHC model. This can include personal stories, outcome improvements (individual or broad), general organizational shifts curred due to this demonstration, etc. e do not include any protected health information. |
| include billing | rovide a short snapshot of your challenges as you implemented the CCBHC model. This can g challenges, staffing challenges, patient challenges, etc. |
| | |
| 30. During th payers? | e CCBHC demonstration, did you experience difficulty billing for behavioral health services to |
| payers? | e CCBHC demonstration, did you experience difficulty billing for behavioral health services to |
| payers? | |
| payers? Yes No If yes, please es | |
| payers? Yes No If yes, please es | xplain. |
| payers? Yes No If yes, please e: 31. Outside t | xplain. |

| Health | |
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| CCBHC Demonstration Survey 2019 | |
| Follow-up | |
| 33. Are you willing to be contacted for follow-up questions? | |
| Yes | |
| ○ No | |
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| 34. If yes, please indicate your preferred method of contact: | |
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APPENDIX B: IRB APPROVAL LETTER



IRB MEMO

Research Integrity Office

3181 SW Sam Jackson Park Road - L106RI Portland, OR 97239-3098 (503)494-7887 irb@ohsu.edu

APPROVAL OF SUBMISSION

May 7, 2019

Dear Investigator:

On May 7, 2019, the IRB reviewed the following submission:

| IRB ID: | STUDY00019763 |
|-------------------------|--|
| Type of Review: | Initial Study |
| Title of Study: | Certified Community Behavioral Health Clinic |
| | (CCBHC) Evaluation Survey |
| Principal Investigator: | Vishnu Mohan |
| Funding: | None |
| IND, IDE, or HDE: | None |
| Documents Reviewed: | CCBHC Survey Draft |
| | Consent Information Sheet- Roundtable |
| | Protocol- CCBHC |
| | Consent Information Sheet- Survey |
| | PPQ Unfunded Study - Signed |
| | |

The IRB granted final approval on 5/7/2019. The study requires you to submit a check-in before 5/5/2022.

Review Category: Exempt Category # 2

Copies of all approved documents are available in the study's **Final** Documents (far right column under the documents tab) list in the eIRB. Any additional documents that require an IRB signature (e.g. IIAs and IAAs) will be posted when signed. If this applies to your study, you will receive a notification when these additional signed documents are available.

Ongoing IRB submission requirements:

- Six to ten weeks before the eIRB system expiration date, submit a check-in..
- Any changes to the project must be submitted for IRB approval prior to implementation.
- Reportable New Information must be submitted per OHSU policy.
- Submit a check-in to close the study when your research is completed.

Version Date: 06/30/2016

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Guidelines for Study Conduct

In conducting this study, you are required to follow the guidelines in the document entitled, "Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects," as well as all other applicable OHSU <u>IRB Policies and Procedures</u>.

Requirements under HIPAA

If your study involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the <u>HIPAA</u> and <u>Research</u> website and the <u>Information Privacy and Security</u> website for more information.

IRB Compliance

The OHSU IRB (FWA00000161; IRB00000471) complies with 45 CFR Part 46, 21 CFR Parts 50 and 56, and other federal and Oregon laws and regulations, as applicable, as well as ICH-GCP codes 3.1-3.4, which outline Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

Sincerely,

The OHSU IRB Office

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