Performance Improvement Project
Implementation & Submission Tool (SAMPLE Santa Teresa County) SUD Clinical

PLANNING TEMPLATE

INTRODUCTION & INSTRUCTION

This tool provides a structure for development and submission of Performance Improvement Projects (PIPs). It is based on EQR Protocol 3: Validating Performance Improvement Projects (PIPs), as a mandatory protocol delivered by the Centers for Medicare & Medicaid Services (CMS) in September of 2012.

The use of this format for PIP submission will assure that the MHP addresses all of the required elements of a PIP. If the MHP uses another format, they must ensure that all of the required elements of the PIP are addressed and included in their submission. PLEASE fully complete each section and answer ALL questions.

- The PIP should target improvement in either a clinical or non-clinical service delivered by the MHP.
- The PIP process is not used to evaluate the effectiveness of a specific program operated by the MHP. If a specific program is experiencing identified problems, changes and interventions can be studied using the PIP process. This can be done to create improvements in the program and should be included in the narrative.
- The narrative should explain how addressing the study issue will also address a broad spectrum of consumer care and services over time. If the PIP addresses a high-impact or high risk condition, it may involve a smaller portion of the MHP consumer population, so the importance of addressing this type of issue must be detailed in the study narrative.
- Each year a PIP is evaluated is separate and specific. Although topic selection and explanation may cover more than one PIP year, every section should be reviewed and updated, as needed, to ensure continued relevance and to address on-going and new interventions or changes to the study.
- If sampling methods are used, the documentation presented must include the appropriateness and validity of the sampling method, the type of sampling method used and why, and what statistical subset of the consumer population was used.
- General information about the use of sampling methods and the types of sampling methods to use to obtain valid and reliable information can be found in Appendix II of the EQR Protocols.¹

¹ EQR Protocol: Appendix II: Sampling Approaches, Sept. 2012, DHHS, Centers for Medicare & Medicaid Services (CMS), OMB Approval No. 0938-0786
**Identification of Plan/Project**

<table>
<thead>
<tr>
<th>MHP Name:</th>
<th>Santa Teresa Mental Health Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td>Seeking Safety Implementation</td>
</tr>
<tr>
<td>Project Leader:</td>
<td>Dr. Kensington Ph.D.</td>
</tr>
<tr>
<td>Check One:</td>
<td>Clinical X Non-Clinical</td>
</tr>
<tr>
<td>Start Date (MM/DD/YY):</td>
<td>11/01/2016</td>
</tr>
<tr>
<td>Completion Date (MM/DD/YY):</td>
<td>06/30/2018</td>
</tr>
<tr>
<td>Projected Study Period (# of months):</td>
<td>20</td>
</tr>
</tbody>
</table>

**Brief Description of PIP:**

The goal of this PIP is to reduce functional impairment due to substance use among youth (ages 12-20 yrs.) who are enrolled in outpatient mental health treatment. All youth age 12-20 receiving County outpatient behavioral health treatment (n=1265) will be screened for substance abuse at intake and at annual review. Those screening positive (estimated at 35%) will receive at least one Seeking Safety module. Seeking Safety is an evidence-based intervention for consumers struggling with substance abuse.

**Step 1: Select & Describe the Study Topic**

1. The PIP Study Topic selection narrative should include a description of stakeholders involved in developing and implementing the PIP. MHPs are encouraged to seek input from consumers and all stakeholders who are users of, or are concerned with specific areas of service.

   - Assemble a multi-functional team (e.g. clinical staff, consumers, contract providers as appropriate).
   - Describe the stakeholders who are involved in developing and implementation of this PIP. Be sure to include CFM group representation.
   - Describe the stakeholders’ role(s) in the PIP and how they were selected to participate.

A multi-functional team was created, with representatives from the following groups.

1. **Administrative Staff:** Administrative staff includes program and division management and clinic-level administration. These stakeholders have the authority and knowledge required for implementation, and will be able to identify and address administrative barriers.
2. **Quality Assurance and Data Analysts:** An Authority and Quality Improvement psychologist and a Children and Youth Behavioral Health Data Analyst have been included on the project team. The role of these participants will be to guide data collection procedures during project implementation, and to provide monthly updates regarding the collection and analysis of data for tracking impact of interventions on youth with co-occurring disorders.
3. **Clinical Staff:** Clinical staff provided input via feedback on the implementation process during site visits, and in a comment section of the online (Survey Monkey) data reporting form. In response to clinician input, changes were made including: a) the project
implementation directives were made to be more consistent at each step; b) the language was simplified; c) input into EHR was added; and d) examples for documentation were provided.

Additional input was solicited from consumers and families via NAMI:

Consumers -- Youth and Family: A 30-minute focus group was conducted in October 2016 with 12-18 year old youth currently in treatment for a substance use disorder. The purpose of the focus group was to obtain feedback regarding possible implementation barriers, and methods to address “Drop-outs” for youth with co-occurring disorders in order to improve outcomes. On October 7, 2016 the Divisional Quality Improvement Committee met with family members from NAMI who provided ideas and input regarding the “Drop-out” rate as well as lack of access to SUD treatment in Juvenile Hall. Information was provided on the Seeking Safety intervention, and opportunities for improvement were discussed to maximize project acceptance and outcomes.

National data validated on SUD youth drug experimentation and use-patterns from SAMHSA (NSDUH 2015) showed a use-rate of up to 55% between 15-25 years of age. Overall, this is the highest risk age group, particularly with experimentation using alcohol and drugs. In addition, some youth have issues rising to serious addiction disorders, as reflected in the 9th and 11th grade confidential youth surveys in the Santa Teresa school districts. This data is used in both prevention and treatment programs countywide for identification of areas at risk, substance use patterns, and levels of risk for youth who are actively using drugs and alcohol as a coping mechanism.

Based on this local and national data, as well as MH service data indicating high levels of drop-outs before completing treatment for youth with co-occurring drug and alcohol problems, the MHP felt a PIP was indicated to enhance system capacity leading to improved treatment outcomes.

2. The PIP Study Topic selection narrative should include a description of stakeholders involved in developing and implementing the PIP.

AGENCY PARTICIPANTS: This PIP includes clinical staff that have been trained in Seeking Safety Interventions, and all office support staff at the following three Children and Youth Behavioral Health outpatient clinics. Additional clinics will be phased in, as the PIP demonstrates success. In addition, Juvenile Hall will be targeted for these new services, as screening indicates a particularly high level of risky drug use in that population.
<table>
<thead>
<tr>
<th>Region</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Region</td>
<td>3115 Redhill Ave., Shipley, CA</td>
</tr>
<tr>
<td>East Region</td>
<td>1200 N. Main St., Santa Bonita CA</td>
</tr>
<tr>
<td>Juvenile Hall</td>
<td>656 30th Ave, Levinson, CA.</td>
</tr>
<tr>
<td>South Region</td>
<td>21632 Wesley Dr., Loma Prieta Beach, CA</td>
</tr>
<tr>
<td>(two sites)</td>
<td>5 Mareblue Ave, Mevery, CA.</td>
</tr>
<tr>
<td>West Region</td>
<td>787 Casa Linda St, Camden, CA.</td>
</tr>
</tbody>
</table>

MHP PIP Committee: The following individuals from Santa Teresa’s Health Care Agency (HCA) Behavioral Health Services (BHS) comprise the PIP Committee.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>George Thinker, Ph.D.</td>
<td>Director, BHS Authority &amp; Quality Improvement Services</td>
</tr>
<tr>
<td>Aida Morales, LCSW</td>
<td>Program Manager, BHS Authority &amp; Quality Improvement Services</td>
</tr>
<tr>
<td>Rich Phillips, Ph.D.</td>
<td>Psychologist, BHS Authority &amp; Quality Improvement Services</td>
</tr>
<tr>
<td>Mary Jones, LCSW</td>
<td>Division Manager, BHS Children and Youth Behavioral Health</td>
</tr>
<tr>
<td>Wilbur Neverland, Ph.D.</td>
<td>Program Manager, BHS Children and Youth Behavioral Health</td>
</tr>
<tr>
<td>Pat Dean, Ph.D.</td>
<td>Program Manager, BHS Children and Youth Behavioral Health</td>
</tr>
<tr>
<td>Janet Reed, PhD</td>
<td>Psychologist, HCA/BHS Children and Youth Behavioral Health</td>
</tr>
</tbody>
</table>
3. Define the problem.
   - The problem to be addressed should be clearly stated with narrative explanation including what brought the problem to the attention of the MHP.
     - What is the problem?
     - How did it come to your attention?
     - What data have you reviewed that suggests the issue is indeed a problem for the MHP? Describe any relevant benchmarks.
   - The study topic narrative will address:
     - What is the overarching goal of the PIP?
     - How will the PIP be used to improve processes and outcomes of care provided by the MHP?
     - How any proposed interventions are grounded in proven methods and critical to the study topic.
   - The study topic narrative will clearly demonstrate:
     - How the identified study topic is relevant to the consumer population
     - How addressing the problem will impact a significant portion of MHP consumer population
     - How the interventions have the potential to impact the mental health, functional status, or satisfaction of consumers served.

Analysis of comprehensive aspects of youth with co-occurring disorder needs, care, and services

Context - The requirements of collaborated and coordinated healthcare under the Affordable Care Act (ACA) is resulting in an increasing number of alcohol/substance abuse and mental health agencies integrating to provide integrated care. This is reflected in the merger of two important associations in California, the County Alcohol and Drug Program Administrators Association of California (CADPAAC) and the County Mental Health Directors Association (CMHDA). Both of these Associations merged in 2014 reflecting the need for integrated care and pooling of resources.

As noted on the Substance Abuse and Mental Health Services Administration (SAMHSA) website, the agency supports an integrated treatment approach for co-occurring mental and substance use disorders, which will result in better outcomes for consumers. Statistics indicate that when compared with the general population, individuals with a mental disorder are more likely to experience a substance use disorder, and people with a substance use disorder are more likely to have a mental disorder. According to the National Survey of Substance Abuse Treatment Services (N-SSATS), about 45% of Americans seeking substance use disorder treatment have been diagnosed as having a co-occurring mental and substance use disorder.
Santa Teresa County Clinical Challenge/Problem To Be Addressed by this Clinical PIP: Screening of local youth age 12-18 years who are Medi-Cal beneficiaries receiving services at Children and Youth Behavioral Health outpatient clinics indicates that approximately 30% scored “at-risk” for a “serious problem” on the CRAFFT (CRAFFT is a mnemonic acronym of first letters of key words in the six screening questions on the tool) alcohol and drug screening tool, and were in need of further assessment and probable SUD treatment. However, there is great concern regarding high drop-out rates from treatment for youth with SUD and MH needs in local clinics. This drop-out data coupled with youth focus group results made it clear there was a serious gap in meeting SUD treatment needs for this population. In exploring reasons for high drop-outs, it was found that clients, families and staff did not feel there was adequate training or focus in treatment on SUD issues and best practices. This PIP explores what might be needed to ensure this is addressed effectively as a core component of the treatment for youth with co-occurring disorders.

Broaden the spectrum of key elements of care and services by placing more clinical focus on SUD treatment

A key aspect of integrating substance use and mental health services is to ensure that clinical staff are proficient (“co-occurring capable”) of screening, identifying, and intervening to address the needed level of care for those individuals experiencing both substance use and mental health disorders.

Although a self-report survey indicated clinical staff were comfortable providing services to those at-risk for substance use disorders, no uniform method to determine each clinician’s level of ability to provide co-occurring services existed. Consequently, Children and Youth Behavioral Health (CYBH) began a three-step training process to prepare and train clinicians to screen, identify, and intervene where indicated for those with a mental health disorder who were also at-risk of substance use. Therefore, this is one of the interventions in this PIP.

The three-step training process began with two three-hour trainings (from March to June 2015) presented by two instructors from UCLA’s Integrated Substance Abuse Program. At the same time, using the CRAFFT Screening Tool for alcohol and drug use, clinical staff systematically implemented screening of all 12-20 year old clients to identify youth in need of treatment. Step three, implemented in June 2015 included a six-hour “Seeking Safety” training from Treatment Innovations. The training utilized a strong trauma component to address the needs of foster youth and others whose history typically includes traumatic experiences. The goal was to reduce drop-outs and improve outcomes, as demonstrated through the CalOMS discharge data set and CSI discharge data.

Project overview

The project will involve the following steps to expand this model and track its impact:

PHASE 1: By 11-15-2016, all five County-operated clinics will have trained all clinical staff in the Evidenced based Practice (EBP) Seeking Safety interventions. In addition, all new clients at the five County BHS clinics, age 12-20, will be administered the CRAFFT at intake as a screening tool for substance abuse risk. All new clients scoring positive for substance use risk (CRAFFT ≥ 2) will receive at
least one module of the Seeking Safety intervention. The number and type of interventions will be determined by the clinical staff, and will be based on client need and the clinician’s clinical judgment as outlined in the Seeking Safety protocol. The Substances and Choices Scale (SACS) will be administered to all clients identified as being at-risk for substance abuse at intake and six weeks after intake. The SACS scores will be used to quantify the impact of the Seeking Safety intervention and the reduction in functional impairment for each client. It is estimated that 28 new clients age 12-20 will be administered the CRAFFT on a monthly basis and eight will score two or higher on the CRAFFT. SACS is administered after the Seeking Safety Module, and so does not duplicate CSI or CalOMS discharge data, which can indicate a successful completion of treatment.

PHASE 2: By 10-1-2017, four contract operated clinics (Pathways Community Services—PCS) will have all clinical staff trained in Seeking Safety interventions. In addition, all new clients at the four Contract clinics, age 12-20, will be administered the CRAFFT at intake as a screening tool for substance abuse risk. All new clients scoring positive for substance use risk (CRAFFT ≥ 2) will receive at least one module of the Seeking Safety intervention. The number and type of interventions will be determined by the clinical staff, based on client need and the clinician’s clinical judgment, as outlined in the Seeking Safety protocol. The Substances and Choices Scale (SACS) will be administered to all clients identified as being at-risk for substance abuse at intake and six weeks after intake. The SACS scores will be used to quantify the impact of the Seeking Safety intervention and the reduction in functional impairment for each client. It is estimated that 90 new clients age 12-20 will be administered the CRAFFT on a monthly basis by these Contract clinics, and 27 will score two or higher on the CRAFFT.

PHASE 3: By 1-1-2018 four additional contract operated clinics (Western Youth Services—WYS) will have all clinical staff trained in the Seeking Safety interventions. In addition, all new clients at these four Contract clinics, age 12-20, will be administered the CRAFFT at intake as a screening tool for substance abuse risk. All new clients scoring positive for substance use risk (CRAFFT ≥ 2) will receive at least one module of the Seeking Safety intervention. The number and type of interventions will be determined by the clinical staff, based on client need and the clinician’s clinical judgment, as outlined in the Seeking Safety protocol. The Substances and Choices Scale (SACS) will be administered to all clients identified as being at-risk for substance abuse at intake and six weeks after intake. The SACS scores will be used to quantify the impact of the Seeking Safety intervention and the reduction in functional impairment for each client. It is estimated that 135 new clients age 12-20 will be administered the CRAFFT on a monthly basis by these four Contract clinics, and 41 will score two or higher on the CRAFFT.
The study question must be stated in a clear, concise and answerable format. It should identify the focus of the PIP. The study question establishes a framework for the goals, measurement, and evaluation of the study.

The study question is, “Can functional impairment due to substance use, (as measured by the Substances & Choices Scale or SACS) among 12-20 year old youth be reduced by 20% through the use of a brief intervention (Seeking Safety Module) while receiving mental health services at a children and youth outpatient clinic?”

**STEP 3: IDENTIFY STUDY POPULATION**

Clearly identify the consumer population included in the study. Include an explanation of how the study will address the entire consumer population, or a specific sample of that population. If the study pertains to an identified sector of the MHP consumer population, how inclusion of all members will occur is required. The documentation must include data on the MHP’s enrolled consumers, as well as the number of consumers relevant to the study topic.

This Step may include:
- Demographic information;
- Utilization and outcome data or information available; and
- Other study sources (such as pharmacy data) that may be utilized to identify all consumers who are to be included in the study.

The Study Population is youth 12-20 year old, who have SUD treatment needs, as identified through administration of the CRAFFT screening tool in MHP Services.

Clinicians at County BHS outpatient clinics will screen all new clients, age 12 or older, for substance abuse risk. Those Medi-Cal beneficiaries age 12-20 who are screened as being “at-risk” on the CRAFFT screening tool (score of two or more) for a more serious substance use problem and who meet the State’s criteria for medical necessity will be included in the study.

A review of the FY15/16 Q1 Access Log for CYBH shows that 98 clients age 12 or older were referred to the five programs included in this study. Approximately 30% are expected to screen positive for substance abuse risk and to receive the study intervention. This yields an estimate of 25 county Medi-Cal clients per quarter to be enrolled in the study. Addition of contract clinics, including those serving youth in the Juvenile Hall, will be added over next two years.

The study question applies only to the study population noted above and will be limited for the following reasons: (1) The use of the CRAFFT screening tool is limited to children and youth age 12 and higher; no screening for alcohol and drug use exists for younger children. (2) SAMHSA reports that most drug use begins around age 12-13 years and includes substances such as tobacco, alcohol, inhalants, marijuana, and prescription drugs (e.g. sleeping pills, anti-anxiety medication), words that may be difficult to read for those age eleven and younger. (3) Youth who score positive on the CRAFFT for being at-risk for a more serious substance use problem demonstrate
a clear need that should be addressed. Those youth not at-risk will not be exposed to interventions where no need for those interventions exists.

The study procedure was refined based on drop-out data and focus groups with youth/family from these five initial clinics. In September 2016, the first stages of implementation in additional clinics was initiated. The planned expansion of the project is shown in the table below. The right column shows clients that are expected to be screened at their annual review. The number who will screen positive is unknown, but expected to be less than the 30% found for new clients, since the annual review clients have already received treatment.

<table>
<thead>
<tr>
<th>Time Period</th>
<th>New Clients Screened Per Month Age 12+</th>
<th>New Clients: 2 &gt; CRAFFT Scores + SACS</th>
<th>New Clients Annually Into Program (Pro-rated)</th>
<th>Screened Annual Open cases</th>
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</thead>
<tbody>
<tr>
<td>November 2015 thru October 2016 (12 Mos)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 County Clinics</td>
<td>25</td>
<td>8</td>
<td>96</td>
<td>656</td>
</tr>
<tr>
<td>4 Contract Clinics*</td>
<td>90</td>
<td>27</td>
<td>27</td>
<td>64</td>
</tr>
<tr>
<td>November 2016 thru December 2016 (2 Mos)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 County Clinics</td>
<td>25</td>
<td>8</td>
<td>16</td>
<td>109</td>
</tr>
<tr>
<td>4 Contract Clinics (PCS)</td>
<td>90</td>
<td>27</td>
<td>54</td>
<td>128</td>
</tr>
<tr>
<td>January 2017 thru June 2017 (6 Mos)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 County Clinics</td>
<td>25</td>
<td>8</td>
<td>48</td>
<td>328</td>
</tr>
<tr>
<td>8 Contract Clinics (PCS, WYS)</td>
<td>235</td>
<td>68</td>
<td>408</td>
<td>1682</td>
</tr>
<tr>
<td>July 2017 thru December 2017 (6 Mos)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 County Clinics</td>
<td>25</td>
<td>8</td>
<td>48</td>
<td>328</td>
</tr>
<tr>
<td>14 Contract Clinics (PCS, WYS, CGC, CSP, SCCS, Seneca)</td>
<td>302</td>
<td>90</td>
<td>540</td>
<td>2099</td>
</tr>
<tr>
<td>TOTALS For 26 Months</td>
<td>817</td>
<td>244</td>
<td>1237</td>
<td>5394</td>
</tr>
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</table>

**STEP 4: SELECT & EXPLAIN THE STUDY INDICATORS**
“A study indicator is a measurable characteristic, quality, trait, or attribute of a particular individual, object, or situation to be studied.”

Each PIP must include one or more measurable indicators to track performance and improvement over a specific period of time.

Indicators should be:
- Objective;
- Clearly defined;
- Based on current clinical knowledge or health service research; and
- A valid indicator of consumer outcomes.

The indicators will be evaluated based on:
- Why they were selected;
- How they measure performance;
- How they measure change in mental health status, functional status, beneficiary satisfaction; and/or
- Have outcomes improved that are strongly associated with a process of care;
- Do they use data available through administrative, medical records, or another readily accessible source; and
- Relevance to the study question.

The measures can be based on current clinical practice guidelines or health services research. The MHP must document the basis for adopting the specific indicator.

In reporting on the chosen indicators include:
- A description of the indicator;
- The numerator and denominator;
- The baseline for each performance indicator; and
- The performance goal.

Specify the performance indicators in a Table.

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2 EQR Protocol 3, Validation of Performance Improvement Project, Sept. 2012, DHHS, Centers for Medicare & Medicaid Services (CMS), OMB Approval No. 0938-0786
Objective, clearly defined, measurable indicators

Substance abuse severity will be measured with Part B of the Substances and Choices Scale (SACS). This ten-item scale is intended for use with clients aged 13-18 years. This instrument demonstrates strong reliability (coefficient alpha r = 0.91; one-week test-retest reliability r = 0.91). Validity was demonstrated by the instrument’s ability to distinguish between a community sample and a clinical sample. A SACS score of 2/20 predicted membership of the clinical group with a sensitivity of 86% and a specificity of 81%. The instrument also showed statistically significant change after treatment.

The CRAFFT tool was chosen as a screening measure because of its brevity and high validity. Knight, Sherritt, Shrier, Harris and Chang (2002) found a sensitivity of 0.92 and a specificity of 0.80 for substance dependence. It is not being used as a criterion measure because it is relatively insensitive to change. For instance, one of the items is, “Have you ever gotten into trouble while you were using alcohol or drugs?”. The response would not be expected to change after recovery from substance use.

Changes in health status, functional status, enrollee satisfaction, or processes of care

The SACS will be used to measure change in functional status following a brief therapeutic intervention. The scale measures the severity of symptoms and degree of impairment due to drug and alcohol use. For instance, one of the items is, “Most of my free time has been spent getting hold of, taking, or recovering from alcohol or drugs.” The SACS will be administered pre- and post-intervention.

Changes in SACS scores can be evaluated by looking at changes in mean scores, or by looking at the percentage of scores above or below a threshold. The former method has greater statistical power, allowing more accurate detection of whether interventions are effective, and it minimizes Type I errors. The later method provides a more easily understood and practical measure of change, and can assess whether or not clients are in a range consistent with significant functional impairment. However, by reducing scores to categories, some of the available information is lost. Both methods are reflected in the table below:

Substances and Choices Scale
Baseline: 5.4, pre-intervention score (standard deviation 4.8)
Goal: <4.0, clinical cutoff
Percent reduction desired: 31%, (0.29 standard deviation)

<table>
<thead>
<tr>
<th>#</th>
<th>Describe Performance Indicator</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Baseline for Performance Indicator (number)</th>
<th>Goal (number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SACS ≥ 4.0 (Clinically significant level)</td>
<td>57</td>
<td>98</td>
<td>58%</td>
<td>46% (20% reduction)</td>
</tr>
<tr>
<td>2</td>
<td>Drop-out Data 2016</td>
<td>52</td>
<td>122</td>
<td>45%</td>
<td>36% (20% reduction)</td>
</tr>
</tbody>
</table>
**STEP 5: SAMPLING METHODS (IF APPLICABLE)**

The MHP must provide the study description and methodology.

- Identify the following:
  - Calculate the required sample size?
  - Consider and specify the true or estimated frequency of the event?
  - Identify the confidence level to be used?
  - Identify an acceptable margin of error?

Describe the valid sampling techniques used?

______N of enrollees in sampling frame
______N of sample
______N of participants (i.e. – return rate)

No sampling used. All clients in county operated clinics to be expanded to contractors in second year.

Medi-Cal beneficiaries (ages 12-20 years) seeking outpatient mental health services will be screened for substance use with the CRAFFT. Those at-risk for substance abuse will be identified as the study population. At-risk clients assigned to clinicians trained in the Seeking Safety intervention will be provided interventions based on at least one module of this program. All clinicians involved in the initial phase of this study have been trained in Seeking Safety and will apply this intervention. Sampling is not used, as assessments will be made of all clients eligible for the study.

The goal is a reduction of 1.4 points on the SACS. For this to be a statistically significant reduction, it would need to represent a reduction of 1.645 standard errors (for an alpha level of 5%, one-tailed test). With a standard deviation of 4.8, this requires a standard error to be 0.85, which corresponds to a sample size of 32. Of course, greater reductions could be detected with smaller sample sizes.

**STEP 6: DEVELOP STUDY DESIGN & DATA COLLECTION PROCEDURES**

A study design must be developed that will show the impact of all planned interventions. Include the information describing the following:

- Describe the data to be collected.

The data to be collected includes...

Initial data will include the CRAFFT and SACS scores. Follow-up data will include the SACS score on re-administration, along with the name of the Seeking Safety module administered, if applicable.
Describe the methods of data collection and sources of the data. How do these factors produce valid and reliable data representing the entire consumer population to which the study indicators apply?

Methods of data collection include clinicians entering client data into an online form (using Survey Monkey) for clients scoring at least two on the CRAFFT. The clients will be identified with a code that can be linked to their medical records while maintaining confidentiality of client information. Data will be entered after initial screening of the client and again after six weeks of enrollment.

Sources of data are the clients who complete the tools. In addition, Service Chiefs will provide logs showing statistics for new intakes, annual reviews, number screening positive on the CRAFFT, and number of initial and follow-up entries into Survey Monkey to allow tracking of the project process.

Describe the instruments for data collection, and how they provided for consistent and accurate data collection over time. The following instruments will be used for data collection: The CRAFFT and the SACS tools. These instruments provide consistent and accurate data collection over time as they are standardized tools administered by the same clinicians for the same clients. Supervision of clinical staff will be carried out by Clinical Supervisors, who are overseen by Service Chiefs.

Describe the prospective data analysis plan. Include contingencies for untoward results. The data analysis plan has been well developed to ensure comprehensive review. Data for clients identified as at-risk for substance abuse will be downloaded from the online form and, using the client identifier, merged with demographic and clinical data found in IRIS, the Electronic Health Record (EHR) system. Data for all clients who received the CRAFFT screening will be downloaded from the EHR.

Data analysis will consider whether the Seeking Safety intervention produced a statistically and clinically significant improvement in substance abuse severity by looking at reductions in SACS scores. A paired-sample t-test will be used to compare pre- to post-intervention SACS scores. A chi-square test was also applied to see whether the number of clients scoring below the clinical threshold of 4.0 on the SACS was reduced.

As the study population grows, improvements will be looked at by demographic characteristics, to determine if certain subgroups are more or less likely to benefit from the intervention, and whether certain Seeking Safety modules are more effective overall for certain populations.

Contingencies for untoward results include loss of key program staff, major changes in referral patterns from schools, etc.

Identify the staff that will be collecting data, and their qualifications. Include contractual, temporary, or consultative personnel. Data will be collected, downloaded and analyzed by Lucy Johns, Ph.D., research psychologist under Quality Division. Lucy has over 12 years of experience in SUD treatment, and is experienced in administering the screening tools as well as analyzing aggregate data. Dayal Singh Khalsa, Research Analyst IV, Children and Youth Behavioral Health Services is a subject matter expert with 15 years of experience working clinically with co-occurring adults and at-risk youth, and he has been involved in several research studies.
The MHP must develop reasonable interventions that address causes/barriers identified through data analysis and QI processes. Summarize interventions in a table that:

- Describes each intervention;
- Identifies the specific barriers/causes each intervention is designed to address;
- Identifies the corresponding indicator that measures the performance of the intervention; and
- Maintains the integrity/measurability of each intervention.

Describe how the interventions will impact the indicators and help to answer the study question.

A series of pre-intervention actions led to this PIP. (1) Identification and defining the problem using data and focus groups; (2) adding screening tools for SUD (CRAFFT) to the service identification system; and (3) training staff in SUD treatment principles and techniques followed by intensive training on Seeking Safety Modules and principles. These processes were done to improve outcomes for youth and allow for evaluation of system-wide application of the Seeking Safety program modules.

These structural changes to the care system for co-occurring youth laid the foundation for this PIP, which focuses on evaluation related to outcomes and decreased drop-out rates as reflected through CalOMS and CSI data.

<table>
<thead>
<tr>
<th>Number of Intervention</th>
<th>Specific Intervention</th>
<th>Barriers/Causes Intervention Designed to Target</th>
<th>Corresponding Indicator</th>
<th>Date Applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Staff Training</td>
<td>Staff unfamiliar with use of CRAFFT and SACS screening tools, and Seeking Safety methodology</td>
<td>Staff fidelity to tools and model (Seeking Safety Adherence Scale - Brief Version)</td>
<td>11-15-2016</td>
</tr>
<tr>
<td>2</td>
<td>Screening with the CRAFFT tool</td>
<td>Co-occurring youth 12-20 years who are under-diagnosed for SUD</td>
<td>CRAFFT Scores</td>
<td>All new clients at Intake</td>
</tr>
<tr>
<td>3</td>
<td>Seeking Safety Treatment Modules</td>
<td>Under-treated substance abuse</td>
<td>SACS Scores</td>
<td>Within 6 weeks of Intake</td>
</tr>
<tr>
<td>4</td>
<td>Expansion of above interventions to contract clinics</td>
<td>Staff unfamiliar with use of CRAFFT and SACS screening tools, and Seeking Safety methodology</td>
<td>CRAFFT and SACS scores, and staff fidelity to tools and model (Seeking Safety Adherence Scale - Brief Version)</td>
<td>10-01-2017 01-01-2018</td>
</tr>
</tbody>
</table>

The *Seeking Safety Adherence Scale - Brief Version* will be used to ensure fidelity and maintain the integrity/measurability of the Seeking Safety intervention. Programs will be asked to monthly submit an intervention adherence checklist, based on a program clinician sitting in and observing a Seeking Safety module implemented by another, randomly selected clinician.
Seeking Safety is an evidence-based practice for substance abuse and, as such, is expected to reduce functional impairment due to substance abuse. It is anticipated that this improvement will be reflected through administration of the SACS, a valid measure of functional impairment due to substance abuse. Seeking Safety, applied to mixed substance abuse/dependence, is rated as having modest research support for adolescents by the Society of Clinical Psychology, a division of the American Psychological Association.

**Step 8: Data Analysis & Interpretation of Study Results**

Data analysis begins with examining the performance of each intervention, based on the defined indicators. (For detailed guidance, follow the criteria outlined in Protocol 3, Activity 1, Step 8.)

- Describe the data analysis process. Did it occur as planned?
- Did results trigger modifications to the project or its interventions?
- Did analysis trigger any follow-up activities?
- Review results in adherence to the statistical analysis techniques defined in the data analysis plan.
- Does the analysis identify factors that influence the comparability of initial and repeat measurements?

The analysis of the study data must include an interpretation of the extent to which the PIP is successful and any follow-up activities planned.

Present objective data analysis results for each performance indicator. A Table can be included (see example), and attach all supporting data, tables, charts, or graphs as appropriate.

<table>
<thead>
<tr>
<th>Performance Indicator</th>
<th>Date of Baseline Measurement</th>
<th>Baseline Measurement (numerator/denominator)</th>
<th>Goal for % Improvement</th>
<th>Intervention Applied &amp; Date</th>
<th>Date of Re-measurement</th>
<th>Results (numerator/denominator)</th>
<th>% Improvement Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances &amp; Choices Scale (SACS)</td>
<td>New client intake</td>
<td>16/29 (SACS ≥ 4.0, clinically significant level), <strong>55%</strong>. (Table above shows 57/98 = 58%, a similar percentage above clinical threshold. N=98 is the total clients entered into the project; N=29 is the number that have completed to date, including re-test with the SACS.)</td>
<td>20%</td>
<td>At least one Seeking Safety module within 6 weeks of intake.</td>
<td>6 weeks after intake.</td>
<td>19/29 (SACS ≥ 4.0, clinically significant level), = 34%</td>
<td>100% - (34%/55%) = 38% improvement</td>
</tr>
</tbody>
</table>

The analysis of the study data must include an interpretation of the extent to which the PIP is successful and any follow-up activities planned.
Present objective data analysis results for each performance indicator. A Table can be included (see example), and attach all supporting data, tables, charts, or graphs as appropriate.

As planned, clinicians regularly entered data in the Survey Monkey form, which was then available for download. A paired-sample t-test was applied and yielded statistically significant results, $t = 2.90, df = 28, p = .0036$ (one-tailed test). No specific factors were found that would influence the comparability of the initial and repeat measures, but treatment-as-usual and spontaneous remission were not controlled in the current non-experimental design.

**Substances and Choices Scale**

| Initial mean score of all participants entered into the program: | Mean = 5.4 | N = 98 |
| Initial mean score of all participants completing Seeking Safety and retested: | Mean = 6.2 | N = 29 |
| Score after completion of at least one Seeking Safety module: | Mean = 3.0 | N = 29 |
| Goal for SACS reduction: | <4.0 (clinical cutoff), 31% |
| Reduction, initial to retest after intervention: | 52% |

Number of new admits, age 12+, at target clinics (estimate): 294
Number qualifying for project (CRAFFT 2+): 98

The number of clients above and below the clinical threshold of 4.0, pre- and post-intervention, are shown in the table below:

<table>
<thead>
<tr>
<th>SACS Re-test</th>
<th>&lt;4.0</th>
<th>4.0+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial SACS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;4.0</td>
<td>11</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>4.0+</td>
<td>8</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>19</td>
<td>10</td>
<td>29</td>
</tr>
</tbody>
</table>

Pre-intervention 16/29 or 55% of clients scored at least 4.0 on the SACS. Post-intervention, this fell to 10/29 or 34%. This change falls just short of statistical significance, $X^2 = 3.80, df = 1, p = .051$. 
As the data grows, follow-up activities will include the analysis of intervention characteristics, such as Seeking Safety modules chosen versus client characteristics. Data from these analyses will be provided to administrators and clinics in order to maximize intervention impact.

In the area of drop-outs versus planned discharges or transfers to lower levels of care, none of the 29 subjects to date have left treatment after or during the seeking safety module. Two clients refused treatment after intake but before beginning seeking safety. This is a significant difference from prior experience where almost half of the clients stopped attending and refused treatment within 60 days of Intake visit.

**STEP 9: ASSESS WHETHER IMPROVEMENT IS “REAL” IMPROVEMENT**

Real and sustained improvement are the result of a continuous cycle of measuring and analyzing performance, thoroughly analyzing results, and ensuring implementation of appropriate solutions. To analyze the results of the PIP the MPH must document the following steps:

- Describe issues associated with data analysis –
  - Did data cycles clearly identify when measurements occurred? Should monitoring have occurred more frequently?
  - Results of statistical significance testing.
  - What factors influenced comparability of the initial and repeat measures?
  - What, if any, factors threatened the internal or external validity of the outcomes?
- To what extent was the PIP successful and how did the interventions applied contribute to this success?
- Are there plans for follow-up activities?
- Does the data analysis demonstrate an improvement in processes or consumer outcomes?

It is essential to determine if the reported change is “real” change, or the result of an environmental or unintended consequence, or random chance. The following questions should be answered in the documentation:

- How did you validate that the same methodology was used when each measurement was repeated?
- Was there documented quantitative improvement in process or outcomes of care?
- Describe the “face validity,” or how the improvements appear to be the results of the PIP interventions.
- Describe the statistical evidence supporting that the improvement is true improvement.
- Was the improvement sustained through repeated measurements over comparable time periods? (If this is a new PIP, what is the plan for monitoring and sustaining improvement?)

Data analysis was done once a sufficient sample was available. Future analysis is planned approximately every 60 days, as the data grows. Statistical significance suggests that the results were generalizable. The sample was representative of CYBH youth initiating treatment, and there were no factors affecting the comparability of measurements. The size of the effect, reducing the SACS score by 50%, strongly suggests that the intervention was effective, but spontaneous remission and treatment-as-usual could have contributed to this effect. The current plan is to expand the interventions to contract clinics and
to youth identified as substances abusers at annual review, in addition to those identified at Intake. As the data grows, it will be possible to identify if certain modules are more effective, and if the intervention is more effective when certain client characteristics are present.

As discussed, CSI and CalOMS data will be used to document drop-out rates from treatment, or treatment refusal post-assessment/intake.