



## CREATION AND IMPLEMENTATION OF AN EHR QUIT SMOKING TOOL IN SAFETY NET CLINICS

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**Abstract:** Tobacco use and secondhand smoke exposure remain a leading cause of morbidity and mortality, especially among families living in poverty. This project will build, implement, evaluate and disseminate a Computerized Physician Order Entry (CPOE) tool for the NextGen electronic health record system that will enable providers to more readily identify smokers and systematize the treatment and referral of smokers to California Smoker's Helpline. The tool will include a bidirectional information referral system with the Helpline. We will evaluate the effectiveness of this tool using a cluster randomized control trial design at 10 clinic sites. We will then disseminate the CPOE tool throughout the Community Health Center Network of Alameda County, which serves Alameda County's lowest income residents.

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### **Overall Goal & Objectives:**

The goal of this project is to build tobacco cessation support tools into the electronic health record (EHR) that systematically increase the number of adult smokers living in poverty who make cessation attempts, and who successfully quit smoking.

To accomplish this goal, this project will build, implement, and evaluate a Computerized Physician Order Entry (CPOE) tool that will enable providers to more readily identify smokers; automate the treatment and referral of smokers; and create a bidirectional information exchange with the California Smokers' Helpline. We will develop this system for NextGen, the electronic health record system used by community-based safety net clinics in Alameda County, and one of the top five electronic health records in the country<sup>1</sup>. We will pilot this system in the Community Health Center Network (CHCN) of Alameda County. We will conduct a rigorous evaluation of the intervention's effectiveness, and through an implementation evaluation we will examine barriers and facilitators to further inform dissemination efforts. We will disseminate the tools throughout the CHCN of Alameda County.

The following are the specific objectives to accomplish this goal.

### **Objectives:**

1. Build tobacco cessation CPOE in NextGen that includes the tools for identifying smokers and household smokers and assisting them to quit.
2. Build a bidirectional e-referral between the NextGen Electronic Health Record (EHR) and the California Smokers' Helpline.
3. Deliver CPOE and e-referral with a brief training to 11 Lifelong Clinics and 5 CHCN Clinics in Alameda County.
4. Evaluate the implementation and impact of the CPOE and e-referral tool on the number of patients screened for tobacco use, Helpline referrals made, the number of tobacco cessation pharmacological agents prescribed to smokers, and assess the quit rate among counseled smokers.

### **Needs Assessment:**

Tobacco use is a major global health crisis, and remains the major cause of annual preventable death in the United States<sup>2</sup>. In the region targeted for this proposal, 13.4% of the 1.5 million residents are smokers, but among certain high risk groups, including people living in poverty and African Americans, the smoking rate is close to 17%<sup>3</sup>. The current smoking rate is highest among young adults between the ages of 18-24 years at 18.6%.<sup>4</sup> In addition to smoking cigarettes, secondhand smoke (SHS) also causes significant morbidity and mortality<sup>5</sup>. Sixty percent of children living at or below 185% of the federal poverty level are estimated to be exposed to SHS<sup>6</sup>, which has been linked to a myriad of health problems including sudden infant death syndrome, pneumonia, ear infections, asthma, attention deficit disorder, and stroke. Adults exposed to SHS are more likely to have heart disease, lung cancer, chronic lung disease, and stroke.<sup>7</sup> Research in pediatrics shows that the vast majority of parents feel it is a pediatrician's job to ask about SHS exposure and that they would accept tobacco cessation

assistance from the pediatrician<sup>8</sup>, demonstrating that healthcare providers have a valuable role in actively supporting family members who want to quit smoking.

Telephone counseling such as the California Smokers' Helpline (Helpline) provides is an evidence based and effective strategy to help smokers quit<sup>9</sup>; Clinicians play a valuable role in connecting patients to the Helpline as they represent the largest driver of calls, at 36.8% of total referrals.<sup>10</sup> Furthermore, when clinicians refer patients to the Helpline, patients have higher quit rates than those who self refer.<sup>11</sup> However, in 2013, only 0.8% of Alameda County's smokers used the Helpline's services<sup>12</sup>, indicating a need for improving referral rates to the Helpline. Additionally, health care providers' rates of advising patients to quit smoking, prescribing tobacco cessation medications, and referral to treatment remain woefully low<sup>13</sup>.

Incorporating tobacco cessation measures into the EHR, and integrating tobacco cessation into the EHR of community health clinics has been shown to increase the number of community health center patients who receive assistance to quit smoking<sup>14</sup>. By adding tobacco cessation into the EHR, adding systematic quality improvement cycles, and integrating tobacco cessation into the clinic workflow, we hope to increase quit attempts and quit rates among low income smokers in Alameda County.<sup>15</sup>

This project builds on the already successful CEASE (Clinical Effort Against Secondhand Smoke Exposure) California intervention funded by First 5 California and led by Dr. Jyothi Marbin, who has been training pediatric clinicians across the state of California on the "Ask, Assist, Connect" model to help smokers quit. Through CEASE, pediatricians are trained to help caregivers quit smoking by screening children for SHS, offering smokers nicotine replacement therapy and connecting them to the Helpline. A major barrier to successful implementation of CEASE is the lack of a systematic, EHR based tool to support clinicians in helping smokers quit.

Our experience with CEASE is supported by the Tri-City clinic within the CHCN. At Tri-City, medical assistants (MA) and clinicians are increasing their efforts to screen patients for tobacco use. However, once screened, it is very difficult to refer patients to the Helpline and offer smoking cessation support. MAs capture the information on paper, and then must remember to manually input and send the information to the Helpline at the end of the day. There is no electronic support for this process now. Building an e-referral would both reduce paperwork for the MAs, allowing them to spend their time on other patient care tasks, and would also systematize the approach to tobacco, so that every patient is screened and offered a referral, and every referral is documented in the patient's chart. The staff at Tri-City Clinic leading this effort is very supportive of this project's proposal (see letter of support from Dr. Page).

The CHCN clinics use the NextGen EHR version 8.3. This proposal will address these gaps by creating a set of tobacco enhancements within NextGen, which include improved tobacco screening, a Computerized Physician Order Entry (CPOE) system with a bidirectional e-referral system, and building reports and lists to help the staff monitor smoking patients and their quit rates for quality improvement efforts. CPOEs are a commonly used clinical decision tool in electronic health records to improve efficiency and patient health outcomes.<sup>16</sup> Bi-directional e-

referrals have been shown to dramatically increase referral rates to state quitlines.<sup>17</sup> Building e-referrals into the CPOE will not only streamline the referral process but will also keep the care team in the loop by updating clinicians on the patient's progress. In addition to referring primary smokers, the CPOE will also be used to systematically screen for, treat, and refer household smokers; ie the smoking caregiver of a child or smokers who live with other adults. Integrating a tobacco cessation CPOE with an e-referral into the EHR will increase clinical screening for tobacco use and secondhand smoke exposure, advising patients to quit, prescribing medications as well as improving clinicians' rates of referring patients to the Helpline.<sup>18</sup>

Bi-directional e-referrals are an area of active development by the North American Quitline Consortium (NAQC)<sup>19</sup>. NAQC has established an e-referral workgroup, whose members have been piloting implementation of e-referrals between health care organizations and quitlines in four states<sup>20</sup>. California is one of these states, but the only e-referral platform currently available is on the Epic system. However, NextGen is the most popular EHR platform for community health centers, in California<sup>21</sup> which serve low income populations with disproportionately high smoking prevalence rates.

This project will take place in the Community Health Center Network (CHCN) in Alameda County, CA. The CHCN is an association of 8 federally qualified health centers (FQHC) that provide primary care to over 175,000 low income and medically underserved residents of Alameda County.<sup>22</sup> The clinic systems included in CHCN are Asian Health Services, Axis Community Health, La Clinica, LifeLong Medical Care, Native American Health Center, Tiburcio Vazquez Health Center, Tri-City Health Center, and the West Oakland Health Council. Most of these systems have a number of clinic sites within Alameda County. These CHCN FQHC clinics serve Alameda County's lowest income residents - 45% of patients are uninsured, and 52% have Medi-Cal, Medicare, or other public insurance. The CHCN clinics serve patients of all ages and races - 35% of CHCN patients are 0-19 years old; 32% are 20-44 years old, and the remainder are 45 and older. CHCN also has a racially diverse patient base - 45% of patients are Hispanic/Latino, 22% are Asian, 15% are Black/African American, and 10% are white.<sup>23</sup>

While NextGen currently has some functionality to allow providers to document smoking status and prescribe medications for smokers who want to quit, currently there is no CPOE for smoking cessation, no integrated solution for referring patients to helplines and no way for clinicians to track referrals. Additionally, there is no systematic way to screen for and document SHS.

This project will also provide a solution for clinics seeking to meet Meaningful Use (MU) Stage 3 criteria, which will take effect in 2017. MU standards incentivize the use of certified EHR technology to improve care coordination and public health, with the goal of producing better clinical outcomes and improved population health outcomes<sup>24</sup>. Clinical sites receive financial incentives for meeting MU standards. The Meaningful Use (MU) Stage 3 standards are not yet finalized, but generally focus on using EHRs to improve patient outcomes.<sup>25</sup> It is likely that they will require that clinics connect smokers to a resource such as the Helpline to help them quit

smoking<sup>26</sup>. Therefore this project will fill a need for clinics by helping them prepare for MU stage 3.

This project will enhance Alameda County's approach to helping low income smokers quit by systematically incorporating smoking cessation CPOEs and e-referrals into the EHR in safety net clinics. NextGen is one of the top 5 EHRs in the country<sup>27</sup> and is used by over 400 community clinics nationwide<sup>28</sup>, suggesting that if this program is successful on a county level, there is the potential to move this innovation upstream and disseminate it to community clinics across the country. Similar pilot work with Epic users at Dean Health in WI led to incorporation of quitline e-referral into the basic Epic software starting in 2015.

### **Project Design & Methods:**

The technology team at Lifelong Medical Care, one of the CHCN members, has many years of experience working with NextGen and is in an excellent and unique position to work with us in creating a CPOE within the NextGen system. The CPOE tool will be based on existing tobacco order sets at other institutions (including the University of California medical centers), and CHCN champion input. The Lifelong team will work with the Helpline to build a bidirectional e-referral in NextGen which will be beta tested at one of the 11 Lifelong clinics. Once the CPOE and referral are finalized, we will randomize the remaining 10 clinics to examine the effectiveness of these EHR tools. Towards the end of the study period, we will then disseminate throughout at least 5 clinics in the CHCN. To facilitate quality improvement (QI) efforts, we will build the CPOE and e-referral using discrete data fields such that a series of data reports can be automatically generated from the EHR to allow clinics to track progress towards smoking cessation goals. Clinic champions will be able to regularly produce reports and share them with providers to track progress and make adjustments to improve screening and smoking cessation intervention efforts

Elements to be included in the NextGen build are described below:

#### **1. Bidirectional e-referral (Figure 1):**

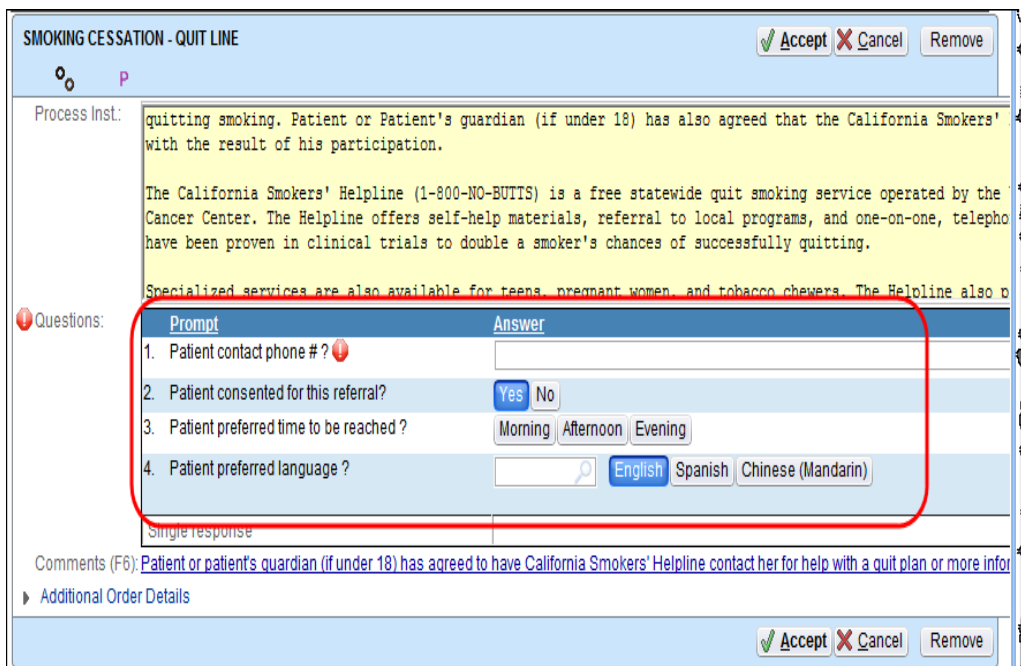
The bidirectional e-referral will dramatically simplify the process of referring patients to the Helpline. Instead of using a paper form to gather information which is later inputted into a web referral form or faxed to the Helpline, an e-referral will allow clinicians and staff to refer patients directly through NextGen. This saves staff time, and also ensures that patients are reliably referred in a timely manner, while at the same time capturing data for quality improvement (QI). In addition, provider will be able to receive messages back from the Helpline regarding their patient's progress. They will be able to follow up with the patient about their quit attempt at subsequent visits and will be able to offer support throughout the quitting process.

The interface will likely be built following the DIRECT project initiative. Once the Helpline receives the referral, there are 7 possible messages that the provider can receive: "The referred patient...":

1. completed the initial intake procedure on <date>
2. scheduled a counseling session on <date>
3. Received a counseling session on <date>
4. Set a quit date of <date>
5. Was mailed educational materials on <date>
6. Was mailed NRT on <date>
7. The Helpline was unable to contact the referred patient or the referred patient refused service. The final attempt was on <date>

Household smokers who consent to the referral can also be referred to the Helpline through the EHR chart of the patient who is being seen. Connecting a household smoker to resources to quit can reduce the burden of secondhand smoke on everyone in the home.

This screenshot from Epic (Figure 1) shows how easily a provider or staff can refer a patient from within the EHR. Household smokers are noted in the “comment” box.



**Figure 1: Bidirectional e-referral in Epic**

## 2. Tobacco Use/Passive Smoke Exposure Screening (Figures 2,3):

Figure 2 is the screen currently used in NextGen 8.3 for recording tobacco use status.

**Tobacco Use**

Have you ever used tobacco?  No/never  Yes  Unknown [Exclusions](#)  Reviewed Updated: 01/13/2015

**Smoking Tobacco Use**

Tobacco type:	Use daily:	Usage per day:	Years used:	Pack year:	Age started:	Age stopped:
<input checked="" type="checkbox"/> Cigarette	<input type="checkbox"/>	2 Packs	28	56.00		
<input type="checkbox"/> Cigarillo	<input type="checkbox"/>	cigarillos				
<input type="checkbox"/> Cigar	<input type="checkbox"/>	cigars				
<input type="checkbox"/> Pipe	<input type="checkbox"/>	pipes				

\*Smoking status: Heavy tobacco smoker

**Non-Smoking Tobacco Use**

Tobacco type:	Use daily:	Usage per day:	Years used:	Age started:	Age stopped:
<input type="checkbox"/> Chewing	<input type="checkbox"/>	units			
<input type="checkbox"/> Smokeless	<input type="checkbox"/>	units			
<input type="checkbox"/> Snuff	<input type="checkbox"/>	units			

Tobacco use status: Occasional cigarette smoker

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**Historical Use**

[Click here to see tobacco history prior to 7.9.1](#)

Encounter Date	Tobacco Type	Usage Per Day	Years Used	Pack Year	Status	Age Started	Age Stopped
10/29/2014	Cigarette	2 Packs	28.00	56.00	Heavy tobacco smoker		
09/15/2014	Cigarette	2 Packs	28.00	56.00			
09/15/2014							
09/15/2014	Cigarette						
09/15/2014							
09/15/2014	Cigarette						

**Figure 2: NextGen 8.3 Tobacco Use Documentation**

The clinic workflow will be adapted so that the patient will be screened for tobacco use and SHS by the Medical Assistant (MA). Screening for tobacco use is being done at most clinics because of Meaningful Use 1 Criteria, which requires documentation of tobacco status for any patient age 13 and older. However, although the data fields for capturing SHS (also called passive tobacco smoke) exposure exist (Figure 3), there is essentially no systematic screening being done for SHS exposure. We are failing to identify an entire cohort of children who are exposed to SHS, and are therefore we missing opportunities to intervene with caregivers who are smoking around their children. As part of this project, we will add a SHS screening question to the MA’s workflow for all patients: “does your child live with anyone who smokes cigarettes?”. This will ensure systematic screening for all patients –including pediatric patients – for SHS exposure. The answer will be documented on the Tobacco Use Screen. The passive smoke exposure screen will remain to allow providers to document further if desired.

**Passive Smoke Exposure**

Have you ever had passive smoke exposure?  No/never  Yes

Exposure in home environment:  No  Yes

Other exposure locations:  Comments:

Tobacco type:

Length of exposure:

Level of exposure:

Characters left: 250

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Comments:

**Figure 3: Passive Smoke Exposure**



This format will allow us to record SHS exposure and tobacco use as discrete data fields, which will allow us to build reports for QI review. Codes can be tied to each field to optimize billing opportunities. These codes can also auto-populate the patient’s problem list, which will help ensure a diagnosis of tobacco use or SHS exposure are consistently applied to a patient.

We can also streamline the Helpline referrals through the screening process. Checking off the “yes” box to “Have you ever used tobacco?” or “Does your child live with anyone who smokes cigarettes?” would cause an alert to fire for the Medical Assistant which would prompt them to ask additional screening questions. If these are answered positively, the MA could directly refer the patient to the Helpline. The action taken will be recorded in the chart. Some patients may tell the MA they are not interested in a Helpline referral, but after further discussion with the provider, may decide that they do desire a referral. This system maximizes opportunities to refer a patient to the Helpline and offers two points of referrals – initiated by either the MA screening or by the provider.

### 3. Creating a Provider Alert (Figures 4,5):

It is critical for providers to receive an alert when a patient is identified as either a smoker or exposed to tobacco smoke. In our proposed tool, the provider will be notified in two ways. First, the “tobacco” alert icon will turn from a question mark to a red exclamation point, indicating that the patient has an active tobacco concern.

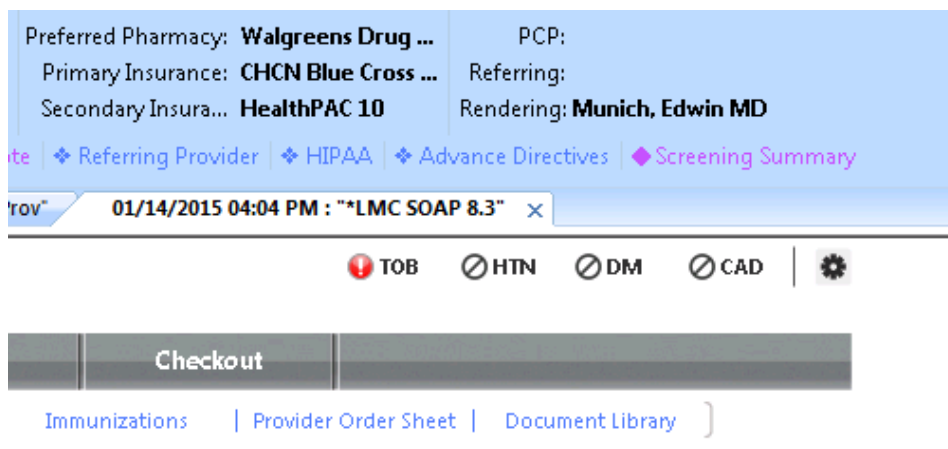
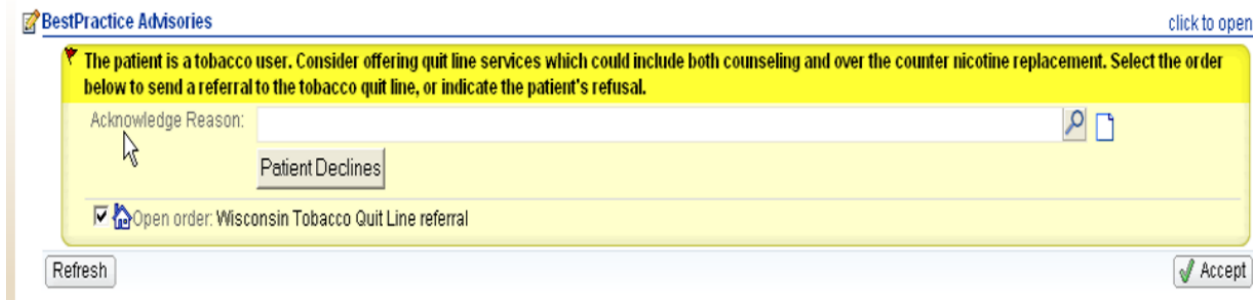


Figure 4: Red Tobacco Warning Serves as a Visual Reminder to Provider

Second, we will build an alert that will pop up on the provider’s screen. They must resolve the alert, or explain why they are not resolving during this visit. Figure 5 shows a “Best Practice Alert” from Epic, as an example of what the provider might see on their screen.



**Figure 5: Best Practice Alert from Epic**

This alert is designed to ensure that the provider takes notice of the smoking status, and either chooses an action to provide referral and support services, or documents why they have not taken action (for example, patient was offered but refused services).

**4. Documenting Tobacco Use History (Figure 6):**

NextGen 8.3 includes a set of fields to document details of tobacco use which capture most of the necessary information (Figure 6). Providers or tobacco cessation counselors can use these existing screens to document tobacco use in greater depth. As part of this project, we will raise providers’ awareness about these screens and the importance of documenting tobacco history.

**History:**  
Smoking status:   
Tobacco use:  [Tobacco Usage](#)

Enc Date	Use	Type	Total PK Yr:
08/08/2012	current	cigarettes	
08/08/2012	xxxx		

Carboxyhemoglobin test result:  Date:

**Cessation counseling:**

Date	Counseled by

**Medication Screening Questions:**

Neg Pos      Neg Pos      Neg Pos

Chest pain:        Eating disorder:        Suicidal ideation:

Depression:        Seizure disorder:        Other neuropsychiatric disorder:

Do any of the following trigger the need to smoke?      Other:

No Yes      No Yes      No Yes

Alcohol:        Driving:        Talking on the phone:

Awakening:        Meals:        TV:

Coffee:        Stress:        Other:

Does the patient smoke in the home?        Does anyone smoke at the patient's work place?

Does the patient awake at night to smoke?        Did anyone close to the patient quit smoking?

Does the patient smoke in the car?

How soon after awakening does the patient smoke the first cigarette?

Methods used in prior tobacco cessation attempts:

Acupuncture       Counseling       Prescription medication      Other:

Cognitive behavioral therapy       Hypnotherapy       Over the counter medication     

**Tobacco Cessation History:**

Encounter Date/Time/	Previous Attempts	Period Tobacco Free	Relapse / Outcome	Method Used	Year Quit

**Figure 6: Tobacco History NextGen 8.3**

**5. Building an Order Set (Figure 7,8):**

The order set we will build in this project will simplify the approach for providers treating tobacco use. The current NextGen orders can be streamlined to allow providers to enter

information more quickly. Currently, providers see the screen below (Figure 7), which allows them to place orders for smokers related to cessation; however, this section is not organized in a manner to allow them to quickly record diagnoses, make medication decisions, or refer to the Helpline.

**Instruction and Orders:**

Status	Order	Diagnosis	ICD9 Code	Date	Timeframe	Reason

Page 1 (Tobacco History, Medication Screening Questions) Page 3 (Outcome, Printing)  
Page 2 (Quick Assessment, Plan, Patient Education) [Page Down](#)

End of treatment outcome:  
 Patient no longer using tobacco  
 Treatment completed patient still using tobacco

If not completed:  
 Patient did not follow up  
 Patient refused treatment  
 Patient transferred to another practice

Comments:

Follow up outcome: (9-12 months from start of treatment)  
 Patient no longer using tobacco  
 Treatment completed patient still using tobacco

If not completed:  
 Patient did not follow up  
 Patient refused treatment  
 Patient transferred to another practice

Comments:

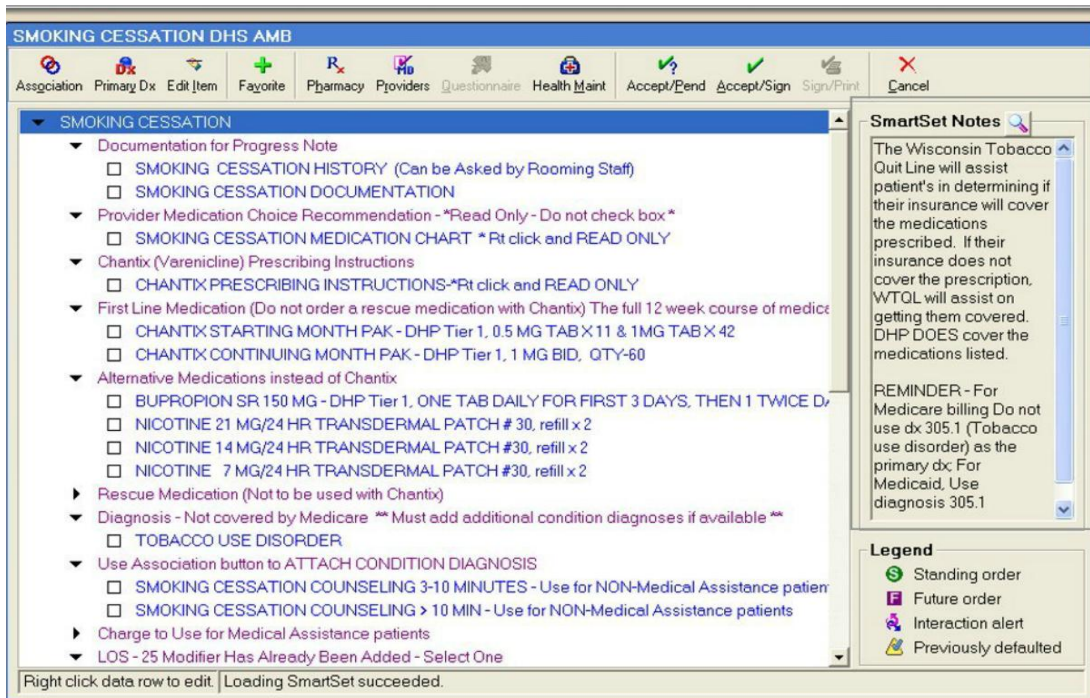
Duration of the visit:  minutes [Submit to Superbill](#)

Comments:

Page 1 (Tobacco History, Medication Screening Questions) Page 3 (Outcome, Printing)  
Page 2 (Quick Assessment, Plan, Patient Education) [Tobacco Cessation](#)

**Figure 7: Orders for NextGen 8.3**

The current interface is too complex. Our tool will significantly simplify this tool to give providers easy access to ordering medications, documenting their interventions, and even billing, as below in an example from Epic (Figure 8):



**Figure 8: Tobacco Order Set from Epic**

The CPOE will include options for documenting SHS exposure in the progress note, filling in the discharge paperwork for the patient with further instructions, and adding the smoking diagnosis to the problem list.

### 7. Advice Documented in Discharge Paperwork:

To further support the provider and patient, the tool will allow the provider to simply click a button to have smoking cessation resources added to the patient’s discharge paperwork. The patients will be able to take home written information on the benefits of quitting and resources to help them quit smoking. This is especially helpful for SHS exposure when the smoker may not be at the visit. The caregiver at the visit can easily pass along relevant and accurate quit resources to the smoker.

### 8. Additional Reports:

By collecting tobacco use information in discrete data fields, users will be able to generate reports on the number of patients who screen positive for tobacco use and SHS, treatment options offered, number of e-referrals made, medications ordered, etc.

Such reports can help to guide clinical care and follow up. Regularly generating tobacco use reports provides each clinician with an up-to-date list of their patients with tobacco use/exposure in the home. The reports can be used to identify families in need of additional support, resources, and follow-up around tobacco cessation and control. Clinicians may choose to utilize a care coordinator or case manager for support, or provide direct follow-up with families that would benefit from increased support and resource referral.

These reports also help with QI cycles at each clinic, by allowing clinic teams to review their progress towards goals on screening, treating, and referring smokers. They also allow leadership teams to identify best practices at high performing clinics that can be shared and replicated at other sites.

### **Developing and Sharing EHR Tools within CHCN:**

The CPOE will be developed and iteratively piloted at one Lifelong clinic sites. This pilot testing will also help us understand and address “bugs” in the tool and workflow problems in implementing the tool. Once we have a final product, we will randomly assign the remaining 10 Lifelong clinics to either an intervention group or a control group. Both intervention and control groups will receive a brief training from the project Principal Investigator and/or a Lifelong Physician Champion on the Ask, Assist, Connect method for helping smokers quit, delivered to all staff and providers. The training will include information about second and thirdhand smoke exposure, medications used to help smokers quit, and the services available through the Helpline, including their online web portal for referrals.

Additionally, the intervention group will be trained on how to use the NextGen CPOE tools. Since the only difference between the two conditions is the NextGen tool, we will be able to evaluate the effectiveness of the tool. Data collection will take place over a nine month period. After the data collection ends, the NextGen enhancements will shared with the former controls so all Lifelong sites will have access to both the training and tool. We will also disseminate the tool to at least five of the remaining CHCN clinic systems.

The Lifelong Physician Champion will play a key role in developing the tool, and will also help with providing access to clinic sites (see Letter of Support from Dr. Porshia Mack). Development of the tool will also be guided by a group of clinic champions from both the Lifelong clinics and the CHCN clinics. We will utilize standard quality improvement strategies to ensure the uptake and effective utilization of the tool.<sup>29</sup> Specifically, a site champion at each clinic will help think through workflow issues and will assist with training and support ongoing quality improvement efforts. The site champions will meet regularly to ensure they have input into the order set and e-referral, as well as plan clinic workflow. Champions will also be responsible for coordinating ongoing tobacco QI efforts at the clinic site, including producing reports and reviewing them regularly with the clinic staff. Each clinic system implementing the NextGen tools will receive a small monetary incentive to help with staffing and/or technological issues related to the project.

### **Evaluation Design:**

There are two components of the evaluation: (1) an outcome evaluation which will examine the effectiveness of the intervention and (2) a process/implementation evaluation which will examine how the intervention is implemented and to identify factors that impede and/or facilitate implementation. It will also be used to assess the extent to which the target audience of clinicians and office support staff are engaged in the development and implementation of the intervention.

The outcome evaluation will examine the effectiveness of the NextGen tobacco enhancement tool on its ability to improve the following:

1. Proportion of patients screened for tobacco use (out of total patients seen in clinics)
2. Proportion of patients identified as smokers (out of those screened)
3. Proportion of patients screened for SHS (out of total patients seen in clinics)
4. Proportion of identified smokers who were referred to the Helpline
5. Proportion and types of smoking cessation support provided (tobacco cessation medication prescriptions written and counseling); and
6. Smoking cessation rates for patients receiving Helpline counseling

We will evaluate the effectiveness of the intervention on its ability to improve screening rates, referrals and smoking cessation support services using a cluster randomized control trial (CRCT) design. Ten Lifelong clinic sites will be randomly divided into two groups of five clinics each. One group will serve as the intervention group, which will receive both the smoking cessation training reviewing the “Ask, Assist, Connect” steps AND the CPOE tool including the e-referral. Clinics assigned to the control group will receive the “Ask, Assist, Connect” training without the CPOE tool. This cluster randomized trial design has been used successfully in our prior evaluations of clinical practice improvement interventions.<sup>30,31</sup>

Data will be collected from each site on the outcome measures described above. At the end of the nine month data collection period, the five control sites will receive the CPOE tool with a brief training. The tool will also be disseminated to five CHCN clinics. For the final months of the project timeline, we will gather data on the number of Helpline referrals from all of the clinics using the CPOE and e-referral.

This design will allow us to evaluate the added value of the CPOE tool, since this will be the only difference between the intervention and control clinics. Although an individual level randomization design would provide greater power than the randomized cluster design, it is not feasible to randomize individuals within a given clinic site since this is a clinic-level intervention. This design provides the maximal rigor balanced with implementation feasibility.

For some outcome measures where data will be gathered exclusively from the EHR at the intervention clinics, we will utilize a pre-post design to examine changes over time that result from use of the CPOE tool. Table 1 provides the list of key outcome measures, the data source and the method used to analyze the data.

**Table 1: Key Outcome Measures, Data Source and Analysis of Data**

Measures	Data Source	Analyses
Proportion of patients screened for tobacco use	<ul style="list-style-type: none"> <li>EHR</li> </ul>	Change from baseline in intervention clinics
Proportion of patients identified as smokers	<ul style="list-style-type: none"> <li>EHR</li> </ul>	Change from baseline in intervention clinics
Patients Screened for SHS	<ul style="list-style-type: none"> <li>Provider surveys</li> <li>EHR</li> </ul>	Intervention vs Controls (CRCT)
Proportion of identified smokers who were referred to the Helpline	<ul style="list-style-type: none"> <li>Helpline data</li> <li>EHR e-referrals</li> </ul>	Intervention vs Controls (CRCT)
Proportion and types of smoking cessation support provided: <ul style="list-style-type: none"> <li>NRT prescriptions</li> <li>counseling</li> <li>cessations support materials</li> </ul>	<ul style="list-style-type: none"> <li>EHR</li> <li>Helpline data</li> <li>Helpline data</li> </ul>	<ul style="list-style-type: none"> <li>Pre-post changes in Intervention Clinics</li> <li>Intervention vs Controls (CRCT)</li> <li>Intervention vs Controls (CRCT)</li> </ul>
Smoking cessation rates among smokers referred to Helpline	<ul style="list-style-type: none"> <li>Telephone surveys conducted by CA Smokers' Helpline</li> </ul>	% smokers who quit smoking compared to published quit rates

**Assessment of the effectiveness of the CPOE tool:**

We will assess effectiveness by looking for differences between the control and intervention group's knowledge of the Ask, Assist, Connect program components and their self-efficacy in their ability to implement the program. We will also compare differences in self-reported screening rates and tobacco treatment medication prescriptions and referrals at the control and intervention sites. At the intervention sites, we will be able to validate self-report data with data gathered from the EHR (via the CPOE tool). At the intervention sites, using the EHR and Helpline data, we will examine changes over time in screening rates, referrals, smoking cessation support provided and actual proportion of smokers who are successful in quitting. We will be able to compare differences in Helpline referrals and Helpline support services provided at the control and intervention sites.

A potential concern with this design is the potential for noncomparability between intervention and control samples despite random assignment. The two samples will be compared on all non-outcome measures. If substantial differences are obtained, they can be statistically balanced by computing a weight for each participant equivalent to the inverse probability of having been assigned to the intervention condition as estimated by regressing condition on those same non-outcome measures.

Analyses will compare data from the intervention and control groups using linear regression for continuous outcomes, Poisson or negative binomial regression for counts, and logistic regression for dichotomous outcomes. Robust variance estimation will be used to adjust for clustering by clinic. Models will contain an indicator of treatment group (intervention vs. control). All intervention by covariate two-way interactions will be tested for statistical significance. Nonsignificant interactions and main effects for covariates will be deleted to obtain the most parsimonious final models possible.

**Sample Size Estimates and Power Analyses:**

We used a very conservative sample of smokers to estimate our power analyses. We estimate approximately 1200 smokers will be included in the study (600 in the intervention group and 600 in the control group).

As shown in Table 2, assuming power = .80 and alpha = .05, the minimum detectable difference in the primary outcome at each time point between the intervention and the control condition is 11, 18 or 23 percentage points depending on whether the intraclass correlation (ICC) assessing the clustering effect of clinics is low, moderate, or high. The range for ICC is suggested by data from Reading et al.<sup>32</sup> The calculated differences in proportions translate into an effect size (Cohen’s h) falling between a small (h=.20) and medium (h=.50) effect size when the ICC is low or moderate, and just above the cutoff for a moderate effect size if the ICC is large. For the intervention condition, the minimum achievable precision for point estimates of proportions is a confidence interval width of 8 percentage points screening rates, 9 percentage points for Helpline referrals, and 10 percentage points for smoking support services.<sup>33</sup>

**Table 2: Power Analyses**

Outcome	N Total/Grp/Clinic	Control Proportion	Minimum detectable change if:		
			ICC=.01 Change (h)	ICC=.05 Change (h)	ICC=.09 Change (h)
Screened for SHSE	1200/600/120	60%	+11% (.228)	+18% (.391)	+22% (.501)
Referred to Helpline	960/480/80	40%	+10% (.241)	+18% (.399)	+23% (.503)
Received smoking cessation support services	768/384/64	20%	+11% (.258)	+18% (.407)	+23% (.511)

We will compare differences in the intervention and control group prior to the intervention and at 6 month follow-up periods on study outcome measures.

**Assessment of Implementation:**

We will track and report the proportion of clinicians/staff trained by site; their reports on the quality of the clinician training; knowledge, attitudes, self-efficacy in using the CPOE tool and in screening and providing smoking cessation support services and referrals. We will administer a pre-post training survey to intervention and control clinics. We will also conduct six month follow-up telephone interviews with clinician champions to examine how the CPOE tool is being implemented and to examine barriers and facilitators to the uptake and implementation of this



health systems change including ease of using the EHR based tool. We will assess participants' satisfaction with the tool via their responses to a short series of 5-point Likert-type agreement scales. We will use descriptive statistics (e.g. mean, mode, standard deviation, minimum and maximum) to analyze ratings. We will report a point estimate and 95% confidence interval for % who agree with each satisfaction statement.

As part of this project, the Helpline will conduct follow up calls with a sample of counseled smokers to ensure that the quit rate of CHCN patients using the Helpline is comparable to those in the published literature for referred smokers.

**Dissemination Plan:**

We anticipate that once the CPOE and bidirectional e-referral are built, we will be able to take advantage of the considerable influence of the CHCN and present this project as a model for dissemination more widely across community health centers. By building smoking cessation treatments into the EHR, harnessing the power and insight of clinic champions and building in regular QI cycles, and eventually by working upstream to NextGen, we hope to ensure sustainability of this intervention far beyond the grant cycle.

**Timeline:**

The first six months of the project will be used to identify site champions and to begin meeting with them to gather their input and support around components of the CPOE and how to best train the clinic staff and disseminate the CPOE. During this time, the technical team will begin building the e-referral and order set.

We will spend one month iteratively piloting the EHR tools with one clinic to understand the challenges and limitations, and make adjustments based on our findings. We will continue meeting with the clinic champions to develop strategies around dissemination and implementation.

Towards the end of year 1, we will start to train the five intervention Lifelong clinics on the Ask, Assist, Connect model with the CPOE tool. We will train the five control sites on the Ask, Assist, Connect model only. We will gather baseline data from all sites and continue to collect data over nine months, and then we will train the control sites on the CPOE. At this time, we will also train at least five additional CHCN clinics on the Ask, Assist, Connect model and the CPOE. We will continue to gather data on Helpline referrals during the final months of the project.

Please see detailed workplan attached.

**Budget:**

See attached

## Endnotes

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- <sup>4</sup> Health of Alameda County Cities and Places report 2010
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- <sup>8</sup> Moss D et al. Accessing adult smokers in the pediatric setting: What do parents think? *Nicotine & Tobacco Research* Vol 8, (1). Feb 2006 67-75.
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- <sup>18</sup> Silfen S et al. Increases in Smoking Cessation Interventions After a Feedback and Improvement Initiative Using Electronic Health Records — 19 Community Health Centers, New York City, October 2010–March 2012 *MMWR* October 17, 2014 / 63(41);921-924
- <sup>19</sup> Personal communication with Linda Bailey, Director, North American Quitline Consortium
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- <sup>21</sup> <http://chcnetwork.org/nextgen-practice-management-system-is-live/>
- <sup>22</sup> Data from CHCN
- <sup>23</sup> Alameda Health Consortium Fact Sheet 2013
- <sup>24</sup> <http://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives>
- <sup>25</sup> [http://www.healthdatamanagement.com/news/What-to-Expect-from-Stage-3-Meaningful-Use-Rule-49686-1.html?pg=2:](http://www.healthdatamanagement.com/news/What-to-Expect-from-Stage-3-Meaningful-Use-Rule-49686-1.html?pg=2)
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