Healthy Living Clinic Initiative Evaluation Plan

Prevention Policy and Practice Group
UC Davis Center for Healthcare Policy and Research
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Introduction

Project Overview

Tobacco use remains the leading cause of preventable death and disability in the United States, resulting in nearly half a million premature deaths annually among Americans 35 years and older. In California, there are approximately 40,000 deaths/year attributable to tobacco-related disease. Besides the terrible human toll, tobacco-related health care costs exceed $13 billion, annually, in the state. In addition, the tobacco burden falls disproportionately on certain population groups based on geography, race/ethnicity, income, and behavioral health status. Many of the individuals in these groups are served by community clinics. Thus, community clinics represent an important partner in the broader efforts to reduce tobacco use in California.

The Healthy Living Clinic Initiative (HLCI), led by the University of California, Davis, Prevention Policy and Practice Group and funded by the California Department of Public Health, California Tobacco Prevention Program (CDPH/CTPP), provides intensive training and technical assistance to up to 40 community clinics serving at-risk populations.

The HLCI enables these community clinics to:

1. Implement quality improvement (QI) methods to improve tobacco cessation efforts;
2. Improve the use of clinical data to track program effectiveness;
3. Provide people who use tobacco with guidance in nutrition, physical activity, and stress management as part of a whole health approach; and
4. Adopt and implement model tobacco-free clinic policies.

The initiative is guided by the *HLCI Quality Improvement Strategy*.

Project Logic Model

The HLCI logic model, shown in Figure 1, illustrates the expected relationship among the intervention components (HLCI project activities) and anticipated outcomes.

Evolution of the Evaluation Plan

The HLCI Evaluation Plan was originally developed in February 2022. The HLCI began working with the first cohort of community clinics on their baseline evaluation activities in September 2022 and – in the spirit of continuous quality improvement – reviewed those activities during the spring of 2023. That review process led to methodological changes entailed in this July 2023 update to the *Evaluation Plan.*

Figure 1: HLCI Logic Model

Interventions	Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes

HLCI Overarching Components
• Advisory Committee
• Quality Improvement (QI) Strategy
• Patient education materials
• Facilitating linkages with Kick It California
• Website
 	
Clinic-Specific Activities
• QI training & consultation
• Development and implementation of clinic-specific Quality Improvement Projects (QIPs) and systems to reduce tobacco use
• Assessment and enhancement of clinic tobacco-free policies
 	
Clinic Cohort Activities
• QI Learning Collaboratives
	• Improved system-level performance
	  • Each clinic has established a QIP to reduce tobacco use
	  • Increased clinic capacity to conduct QIP
	  • Monitored progress of clinic-specific QIPs and clinic cohort performance
	  • Enhanced use of EHR to conduct tobacco cessation activities
	  • Systematic referral established with Kick It California
	
	• Improved tracking of process metrics for clinic-specific performance (e.g., improved workflow, refined tobacco-free policies)
	
	• Patients have effectively used materials, focusing on nutrition, physical activity, and stress management as part of a whole health approach
	
	• Website, functioning as a central hub for networking, marketing, and materials dissemination, has been established
	
	• HLCI activities and learnings have been shared with local, state-level, and national audiences
	
	• QI Learning Collaboratives have been established and have advanced a shared agenda
		• Patients received tobacco cessation support using a whole health approach
		
		• Increased clinic referrals to Kick it California
		
		• A tobacco cessation system has been fully implemented that includes identification, management, and follow-up (e.g., Ask-Advise-Act model)
		
		• Clinics have consistently identified tobacco-using patients and referred for treatment, including counseling and medication support
		
		• Increased quit attempts
		
		• Model tobacco-free policies have been implemented
		
		• QI Learning Collaboratives have accelerated innovation
			• Increased successful quitting
			
			• Demonstration of clinic commitment to tobacco cessation system and policy improvement
			
			• Increase in clinics adopting a whole health approach to supporting cessation
			
			• Improved health and well-being among former tobacco users

Evaluation Overview

The HLCI is evaluated using methods assessing both process and outcome measures. The initiative combines mixed-methods and baseline and follow-up measurements for most evaluation activities. The three-cohort structure of the HLCI provides an opportunity to advance both clinic- and system-level quality improvement, including the use of learning collaboratives. HLCI evaluation activities – from instrumentation through dissemination – is guided by principles of cultural competence[1] and participatory data use.[2]

All HLCI activities include a process evaluation component. Process evaluation is important to QI projects because it enables implementers and other stakeholders to understand the extent to which project activities are taking place as intended, the extent to which participants are being exposed to the project as planned, and the experience of participants. Based on these findings, adjustments to the intervention activities can be made, as needed.[3] In addition, process evaluation l ensures that materials adapted and developed by the program are appropriate for the target audience(s) and support the intended outcomes.

HLCI conducts outcome evaluations to measure changes at each participating clinic in various domains, enabling an overall assessment of the extent to which program outcomes have been achieved. Baseline assessments for each clinic are crucial to developing the clinic-specific QI plan, since clinics can be expected to be at different levels of performance. Baseline and follow-up data, used in concert, enables measurement of progress toward meeting project objectives.

Process Evaluation

Each activity in the HLCI scope of work has tracking measures that are used to determine if project activities are occurring, and whether participants are being exposed to the project, as planned. Table 1 shows the list of questions, data sources, frequencies, and methods for the process evaluation.

Table 1: Process evaluation questions, data sources, frequencies, and methods

Question	Data Source	Frequency	Method
Is the Advisory Committee engaged in the project?	Membership list	Minimum once, ad hoc updates	List
	Meeting agendas	Per meeting	Agenda
	Meeting minutes	Per meeting	Minutes

[1] The Tobacco Control Evaluation Center. (2012). “Culture in Evaluation #11: Making Your Evaluations More Culturally Competent.” http://tobaccoeval.ucdavis.edu/documents/Culture_MakingYourEvaluationsMoreCulturallyCompetent_2012.pdf
[2] https://mailchi.mp/d5f863a46d60/how-does-power-affect-tobacco-control-2457117
[3] Hulscher, M. E., et al. (2003). "Process evaluation on quality improvement interventions." Qual Saf Health Care 12(1): 40-46.

Question	Data Source	Frequency	Method
	Contact log	Ad hoc	Log
Is there a strategy for implementing clinic-level QI projects?	QI Strategy	Once	Report
Are the activities to support clinic QI happening?	QI training agenda	Once per cohort	Agenda
	QI training list of participants	Once per cohort	List
	QI training presentations	Once per cohort	Presentations
	QI training post-training assessment	Once per cohort	QI training assessment tool
	Leadership calls consultation log	Once per month per cohort	Log
	QI Learning Collaborative agenda	Once per quarter per cohort	Agenda
	QI Learning Collaborative participant lists	Once per quarter per cohort	List
	QI Learning Collaborative post-meeting surveys	Once per quarter per cohort	Online mixed-methods survey
Are there educational materials to address patients' concerns about cessation-related weight gain and are they appropriate for the patient population?	List of tools, techniques, and approaches	Once	List
	Educational materials	Once (minimum 3 materials)	Materials
	Consumer testing protocol	Once	Focus group (minimum 3 groups)
	Consumer testing results summary	Once	Summary report
	Clinic feedback on educational materials	Once per cohort (staff key respondent follow-up interviews)	Key respondent interviews
Are project results and learnings disseminated at local, state, and national level?	Outreach meetings log	Minimum 5; ad hoc updates	Log
	CDPH/CTPP-hosted meeting agendas	Minimum once; ad hoc updates	Agenda
	CDPH/CTPP-hosted meeting participant lists	Minimum once; ad hoc updates	List
	Manuscript	Minimum once	Manuscript
	CDPH/CTPP conference presentation(s)	Minimum once; ad hoc updates	Presentation
	National conference presentation(s)	Minimum once per year; ad hoc updates	Presentation
Is there a process for improving clinics' tobacco-free policies?	Model Tobacco-free Policy	Once	Policy
	Model Tobacco-free Policy Audit Tool	Once	Mixed methods audit tool

Question	Data Source	Frequency	Method
	Model Tobacco-free Policy Improvement Worksheet	Once	Template
Is the project coordinating with CTPP and other stakeholders?	CDPH/CTPP cessation workgroup meeting logs	Minimum 8 per year	Participation log
Is there a program website meeting expected functionality?	Website screenshots	Minimum once; ad hoc updates	Screenshots
Do project interns have an opportunity to learn and practice public health implementation and research?	Intern Project Presentation	Once per year	Presentation
	Intern Project Report	Once per year	Report
Has Institutional Review Board (IRB) approval been obtained?	IRB approval or exemption/exclusion letter	Minimum 2 (once for focus groups, once for key respondent interviews)	Letter
	Amended IRB approval or exemption/exclusion letter, as needed	Ad hoc	Letter
Is there an Evaluation Plan?	Draft Evaluation Plan	Once	Plan
	Final Evaluation Plan	Once	Plan
Are there effective instruments for clinic baseline and follow-up assessments?	Staff and patient draft key respondent interview guides	Once	Key respondent interview guides
	Staff and patient key respondent interview pilot test results	Once	Summary
	Revised staff and patient data collection tools, as needed	Once	Revised data collection tools
	Model Tobacco-Free Policy Audit Tool	Once	Mixed methods audit tool
	Audit/data collection training agenda	Once per cohort	Agenda
	Audit/data collection training schedule	Once per cohort	Schedule
Have baseline and follow-up data been collected for each clinic?	Clinic data collection data sets	Two per clinic	Data file
	Clinic data collection incentive distribution log	Twice per cohort	Log
	Clinic data collection recruitment plan	Twice per clinic	Plan

Question	Data Source	Frequency	Method
	Data quality assurance activities	Monthly (during data cleaning)	Verbal updates at monthly calls
	Clinic data collection codebook	Once; ad hoc updates	Codebook
	Clinic data collection data dictionary	Once; ad hoc updates	Data dictionary
Has the project been evaluated?	Draft Final Evaluation Report	Once	Report
	Final Evaluation Report	Once	Report

Outcome Evaluation

HLCI assesses outcome variables across several domains to evaluate progress. Table 2 shows the list of questions, data sources, frequencies, and methods for the outcome evaluation.

Table 2: Outcome evaluation questions, data sources, frequencies, and methods

Question	Data source	Frequency	Method
What changes have taken place in the culture, capacity, and readiness of community clinics to adopt and implement strong protocols to identify and treat nicotine addiction? • What barriers and facilitators to adopting effective tobacco cessation systems have been encountered/identified?	Staff and patient data collection	Twice per clinic (baseline and follow-up)	Key respondent interviews, quantitative surveys, and focus groups
	Assessment of health system workflow and protocols through staff key respondent interviews	Twice per clinic (baseline and follow-up)	Key respondent interviews
Have clinics made progress in adopting the elements of the Model Tobacco-Free Worksite Policy? • What barriers/facilitators were encountered along the way?	Assessment of tobacco-free clinic policy	Twice per clinic (baseline and follow-up)	Mixed-methods policy audit
What changes have taken place to measure and improve gold standard tobacco cessation-related metrics (e.g., in reference to the Ask-Advise-Act model)?	American College of Preventive Medicine (ACPM) patient	Twice per clinic (baseline and follow-up)	Review of eligible patients/encounters in a defined period (EHR reports + chart review)

Question	Data source	Frequency	Method
	metrics[4] (see Appendix A)		
What changes have taken place to increase tobacco cessation among clinic patients?	ACPM patient metrics	Twice per clinic (baseline and follow-up)	Review of eligible patients/encounters in a defined period (EHR reports + chart review)
What changes have taken place in diet, physical activity, and stress management practice to support tobacco cessation, improve health and well-being, and address cessation-related weight gain?	Assessment of health systems workflow and protocols through staff key respondent interviews	Twice per clinic (baseline and follow-up)	Key respondent interviews
How did the QI intervention support achievement of the desired outcomes in each clinic?	Staff key respondent interviews	Twice per clinic (baseline and follow-up)	Key respondent interviews
	Assessment of health system workflow and protocols through staff key respondent interviews	Twice per clinic (baseline and follow-up)	Key respondent interviews
	Assessment of tobacco-free clinic policy	Twice per clinic (baseline and follow-up)	Mixed-methods audit

Instrumentation

Many data sources (e.g., lists, logs, agendas) provide CDPH/CTPP with the information needed to evaluate progress without requiring formal surveys and other instrumentation. The remaining process evaluation and all outcome evaluation data sources will be created, based upon applicable literature, adapted methods, and in-house de novo instrumentation. While some instrumentation will be standardized across all clinics and cohorts and can be finalized early in HLCI, others will require responsiveness and individualized adjustments (e.g., key respondent

[4] American College of Preventive Medicine. (2021) "Strategic Roadmap for the Integration of Tobacco Use and Dependence Interventions into Clinical Care Settings." doi: https://www.acpm.org/getmedia/105b9dea-fd92-4f9f-b24b-3131e359271e/acpm-osh_strategic-roadmap-for-the-integration-of-tobacco-use-and-dependence_final_5-13-21.pdf.aspx

interview guides) as well as tailoring for each clinic (e.g., ACPM patient metrics that depend on specific EHRs, available packages/modules, documentation practices, and reporting complexity).

Sampling Plan and Sample Sizes

Process Evaluation

Each of the three focus groups had seven participants, selected to represent the socio-economic and demographic profile of community clinic clientele in California. All other process evaluation activities will not require a sampling plan and sample sizes.

Outcome Evaluation

There are three outcome evaluation areas with sampling considerations: patient perspective-gathering, staff key respondent interviews, and ACPM patient metrics.

Patient perspective-gathering. The HLCI's original plan was to conduct patient key respondent interviews with current patients who are adults (age 18 or over), are comfortable expressing themselves in English, and who confirmed tobacco use at their last visit or who self-identify as tobacco users. The intention was to taper the number of respondents across the 3 clinic cohorts, to maximize learning at the beginning of the HLCI. In this plan, 125 patients total would be interviewed: 5 patients from each of the 10 clinics in the first cohort (50 total), 3 from each of the 15 clinics anticipated for the second cohort (45 total), and 2 from each of the 15 clinics anticipated for the third cohort (30 total).

The HLCI and the first cohort of clinics duly set out to recruit 50 patients for interviews; the process of advertising, recruiting for, and scheduling individual interviews proved to require more time and effort than had been anticipated. In the interest of providing clinics with results in a timely fashion, the HLCI pivoted starting with the second cohort to a new approach: a brief online survey paired with a cohort-wide focus group. The HLCI will aim for a minimum of 10 survey responses per clinic at both baseline and follow-up time points, and a minimum of 2 focus group participants per clinic at both baseline and follow-up time points.

Staff key respondent interviews. For the staff key respondent interviews, participants will consist of current clinic staff who are adults (age 18 and over) and are comfortable expressing themselves in English. For comparability and consistency, each clinic Project Coordinator will be the primary respondent. Other staff may also participate in the interviews (e.g. leadership, clinicians, QI specialists), if indicated.

ACPM Patient Metrics. For the ACPM patient metrics, the HLCI adapted a new methodology after the experience of working with the first cohort of clinics on baseline data collection.

Baseline for the first cohort: the baseline clinic sample will be drawn from the eligible patient population that had a clinic encounter in months 1-3. The follow-up clinic sample will be drawn from the eligible patient population that had a clinic encounter in months 11-13 of the initiative. Each metric has a different numerator and denominator (see Appendix A). Sample sizes, denominators, and number of encounters will vary depending on patient volume and clinic capacity.

All other measurements: Baseline metrics will be drawn from the 12-month September-to-August period preceding the clinic's engagement in the initiative. Follow-up metrics will be drawn from the 12-month September-to-August period comprising months 2-13 of the clinic's engagement in the initiative. Metric 1 (see Appendix A) will be drawn from the eligible patient population that had 2 medical or 1 preventive encounters in the time period; the exact number of patients depends on each clinic's patient volume. Metric 2 is a subset of Metric 1. Metrics 3 – 7 will be calculated from a random sample of 100 patients who use tobacco in the time period; if a clinic has fewer than 100 patients who use tobacco for either the baseline or follow-up time periods, the chart review will be conducted on all patients who use tobacco.

Data Management

All data will be reviewed after collection for completeness and consistency. A codebook will be produced for quantitative data. Data will be retained for a period of 7 years after the end of the project. Some data will contain identifying information, and some will not. All data will be handled in accordance with approved UC Davis IRB protocols. For example:

- Certain tracking measures, such as lists and logs associated with the Advisory Committee and those relating to QI training, will contain identifying information because it is useful for evaluation. The data will be maintained on a secure, encrypted platform requiring a password for access.
- For key respondent interviews and focus groups, participant contact information (necessary for the logistics of organizing data collection and providing incentives), recordings, and transcripts will be kept on an encrypted device requiring a password for access. Names/identifying information will be removed from the transcripts. A key will be retained to associate each participant with the views they expressed in order to associate non-identifying demographic information collected from the participants. The key will be kept on an encrypted device requiring a password for access.
- For surveys, respondent contact information will be collected only for the purpose of providing incentives; this information will be kept on an encrypted device requiring a password for access. Non-identifying demographic information obtained from survey respondents will be stored separately from contact information.
- Clinic assessment data will not be de-identified as they are needed for evaluation. These data will be maintained on a secure, encrypted platform requiring a password for access.
- ACPM patient metrics will be received by HLCI without identifying information except for the clinic of origin. The data will be maintained on a secure, encrypted platform requiring a password for access.

Analysis and Dissemination

HLCI will follow three principles in its dissemination and use of evaluation data. First, HLCI will abide by its own raison d'être by using evaluation data for QI, both within and between clinic cohorts. Second, in the spirit of effectiveness, transparency, and participatory evaluation, findings will be shared with CDPH/CTPP, leadership of each participating clinic, and other stakeholders, as appropriate. Third, to ensure their utility, write-ups of HLCI evaluation activities will follow SQUIRE 2.0[5] standards.

Data Analysis

Process and outcome evaluation data will be analyzed in a timely manner, using appropriate analytic techniques, to inform the QI process and answer evaluation questions. Specifically:

- Participant feedback on training and meetings will be reviewed regularly by the HLCI team.
- Tracking measures will be reviewed regularly by the HLCI team to evaluate performance.
- Key respondent interviews and focus group results will be transcribed, coded, and analyzed.
- Clinic assessment data (including ACPM patient metrics):
    - Quantitative information may be recoded or computed to create composite variables.
    - Qualitative information will be coded.
    - Each clinic will receive baseline and follow-up reports to inform their near- and longer-term QI efforts.

Reporting to CDPH/CTPP and Stakeholders

Routine reporting will be shared with CDPH/CTPP as required in the HLCI scope of work. Relevant process and outcome evaluation results will be shared with CDPH/CTPP, all clinics in the cohort, and among clinics, as appropriate, to advance QI and clinical outcomes.

Selected evaluation results and HLCI-developed materials will be posted on the HLCI website for general audiences. More detailed evaluation documents may be shared with other parties, as appropriate.

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[5] Davies, L. and G. Ogrinc (2015). "New SQUIRE publication guidelines: supporting nuanced reporting and reflection on complex interventions." BMJ Qual Saf **24**(3): 184-185.

Scientific Dissemination

Important findings from the HLCI will be shared at appropriate scientific meetings, in consultation with CDPH/CTPP. Evaluation results from the HLCI also will be written up, in consultation with CDPH/CTPP, and submitted to a peer-reviewed journal.

Evaluation Timeline

Clinic participation in HLCI evaluation activities will be organized to minimize burden on clinic staff and harmonize with HLCI intervention activities. A sample timeline for clinic engagement with HLCI evaluation activities is shown in Figure 2.

Figure 2: Clinic evaluation timeline

Clinic Engagement in Evaluation Activity	Cohort Month																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Patient Metrics		X												X				
Staff KRI	X												X					
Patient survey	X												X					
QI Training Assessment	X																	
QI Learning Collaborative Surveys			X			X			X			X			X			
Tobacco-Free Policy Audit			X												X			

Appendix A: Patient metrics

HLCI Metrics

The HLCI metrics are based upon quality measures from the Strategic Roadmap for the Integration of Tobacco Use and Dependence Interventions into Clinical Care Settings,[6] developed by the American College of Preventive Medicine through a grant from the Centers for Disease Control and Prevention.

Tobacco Cessation Metrics

1. Percentage of patients whose tobacco use status is documented
2. Percentage of patients who are documented as having reported tobacco use (TUP)
3. Percentage of TUP who are documented as receiving advice to quit
4. Percentage of TUP who are documented as having been referred to and/or prescribed treatment
5. Percentage of TUP who are documented as having received treatment among patients referred to and/or prescribed treatment
6. Percentage of TUP who are documented as having received treatment
7. Percentage of TUP who changed from using tobacco to not using tobacco by end of period

[6] American College of Preventive Medicine. (2021) "Strategic Roadmap for the Integration of Tobacco Use and Dependence Interventions into Clinical Care Settings." doi: https://www.acpm.org/getmedia/105b9dea-fd92-4f9f-b24b-3131e359271e/acpm-osh_strategic-roadmap-for-the-integration-of-tobacco-use-and-dependence_final_5-13-21.pdf.aspx

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