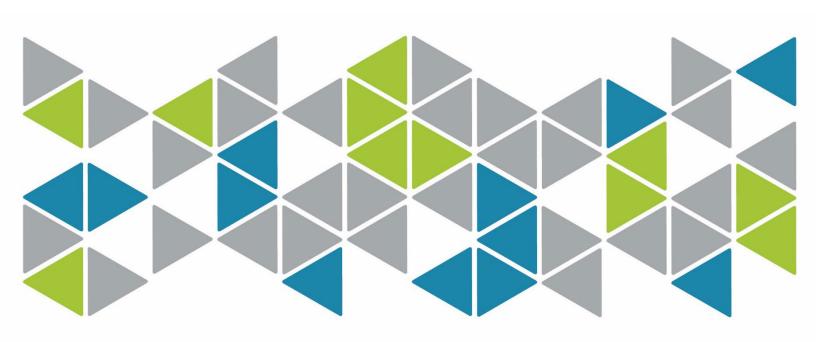# Healthy Living Clinic Initiative Evaluation Plan

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UC Davis Center for Healthcare Policy and Research
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# Contents

# 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 Control Program (CDPH/CTCP), will provide intensive training and technical assistance to up to 40 community clinics serving at-risk populations.

The HLCI will enable 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 will be guided by the *HLCI Quality Improvement Strategy* (see Appendix A).

**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.

**Figure 1: HLCI Logic Model**

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

# Evaluation Overview

The HLCI will be 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 quality collaboratives. HLCI evaluation activities – from instrumentation through dissemination – will be 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 will ensure that materials adapted and developed by the program are appropriate for the target audience(s) and support the intended outcomes.

HLCI will conduct 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 will be 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, will enable measurement of progress toward meeting project objectives.

**Process Evaluation**

Each activity in the HLCI scope of work has tracking measures that will be 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 |

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[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 |
|---|---|---|---|
| | Meeting minutes | Per meeting | Minutes |
| | 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 Collaborative agenda | Once per quarter per cohort | Agenda |
| | QI Collaborative participant lists | Once per quarter per cohort | List |
| | QI 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 informant follow-up interviews) | Key informant interviews |
| Are project results and learnings disseminated at local, state, and national level? | Outreach meetings log | Minimum 5; ad hoc updates | Log |
| | CDPH/CTCP-hosted meeting agendas | Minimum once; ad hoc updates | Agenda |
| | CDPH/CTCP-hosted meeting participant lists | Minimum once; ad hoc updates | List |
| | Manuscript | Minimum once | Manuscript |
| | CDPH/CTCP 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 Worksite Policy | Once | Policy |
| | Model Tobacco-free Worksite Policy Audit Tool | Once | Mixed methods audit tool |

| Question | Data Source | Frequency | Method |
|---|---|---|---|
| | Model Tobacco-free Worksite Policy QI method | Once | Template |
| Is the project coordinating with CTCP and other stakeholders? | CDPH/CTCP 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 informant 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 informant interview guides | Once | Key informant interview guides |
| | Staff and patient key informant interview pilot test results | Once | Summary |
| | Staff and patient revised key informant interview guides, as needed | Once | Key informant interview guides |
| | Model Tobacco-Free Worksite 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 |

| Question | Data Source | Frequency | Method |
|---|---|---|---|
|  | Clinic data collection recruitment plan | Twice per clinic | Plan |
|  | 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 will assess 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?<br><br>• What barriers and facilitators to adopting effective tobacco cessation systems have been encountered/identified? | Staff and patient key informant interviews | Twice per clinic (baseline and follow-up) | Key informant interviews |
|  | Assessment of health system workflow and protocols through staff key informant interviews | Twice per clinic (baseline and follow-up) | Key informant interviews |
| Have clinics made progress in adopting the elements of the Model Tobacco-Free Worksite Policy?<br><br>• What barriers/facilitators were encountered along the way? | Assessment of tobacco-free clinic policy and staff key informant interviews | Twice per clinic (baseline and follow-up) | Mixed-methods policy audit and key informant interviews |
| What changes have taken place to measure and improve gold standard tobacco cessation-related metrics (e.g., in reference to the Ask-Advise-Refer model)? | American College of Preventive Medicine (ACPM) | Twice per clinic (baseline and follow-up) | Review of eligible patients/encounters in a defined period |

| Question | Data source | Frequency | Method |
|---|---|---|---|
| | patient metrics[4] (see Appendix B) | | |
| 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 |
| 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? | Staff and patient key informant interviews | Twice per clinic (baseline and follow-up) | Key informant interviews |
| | Assessment of health systems workflow and protocols through staff key informant interviews | Twice per clinic (baseline and follow-up) | Key informant interviews |
| How did the QI intervention support achievement of the desired outcomes in each clinic? | Staff key informant interviews | Twice per clinic (baseline and follow-up) | Key informant interviews |
| | Assessment of health system workflow and protocols through staff key informant interviews | Twice per clinic (baseline and follow-up) | Key informant interviews |
| | Assessment of tobacco-free clinic policy | Twice per clinic (baseline and follow-up) | Mixed-methods audit and interview |

## Instrumentation

Many data sources (e.g., lists, logs, agendas) provide CDPH/CTCP 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 informant

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[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 will have seven participants, who will be 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 key informant interviews, staff key informant interviews, and ACPM patient metrics.

*Patient key informant interviews.* For the patient key informant interviews, participants will consist of 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 number of patients who are interviewed per clinic will taper across the 3 clinic cohorts, to maximize learning at the beginning of the HLCI. One hundred twenty-five patients overall will be interviewed: 5 patients from each of the 10 clinics anticipated for the first cohort (50 patients for the first cohort), 3 patients from each of the 15 clinics anticipated for the second cohort (45 patients for the second cohort), and 2 patients from each of the 15 clinics anticipated for the third cohort (30 patients for the third cohort).

*Staff key informant interviews.* For the staff key informant 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 interviews may be conducted, if indicated.

*ACPM Patient Metrics.* For the ACPM patient metrics, 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 B). Sample sizes, denominators, and number of encounters will vary depending on patient volume and clinic capacity.

## 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 informant 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.
- 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 in aggregate and as indicators, 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/CTCP, 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 informant interviews and focus group results will be transcribed, coded, and analyzed.

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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.

- 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/CTCP and Stakeholders**

Routine reporting will be shared with CDPH/CTCP as required in the HLCI scope of work. Relevant process and outcome evaluation results will be shared with CDPH/CTCP, 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.

**Scientific Dissemination**

Important findings from the HLCI will be shared at appropriate scientific meetings, in consultation with CDPH/CTCP. Evaluation results from the HLCI also will be written up, in consultation with CDPH/CTCP, 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 | X | | | | | | | | X | X | X | | | | | |
| Key Informant Interviews | | | | | | | | | | | | | | | | | | |
| Staff | X | | | | | | | | | | | | X | | | | | |
| Patients | X | | | | | | | | | | | | X | | | | | |
| QI Training Assessment | X | | | | | | | | | | | | | | | | | |
| QI Collaborative Surveys | | | X | | | X | | | X | | | X | | | X | | | |
| Tobacco-Free Policy Audit | X | | | | | | | | | | | | X | | | | | |

## Appendix B: 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 tobacco-using patients (TUPs) who are offered treatment (including referrals to Kick It California)
2. Percentage of TUPs who are provided treatment
3. Percentage of TUPs who are advised to quit among patients seen in a defined period
4. Percentage of TUPs who successfully quit (abstinent 7 months after quit date)
5. Percentage of TUPs who received treatment among patients referred for treatment
6. For TUPs receiving tobacco cessation treatment, report on the type of treatment

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[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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