

SHORT TITLE: Comprehensive smoking treatment program reach and effectiveness

1 A comprehensive smoking treatment program for a healthcare system: Evaluating reach and
2 effectiveness in primary care in a stepped-wedge design

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19 **KEYWORDS:** smoking cessation, opt-out, proactive outreach, system change, primary care

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Abstract

Background: Effective treatments for smoking cessation exist but are underused. Proactive, opt-out, chronic treatment may enhance the reach of such treatment and reduce the prevalence of smoking in healthcare systems.

Methods: All 6 adult primary care clinics in a healthcare cooperative launched a population-based Comprehensive Tobacco Intervention Program (CTIP) in 3 waves in a stepped-wedged design. The opt-out CTIP used electronic health record (EHR) tools to facilitate clinician-delivered pharmacotherapy and counseling, deploy tobacco care managers to conduct phone outreach and coordinate care with primary care clinicians, and prompt multimethod outreach to patients not attending clinic visits. EHR data were analyzed to assess CTIP reach and effectiveness.

Findings: Smoking cessation treatment reach increased significantly after CTIP launch in 5 of 6 clinics, and was significantly higher when clinics were active vs. inactive in CTIP in the stepped-wedge design. Across clinics, rates of delivering smoking cessation treatment to clinic patients increased from 12.9% pre-implementation to 24.0% post-implementation. Rates of converting from current to former smoking status in the EHR were also higher in active vs. inactive clinics, and increased from 2.1% pre-implementation to 10.5% when all clinics were active in CTIP. Reach was particularly high in historically underserved groups, including African-American, Hispanic, and Medicaid-eligible patients.

Conclusions: Implementation of a comprehensive, opt-out, chronic-care program aimed at all patients who smoke in the entire health system was associated with increases in the rates of providing smoking cessation pharmacotherapy and counseling and rates of quitting smoking. Proactive outreach to all individuals who smoke engages many patients who do not receive cessation treatments at clinic visits and may help reduce disparities in treatment access.

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Introduction

Primary care offers a favorable context and opportunities for intervening with patients who smoke [1-4]. However, it has proven very difficult to engineer smoking intervention programs that are both highly effective and well-suited for broad dissemination in real-world settings. Approaches to delivering smoking treatments in primary care that rely upon direct intervention by primary care clinicians have yielded disappointing results, as clinicians often do not address their patients' smoking [5-8]. Challenges to delivering comprehensive smoking cessation treatment (i.e., both counseling and pharmacotherapy) in primary care include clinician time pressure and lack of awareness of cessation resources [9-10]. These barriers have led to ask-advise-refer/connect approaches that shift the task of providing cessation counseling and medication to external services, such as telephone-based tobacco quitlines [11]. Unfortunately, results show little use of such referral programs by clinic staff [12-14] and low rates of enrollment in quitline services; only a third or so of referred patients take such calls [15-17].

Electronic health record (EHR) tools have been developed to prompt primary care staff and/or clinicians to assess smoking status, recommend smoking treatment, and refer patients to treatment resources. This approach has enhanced staff engagement, identification of smoking status, and treatment referral or delivery [18-21]. Additionally, closed-loop EHR methods were developed to inform clinicians of referral outcomes (i.e., 'eReferral' [12]).

Multi-site studies using an EHR-enabled, closed-loop referral approach have shown that it increases both referrals to smoking treatment and treatment engagement. A recent cluster-randomized controlled trial of EHR-enhanced, closed-loop quitline e-Referral showed that patient acceptance of quitline referral increased 3-4 fold versus fax referral, and patient acceptance of quitline calls (i.e., smoking treatment engagement) increased about 4-fold [13]. Similar findings occurred with a subsequent EHR-based, closed-loop eReferral strategy [22].

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71 Such strategies appear to be especially effective in engaging traditionally underserved
72 populations in smoking treatment, such as African-American patients and those eligible for
73 Medicaid [23]. However, research reveals the need for further improvement. Although treatment
74 engagement rates are improved by eReferral, they are still fairly low. While about 18-20% of
75 those smoking in Fiore et al., [13] accepted quit line eReferral, only about one-third of those
76 eReferred subsequently accepted a call from the quitline, resulting in only about 5% of patients
77 who smoked engaging in treatment (also see [20]).

78 The current study evaluated the reach and effectiveness of a comprehensive approach
79 to smoking cessation intervention for primary care, one that addresses gaps in smoking
80 cessation treatment delivery revealed by prior research. It incorporated features of prior EHR-
81 based systems: i.e., EHR-prompted smoking status assessment, advice, treatment offer, EHR-
82 facilitated medication orders, and eReferral with feedback. In addition, it comprised additional
83 features designed to address limitations of past EHR based strategies: 1) an opt-out approach
84 [24] to increase the rate of smoking cessation treatment acceptance; 2) multiple smoking
85 cessation treatment options to increase treatment acceptance; 3) a smoker registry to guide
86 multimedia mass communication outreach to increase smoking treatment reach; 4) targeted
87 phone outreach to all patients who smoke at least once per year, conducted by healthcare
88 system tobacco cessation outreach specialists (TCOS); 5) TCOS coordination of smoking care
89 with primary care clinicians to increase clinician engagement in smoking intervention efforts;
90 and 6) phone-based TCOS-delivered smoking intervention to reduce attrition caused by
91 patients' failing to accept tobacco quitline calls (as calls originating from the healthcare system
92 may be more likely to be answered than out-of-state calls from a quitline). In essence, this
93 comprehensive smoking treatment program was intended to optimize smoking treatment by
94 integrating diverse, complementary intervention strategies to address prior gaps in smoking
95 treatment delivery in primary care.

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120 service delivery. We analyzed changes in reach and effectiveness as a function of assigned
121 CTIP launch timeline in the stepped-wedge design (Fig. 1).

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123 **Fig. 1. Schedule for the introduction of the CTIP in the stepped-wedge design.** Each
124 cohort comprised two different primary care clinics.

125 This study was approved by the Health Sciences Institutional Review Board of the
126 University of Wisconsin (protocol number 2017-0529). Because EHR data collected during
127 routine clinical care were analyzed anonymously, informed consent was not collected from
128 patients.

129 **Healthcare system and patient population**

130 The healthcare system comprises 6 primary care clinics and is a non-profit, member-
131 owned health plan that is both an insurer and healthcare delivery system. It provides primary
132 care and specialty care to over 60,000 members living in and around Dane County, Wisconsin,
133 and serves both suburban and rural communities. The target population for CTIP was adult
134 primary care patients (≥ 18 years) satisfying criteria for current smoking via smoker registry
135 listing based on smoking status, recent diagnosis, or recent procedure code data. Those who
136 used other forms of tobacco or nicotine exclusively were not targeted for CTIP.

137 **Procedures**

138 Prior to CTIP launch, a suite of EHR tools was built in collaboration with Epic Systems
139 Corp. (Verona, WI) to enable a comprehensive, chronic care approach to tobacco treatment.
140 These tools are now part of the foundation program in Epic and are detailed in a setup manual
141 [29]. These tools were then customized to the healthcare system's Epic platform and workflows.
142 A new Tobacco Cessation Outreach Specialist (TCOS) position was developed within the
143 healthcare system Population Health Department, and EHR support and functionalities were
144 created to support this new role. One TCOS was hired in Q4 of 2017 and another in Q3 2018.

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145 They were trained by the healthcare system regarding system procedures, policies, and
146 workflows (e.g., for telephone encounters, pending orders for medication for primary care
147 clinician approval). Research staff at the University of Wisconsin Center for Tobacco Research
148 and Intervention (UW-CTRI) provided initial training in smoking cessation interventions and the
149 TCOSs completed additional accredited training in tobacco treatment. At each clinic launch,
150 UW-CTRI outreach staff provided on-site trainings for clinic staff on the EHR tools and on the
151 role of the healthcare system TCOS. All six primary clinics (no satellites, small clinics, or those
152 co-located with other systems were included) launched CTIP on a staggered schedule as per
153 the stepped-wedge design (Fig. 1), with staggered quarterly bulk outreach beginning at the
154 initial launch date.

155 **Intervention elements**

156 **Cigarette use registry**

157 This EHR registry identified patients who smoked cigarettes based on vital sign
158 assessment of tobacco use at a clinical visit, a diagnostic code for tobacco dependence, a
159 prescription for stop-smoking medication, or tobacco intervention billing codes in the past year.

160 **Mass communication outreach**

161 Mailed letters and/or EHR patient portal messages introduced both the program and the
162 TCOS for each patient's clinic. Patients on the smoking registry were sent these messages
163 during their clinic's launch week. These patients were also sent brief educational materials
164 (flyers/letters), program reminders (postcards/magnets), and 2-week sample kits of nicotine
165 patches distributed via postal mail. Bulk outreach efforts occurred quarterly, with the type of
166 material varying across quarters. Every bulk outreach wave included TCOS contact information
167 and encouraged patients to call for more information.

168 **In-clinic intervention**

169 Clinic staff followed existing standard practices of asking about tobacco use and
170 documenting use status in the EHR during the rooming process. For every patient in the
171 smoking registry who had a primary care visit, an EHR alert prompted clinicians with wording to
172 advise cessation and arrange tobacco use intervention (as per the opt-out principle). A
173 customized tobacco treatment order set facilitated the clinician's recording a quit date, referring
174 to the TCOS, and ordering medications (e.g., varenicline and combination patch and mini-
175 lozenge nicotine replacement therapy) using standard formulations and dosing schedules.

176 The EHR alert to the clinician was suppressed for 30 days following each appearance of
177 the prompt to prevent the clinician from addressing smoking treatment repeatedly within a short
178 time window. Based on stakeholder input, the duration was changed at Q3 2019 to a 90-day
179 suppression window to reduce burden on clinicians and TCOS.

180 **Phone outreach**

181 Reports in the EHR guided TCOS phone outreach. Outreach calls, in descending order
182 of priority, were made to: 1) patients who had a primary care visit at an active clinic 1-2 weeks
183 ago but did not set a quit date at the visit; 2) patients on the EHR cigarette registry who had not
184 been seen at their assigned primary care clinic in the past year. In these outreach calls, patients
185 were advised to quit, and, if a patient agreed to a quit day, medications were prescribed (via
186 pending orders approved by primary care clinicians), and counseling was delivered. Thus, every
187 patient who smoked and had a primary care visit could enter smoking treatment during the
188 primary care visit or via phone follow-up after a visit. Further, TCOS made outreach calls to
189 patients who had not had a past-year visit at their primary care clinic.

190 TCOS proactively called all patients with an upcoming or recent quit date (set by the
191 clinician or the TCOS). These cessation support calls included a pre-quit call (2-5 days before a
192 target quit date or TQD), a post-quit call (3-7 days after the TQD), and a follow-up call (4-6
193 weeks after the TQD). At each of these calls, TCOS offered brief counseling, discussed

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194 medication needs and use, assessed plans to continue with the current quit plan or set a new
195 quit date, and offered treatment extenders via quitline or text-based program. The TCOS had
196 EHR tools to electronically refer patients to the Wisconsin Tobacco Quit Line (WTQL) and/or to
197 the National Cancer Institute text-message cessation-support program, SmokefreeTXT [30].

198 **Coordination of care**

199 The TCOS coordinated care with primary care clinicians: e.g., pending orders for
200 medication and alerting them to referral to other resources (e.g., behavioral health) as needed.
201 TCOS notes regarding CTIP outreach and smoking cessation support were recorded in the
202 EHR and visible to patients' care teams.

203 **Measures**

204 Data on outreach efforts, contact rates, treatment activities/reach, and quitting smoking
205 were collected from the EHR in this pragmatic study rather than from *ad hoc* research
206 assessments. To mask patient identification by researchers, patient visits were aggregated to
207 the patient-month level by the healthcare system, with counts of CTIP treatment eligibility,
208 offers, and delivery available for each month for each patient. Data from a clinic's launch month
209 were not analyzed since launch timing relative to visits could not be determined within that
210 month.

211 Patient demographics, insurance type, clinic visits, and assigned primary care clinic
212 were extracted from the EHR. The sample of interest comprised patients who were on the
213 smoking registry for at least one month in a study period. Demographic data (age, sex, race,
214 and ethnicity) were extracted from the most recent records available for a patient in a given
215 study phase (pre- vs. post-implementation). Insurance type could and often did vary across time
216 within patients, so each insurance type (commercial, Medicare, Medicaid, other or unknown)
217 was coded as binary (1=ever had this insurance, 0=never had this insurance) for each study
218 phase. All adult patients active on the smoking registry were eligible for intervention at all

219 primary care visits (including prenatal visits), unless they had an indicator in the EHR indicating
220 that they should not be contacted (0.7% opted out of CTIP outreach). Interpreters were
221 available at clinic visits and TCOS calls for patients who did not speak English.

222 Treatment reach was computed as the number of patients receiving a treatment
223 component divided by the total number of patients eligible for that component. Reach rates were
224 sometimes computed by study period, and sometimes collapsed across periods within a phase
225 (i.e., either pre- or post-implementation). As Fig. 1 indicates, the four study periods reflect a
226 baseline period and 1-3 periods after the baseline, depending on cohort.

227 Treatment reach rates were computed to determine what proportion of eligible patients
228 received orders for smoking cessation pharmacotherapy and/or received smoking cessation
229 counseling from either their clinician or a TCOS (noted in billing data or via a CTIP-specific
230 order set). Outreach was assessed via completion rates for types of TCOS outreach call,
231 whether calls prompted patients to create or confirm a quit plan, and whether medication orders
232 were sent to the primary care clinician for approval.

233 Effectiveness was measured by computing the rate at which patients on the smoking
234 registry in each study period converted to “former smoking” status in that period, as recorded in
235 the EHR. Multiple members of a patient’s care team could update a patient’s smoking status,
236 including TCOS who updated a patient’s status to “former smoking” if a patient reported stable
237 abstinence (i.e., at least one week of abstinence) at a 4-6 week post-TQD follow-up call.

238 **Data analysis**

239 **Descriptive statistics**

240 Summary statistics (counts and percentages for categorical variables, means and
241 standard deviations for continuous variables) were computed to characterize the population of
242 patients on the smoking registry in each study phase (pre- vs. post-implementation) overall, and
243 by clinic. The proportion of patients on the smoking registry who were seen in clinic and/or were

244 eligible for TCOS outreach was computed by study period and phase. Differences between the
245 demographic and insurance composition of patient panels for each clinic were tested with Chi-
246 square tests.

247 **Reach**

248 Reach was computed at the patient- (rather than clinic visit-) level in each study period
249 and phase. Chi-square tests were used to assess horizontal effects (differences across the pre-
250 and post-implementation phases, within clinics) and vertical effects (differences between clinics
251 that had already launched CTIP vs. those still in the pre-implementation phase, within study
252 period) in the stepped-wedge design [27].

253 Post-implementation, the reach of TCOS services was computed by calculating the
254 proportion of patients eligible for a particular TCOS outreach activity who were reached by the
255 TCOS, set or confirmed a target quit date, and/or were ordered smoking cessation medication
256 via the TCOS. There was no comparable proactive patient outreach program available pre-
257 implementation for comparison. As such, descriptive data regarding reach by type of TCOS
258 outreach and by study period are presented without statistical tests of reach differences across
259 outreach types, periods, or clinics.

260 **Representativeness of reach**

261 Chi-square and t-tests were used to compare rates of medication ordering and/or
262 counseling provision across patient subpopulations defined by sex, race, ethnicity, insurance
263 type, or age in the post-implementation period.

264 **Effectiveness**

265 Effectiveness was determined by comparing the rate at which patients on the smoking
266 registry switched from active smoking status to 'former' smoking status in the EHR in each study
267 period. Chi-square tests were used to compare smoking quit rates between the inactive (not yet
268 implemented) and active (implemented) study phases within Periods 2 and 3 (i.e., the middle

269 steps in the stepped-wedge design), and across Periods 1 (pre-implementation) and 4 (post-
270 implementation).

271 **Results**

272 **Descriptive statistics**

273 **Characteristics of smoking registry patients**

274 Characteristics of adult patients on the smoking registry are summarized separately for
275 the pre-implementation and post-implementation phases in Table 1. As shown in Table 1, clinics
276 had similar gender distributions, but assigned patient panels varied significantly across clinics in
277 terms of race, ethnicity, and insurance type. Overall, most identified as White, non-Hispanic,
278 and were commercially insured. Panel characteristics were largely stable across study phases
279 (Table 1), but some pre-to-post implementation differences were observed in race, ethnicity,
280 and insurance coverage, such that missing data rates fell from pre- to post-implementation. On
281 average, patients attended 2.6-2.7 visits per phase (range=1.0-3.3 visits pre- vs. post-
282 implementation).

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Table 1. Patient-level counts (and percentages) of demographic groups and mean age and number of visits (and standard deviation) for all patients who smoke seen in clinic, by implementation phase (pre vs. post), overall (collapsed across clinics) and by clinic.

N	Overall ^a		Clinic 1		Clinic 2		Clinic 3		Clinic 4		Clinic 5		Clinic 6	
	Pre ^a 7077	Post ^a 6672	Pre 312	Post 401	Pre 1420	Post 1697	Pre 1118	Post 1023	Pre 1369	Post 1408	Pre 713	Post 508	Pre 2409	Post 2001
Sex^b														
Women	3187 (45.0)	3075 (46.1)	156 (50.0)	197 (49.1)	687 (48.4)	828 (48.8)	507 (45.3)	487 (47.6)	591 (43.2)	632 (43.2)	345 (48.4)	262 (51.6)	1045 (43.4)	896 (44.8)
Men	3885 (54.9)	3583 (53.7)	156 (50.0)	204 (50.9)	733 (51.6)	865 (51.0)	611 (54.7)	535 (52.3)	776 (56.7)	773 (56.7)	368 (51.6)	246 (48.4)	1361 (56.5)	1098 (54.9)
Unknown	5 (0.1)	14* (0.2)	0	0	0	4 (0.2)	0	1 (0.1)	2 (0.1)	3 (0.2)	0	0	3 (0.1)	7 (0.3)
Race^{cd}														
African American	746‡ (10.5)	718‡ (10.8)	4 (1.3)	7 (1.7)	97 (6.8)	125 (7.4)	76 (6.8)	72 (7.0)	209 (15.3)	208 (14.8)	55 (7.7)	44 (8.7)	349 (14.5)	306 (15.3)
Other minority group	308‡ (4.4)	277‡ (4.2)	5 (1.6)	6 (1.5)	40 (2.8)	47 (2.8)	52 (4.7)	44 (4.3)	70 (5.1)	73 (5.2)	30 (4.2)	18 (3.5)	123 (5.1)	99 (4.9)
White	5059‡ (71.5)	4875*‡ (73.1)	264 (84.6)	357 (89.0)	1051 (74.0)	1282 (75.5)	928 (83.0)	839 (82.0)	920 (67.2)	969 (68.8)	446 (62.6)	356** (70.1)	1626 (67.5)	1340 (67.0)
Unknown	964‡ (13.6)	802*‡ (12.0)	39 (12.5)	31* (7.7)	232 (14.3)	243 (14.3)	62 (5.5)	68 (6.6)	170 (12.4)	158 (11.2)	182 (25.5)	90** (17.7)	311 (12.9)	256 (12.8)
Ethnicity^d														
Hispanic	268‡ (3.8)	252‡ (3.8)	6 (1.9)	8 (2.0)	41 (2.9)	59 (3.5)	31 (2.8)	21 (2.1)	54 (3.9)	71 (5.0)	26 (3.6)	17 (3.3)	118 (4.9)	91 (4.5)
Not Hispanic	5789‡ (81.8)	5555* ^o (83.3)	247 (79.2)	332 (82.8)	1102 (77.6)	1360 (80.1)	1029 (92.0)	934 (91.3)	1137 (83.1)	1177 (83.6)	501 (70.3)	395** (77.8)	1987 (82.5)	1657 (82.8)
Unknown	1020‡ (14.4)	865*‡ (13.0)	59 (18.9)	61 (15.2)	277 (19.5)	278* (16.4)	58 (5.2)	68 (6.6)	178 (13.0)	160 (11.4)	186 (26.1)	96 (18.9)	304 (12.6)	253 (12.6)
Insurance^d														
Commercial	5711‡ (80.7)	5508** ^o (82.6)	264 (84.6)	354 (88.3)	1198 (84.4)	1452 (85.6)	924 (82.6)	858 (83.9)	1087 (79.4)	1145 (81.3)	645 (90.5)	455 (89.6)	1803 (74.8)	1544 (77.2)
Medicaid	1547‡ (21.9)	1461‡ (21.9)	41 (13.1)	45 (11.2)	250 (17.6)	300 (17.7)	197 (17.6)	197 (19.3)	327 (23.9)	315 (22.4)	102 (14.3)	75 (14.8)	714 (29.6)	623 (31.1)
Medicare	657‡ (9.3)	587‡ (8.8)	36 (11.5)	42 (10.5)	116 (8.2)	124 (7.3)	129 (11.5)	114 (11.1)	122 (8.9)	111 (7.9)	36 (5.0)	36 (7.1)	240 (10.0)	193 (9.6)
None or unknown	2726‡ (38.5)	2030*** [†] (30.4)	97 (31.1)	116 (28.9)	589 (41.5)	560*** (33.0)	396 (35.4)	273*** (26.7)	585 (42.7)	456*** (32.4)	173 (24.7)	123 (24.2)	989 (41.1)	633*** (31.6)

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<i>Pregnant</i>	43 (0.6)	55 (0.8)	0	0	3 (0.2)	14* (0.8)	5 (0.4)	4 (0.4)	14 (1.0)	15 (1.1)	1 (0.1)	2 (0.4)	22 (0.9)	24 (1.2)
<i>Age^e M (SD)</i>	42.0 (14.0)	42.9 (14.2)	45.0 (14.2)	46.6 (14.2)	43.3 (13.6)	43.4 (13.7)	43.5 (14.5)	44.3 (14.5)	42.0 (13.9)	42.1 (14.0)	37.3 (13.2)	40.7 (14.7)	41.3 (13.9)	42.2 (14.2)
<i>Clinic visits M (SD)</i>	2.6 (3.3)	2.7 (3.4)	2.1 (2.9)	3.3 (4.0)	1.9 (2.2)	2.2 (2.7)	2.3 (3.0)	0.9 (1.4)	2.2 (2.6)	2.5 (2.9)	1 (1.7)	1 (1.4)	2.9 (3.8)	2.3 (3.1)

283 ^a The overall total is less than the total summed across clinics because some patients were assigned to multiple clinics in a given
 284 phase.

285 ^b Transgendered individuals were coded in their self-identified gender category rather than sex at birth. Those with non-binary
 286 identities or missing sex were coded as missing.

287 ^c Patients identified as American Indian/Native Alaskan, Asian, or Hawaiian/Pacific Islander were coded as members of Other
 288 Minority groups to prevent inadvertent identification of patients in these low-frequency categories.

289 ^d Clinics varied significantly in terms of distribution of patients in one category vs. all others for race, ethnicity, and insurance. The p
 290 value of Chi-Square tests with 5 degrees of freedom are indicated with the following symbols: ° p<.05; † p<.01; ‡ p<.001

291 ^e Age was coded in 5-year bins up to age 75 to avoid inadvertent identification of patients; continuous age was computed by taking
 292 the midpoint of 5-year bins, or 78 if over 75.

293 * p<.05, **p<.01, *** p<.001 for Chi-square tests of within-clinic pre- to post-implementation differences for each category vs. all
 294 others

295 **Participant flow**

296 Fig. 2 provides an expanded Consolidated Standards of Reporting Trials (CONSORT)
297 diagram that depicts patient volumes, treatment reach, and rates of quitting (switching from
298 current to former smoking status in the EHR), by study period and phase [inactive (pre-
299 implementation) vs. active (post-implementation)]. Because of churn in the health system, the
300 size of the overall adult patient panel size and smoking prevalence in the panel varied across
301 study periods. Although the maximum number of patients identified as smoking in a given single
302 period is 6,699 (Period 4), the total number of patients eligible for CTIP across periods 2-4 was
303 considerably larger (N=10,571) in this open cohort. Smoking prevalence across all clinics was
304 5.7% in Period 1, 7.7% in Period 2, 6.9% in Period 3, and 7.3% in Period 4. In addition, because
305 of unequal durations of each study period, the number and proportion of patients seen in clinic
306 varied markedly by period, ranging from 29.7% to 80.8% of those on the registry of currently
307 smoking patients.

308

309 **Fig. 2. Expanded CONSORT diagram.** Number (and percentage from the previous step) of
310 patients retained in each step are displayed by study period and implementation status (active
311 vs. inactive). Gray shaded boxes show rates of CTIP treatment activities post-implementation
312 (periods 2-4) including: clinician advice to quit smoking (Advice), setting a target quit date
313 (TQD), ordering smoking cessation medication (Meds), clinician referral to the Tobacco
314 Cessation Outreach Specialist (TCOS), proactive calls from the TCOS (Called), and phone
315 contact with the TCOS (Reached). Effectiveness was measured by conversion to former
316 smoking status (Quit) for those on the smoking registry in the EHR in each period.

317

318 **Reach of treatment by study phase, cohort, and period**

319 **Clinician intervention reach**

320 Fig. 2 shows overall rates of treatment reach, in clinic and via the TCOS, by study phase
321 (inactive vs. active) and study period, collapsed across clinics. Across all the active study
322 clinics, 6,672 of 10,571 (63.1%) patients on the smoking registry were seen in at least one
323 active clinic in the post-implementation phase. The EHR alert for clinicians fired for the vast
324 majority of patients seen in active clinics over the course of the study, ranging from 82.6% to
325 93.0% of patients in the smoking registry (Fig. 2). The alert firing rate is likely below 100%
326 because patients could enter the smoking registry at or after their clinic visit. Overall, 18.9%-
327 37.3% of patients for whom the EHR alert fired in an active study phase received advice to quit
328 (Fig. 2) during a clinic visit. Fig. 2 also shows that rates of smoking intervention for such patients
329 by a clinician (setting a quit date, ordering smoking cessation medication and/or referral to the
330 TCOS) were especially high (>21%) in active clinics in Phase 2 and lower (5.2%-13.2%) in
331 Periods 3-4.

332 **TCOS intervention reach**

333 Fig. 2 shows that, collapsed across clinics, 55.4%-80.2% of patients on the smoking
334 registry were due for outreach from the TCOS at least once during each active period. Of these,
335 30.6%-48.1% were actually contacted, 8.8%-11.5% set a target quit date (TQD) during their
336 contact and developed a quit plan with the TCOS, and 8.1%-9.5% were ordered new or
337 additional stop-smoking medications.

338 **Reach of treatment by clinic and period**

339 Table 2 displays clinic-specific rates of receiving medication and/or counseling from the
340 clinician and/or TCOS, at the patient level (collapsed across visits for individual patients), for
341 each study period. Treatment reach rates varied significantly across clinics in period 1 (pre-
342 implementation for all clinics). Within clinic, significant horizontal effects (differences in pre- vs.
343 post-implementation reach rates) were observed in 5 of the 6 clinics. Only Clinic 2 did not show
344 a significant increase in rates of treatment ($p > .53$), despite a slight uptick in treatment rates in

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345 the final study period. Clinic 2 was undergoing construction for most of period 3, and this caused
346 disruptions in care (e.g., some clinicians from Clinic 2 were practicing out of Clinic 1 for at least
347 part of period 3). The same pattern of results held for medication ordering, delivery of cessation
348 counseling, or any treatment (medication and/or counseling).

349

350 **Table 2. Overall patient-level rates (n & %) of smoking cessation treatment delivered by clinic staff or TCOS to patients**
 351 **assigned to or seen in each clinic pre- and post-implementation. Pre-launch rates are unbolded, and post-launch rates are**
 352 **bolded.**

Clinic	Received any cessation treatment (medication and/or counseling)				Prescribed cessation medication				Received cessation counseling from clinician and/or TCOS			
	Period 1	Period 2	Period 3	Period 4	Period 1	Period 2	Period 3	Period 4	Period 1	Period 2	Period 3	Period 4
	Jan-Dec	Jan-Jun	Jul-Oct	Nov 2018-	Jan-Dec	Jan-Jun	Jul-Oct	Nov 2018-	Jan-Dec	Jan-Jun	Jul-Oct	Nov 2018-
	2017	2018	2018	Feb 2020	2017	2018	2018	Feb 2020	2017	2018	2018	Feb 2020
1	50 ^{aa} (15.6%)	85 (30.8%)	40 (18.0%)	90 (29.3%)	48 ^{aa} (15.0%)	77 (27.9%)	37 (16.7%)	81 (26.4%)	8 ^{aa} (2.5%)	53 (19.2%)	23 (10.4%)	40 (13.0%)
2	203 (15.6%)	177 (15.6%)	93 (8.9%)	263 (18.7%)	153 (11.8%)	138 (12.1%)	83 (8.0%)	224 (15.9%)	89 (6.8%)	105 (9.2%)	42 (4.0%)	108 (7.7%)
3	127 ^a (13.6%)	60 (7.4%)	76 (10.1%)	142 (15.4%)	108 ^a (11.5%)	50 (6.1%)	69 (9.1%)	128 (13.9%)	47 ^a (5.0%)	18 (2.2%)	32 (4.2%)	27 (2.9%)
4	190 ^{aa} (16.1%)	76 (7.8%)	162 (18.6%)	397 (32.1%)	130 ^{aa} (11%)	63 (6.4%)	127 (14.6%)	339 (27.4%)	111 ^{aa} (9.4%)	20 (2.0%)	110 (12.6%)	216 (17.5%)
5	27 ^{aa} (4.5%)	24 (6.4%)	23 (7.2%)	120 (23.6%)	24 ^{aa} (4.0%)	23 (6.1%)	16 (5.0%)	92 (18.1%)	9 ^{aa} (1.5%)	7 (1.9%)	11 (3.4%)	93 (18.3%)
6	218 ^{aa} (10.9%)	121 (7.2%)	110 (7.3%)	521 (26.1%)	168 ^{aa} (8.4%)	103 (6.2%)	102 (6.7%)	469 (23.5%)	106 ^{aa} (5.3%)	40 (2.4%)	25 (1.7%)	266 (13.3%)
χ^2	58.5 ^b	140.6 ^c	36.6 ^c	85.4 ^b	41.9 ^b	105.9 ^c	17.1 ^c	76.6 ^b	55.5 ^b	188.4 ^c	62.1 ^c	138.5 ^b
<i>n</i>	6334	5251	4721	6375	6334	5251	4721	6375	6334	5251	4721	6375
<i>p</i>	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001

353 ^a 2x2 Chi-square test of within-clinic horizontal effect (differences in treatment rates across pre- vs. post-implementation phases,
 354 collapsed across periods within phases) p<.05; ^{aa} Chi-square test of horizontal effects p<.0001

355 ^b Chi-square test indicates significant variability in treatment rates across clinics in period 1 or period 4

356 ^c 2x2 Chi-square test of between-clinic vertical effects (differences between clinics that are in pre- vs. post-implementation phases
 357 within periods 2 or 3).

358 Vertical effects (comparison of clinics actively implementing the program vs. those still in
359 the pre-implementation phase in the same period) were significant in both Periods 2 and 3. In
360 Period 4, when CTIP implementation was active in all clinics, clinics continued to vary
361 significantly in treatment reach for all 3 outcomes (any treatment, medication ordering, cessation
362 counseling).

363 **Reach of TCOS phone outreach by call type**

364 Table 3 displays the proportion of patients eligible for each type of TCOS phone
365 outreach activity post-implementation across all clinics who: were successfully reached by a
366 TCOS; created a new quit plan with a new target quit date; confirmed working toward an
367 existing target quit date (if applicable); or were ordered new or additional medication. There was
368 no proactive patient outreach program available pre-implementation for comparison.
369

370 **Table 3. Patient-level reach of TCOS services post-implementation, by outreach type.**

Outreach Type	Reached by Phone	Created Quit Plan	Confirmed Quit Plan^c	Reported Abstinence	Ordered Medication
Annual^a (if not seen in clinic in the past year, n=2014)	1093 (54.3%)	181 (9.0%)	--	--	182 (9.0%)
Recent visit (if recent clinic visit, no quit date, n=3964)	2006 (50.6%)	417 (10.5%)	--	--	360 (9.1%)
Pre-quit (if quit date in the next 2-5 days, n=886)	429 (48.4%)	116 (13.1%)	252 (28.4%)	--	46 (5.2%)
Post-quit (if quit date in the last 3-7 days, n=948)	434 (45.8%)	107 (11.3%)	237 (25.0%)	319 (33.6%)	34 (3.6%)
Follow-up (if quit date 4-6 weeks ago, n=869)	396 (45.6%)	87 (10.0%)	--	175 (20.1%)--	46 (5.3%)
Patient-initiated^b (if patient called TCOS, N=10571)	454 (4.3%)	164 (1.6%)	--	--	197 (1.9%)

371 ^a To be included in this category, patients had to appear on the list of patients who have not had a visit in at least a year for at least 2
 372 consecutive months, as many patients would appear on the list for only a few days, too short a time window for outreach to occur.

373 ^b The denominator used to compute rates of patient-initiated contact was the number of patients on the smoking registry in an active
 374 clinic in periods 2-4.

375 ^c Patient confirmed that they were still trying to adhere to the quit plan and the target quit smoking date.

376 Across the active, post-implementation study phase, at least 50% of those eligible for
377 TCOS-initiated Recent Visit outreach or Annual outreach (see Table 3) were reached by phone
378 at least once. Table 3 shows actions taken based on the types of outreach contacts. The
379 patient-level reach rates in Table 3 are slightly higher than the contact rates in Fig. 2, likely due
380 to cumulative effects that accrue when collapsing across study period.

381 Among patients who previously set a target quit date (with either a TCOS or a clinician),
382 45% or more were reached for each type of call tied to the quit date (pre-, post-, or follow-up).
383 The narrow call windows for these calls (Table 3) may have suppressed contact rates relative to
384 other outreach calls. At the pre- and post-quit calls, 25.0%-28.4% of those eligible for these calls
385 (54.6%-58.7% of those reached by phone) confirmed they were committed to their original quit
386 date and plan, and another 11.3%-13.1% eligible for these calls (24.7%-27.0% of those reached
387 by phone) set a revised quit date. As such, more than one-third of those eligible for, and more
388 than three-quarters of those reached for pre- or post-quit TCOS cessation support, indicated
389 they were working toward a quit date. Medication orders were placed for 3.6%-5.3% of those
390 eligible (7.8%-10.7% of those reached by phone) for TCOS support before or after a target quit
391 date. At the post-quit call (3-7 days post-TQD), another 33.6% of patients due for this outreach
392 (73.5% of those reached) reported achieving abstinence and therefore had no need to set a
393 new quit date. Four to six weeks after a target quit attempt, 20.1% (44.2% of those reached by
394 phone) of those due for follow-up reported they were no longer smoking, another 10.1% of
395 patients (22.0% of those reached by phone) set a new quit date, and 5.3% (11.6% of those
396 reached by phone) were ordered new or more medication.

397 Less than 5% of patients initiated contact with the TCOS (Table 3). Of these, more than
398 a third (36.1%) created a new quit plan and 43.4% were ordered cessation medication. Rates of
399 TCOS referral of patients to the Wisconsin Tobacco Quit Line and/or SmokefreeTXT were low
400 across all TCOS call types, occurring for no more than 1% of patients due for each type of
401 TCOS outreach.

402 **Representativeness of reach**

403 Rates of any medication, any counseling, and TCOS treatment specifically, were
404 compared across patient subpopulations defined by sex, race, ethnicity, insurance type, or age
405 in the post-implementation period. Table 4 shows that reach differed significantly across groups.
406 African-American patients had higher rates of receiving any and all treatment components than
407 did other racial groups, while White patients accepted TCOS services and any counseling at
408 lower rates. Hispanic patients accepted TCOS services at particularly high rates, whereas non-
409 Hispanic patients had higher rates of pharmacotherapy orders. Medicaid-eligible patients were
410 especially likely to receive any smoking treatment, and specifically, pharmacotherapy and
411 TCOS service acceptance. Those who had commercial insurance had especially lower rates of
412 accepting TCOS services than did those who never had commercial insurance, while those with
413 unknown or uninsured status at any point in the study had lower rates of pharmacotherapy
414 orders and any treatment than did those who never lacked insurance.

415

416 **Table 4. Representativeness of patient-level reach of smoking cessation treatment during the post-implementation phase**
 417 **across all clinics and periods 2-4 (N=10571).**

	Received any cessation treatment (medication and/or counseling)	Prescribed cessation medication	Received cessation counseling	Received TCOS treatment
Sex				
Men (n=5598)	1029 (18.4%)**	916 (16.4%)	598 (10.7%)	273 (4.9%)
Women (n=4956)	1012 (20.4%)**	866 (17.5%)	580 (11.7%)	251 (5.1%)
Other/unknown (n=17)	6 (35.3%)	5 (29.4%)	2 (11.8%)	1 (5.9%)
Race				
White (n=7895)	1533 (19.4%)	1347 (17.1%)	848 (10.7%)*	345 (4.4%)***
African American (n=1010)	229 (22.7%)**	210 (20.8%)***	140 (13.9%)**	95 (9.4%)***
Other minority (n=384)	61 (15.9%)	58 (15.1%)	36 (9.4%)	26 (6.8%)
Unknown (n=1282)	224 (17.5%)	172 (13.4%)***	156 (12.2%)	59 (4.6%)
Ethnicity				
Hispanic (n=364)	63 (17.3%)	57 (15.7%)	37 (10.2%)	29 (8.0%)**
Not Hispanic (n=8750)	1721 (19.7%)	1522 (17.4%)**	972 (11.1%)	439 (5.0%)
Unknown (n=1457)	263 (18.1%)	208 (14.3%)**	171 (11.7%)	57 (3.9%)*
Insurance				
Commercial (n=8778)	1698 (19.3%)	1470 (16.7%)	987 (11.2%)	415 (4.7%)*
Medicare (n=1030)	194 (18.8%)	170 (16.5%)	112 (10.9%)	49 (4.8%)
Medicaid (n=2140)	461 (21.5%)**	430 (20.1%)***	259 (12.1%)	150 (7.0%)***
Uninsured (n=3131)	526 (16.8%)***	461 (14.7%)***	328 (10.5%)	150 (4.8%)
Age [M (SD)] [43.8 (14.1)] years	45.9 (12.8)***	45.8 (12.7)***	45.7 (12.8)***	44.2 (12.8)

418 *** p<.001, **p<.01, * p<.05 in a Chi-square test comparing the group in this row against all other rows for this variable

419 **Effectiveness**

420 The rate at which patients on the smoking registry switched from an active smoking
421 status to a former smoking status, as recorded in the EHR, increased significantly from 2.1% at
422 baseline (Period 1) to 10.5% in post-implementation Period 4, as shown in Fig. 2 (*Chi-square*
423 ($N=11,486$)= 301.9 , $p<.0001$). Within study Period 2, when 2 of the clinics were active and 4
424 were inactive in CTIP, rates of switching to former smoking were significantly lower in the
425 inactive clinics (0.4%) than the active clinics (6.9%; *Chi-square* ($N=6,768$)= 264.6 , $p<.0001$). The
426 same pattern was observed in Period 3, in which 4 clinics were active and 2 inactive in CTIP;
427 0.7% of patients in the inactive clinics converted to former smoking compared with 6.6% in the
428 active clinics (*Chi-square* ($N=5,322$)= 122.8 , $p<.0001$).

429 **Discussion**

430 The introduction of a comprehensive, health system-wide primary care smoking
431 treatment program resulted in statistically significant increases in rates of delivery of any
432 smoking treatment, cessation medication orders, and cessation counseling, as well as higher
433 smoking cessation rates. The stepped-wedge design showed that such increases were strongly
434 related to the timing of program introduction across clinics.

435 One distinctive feature of the comprehensive program was aggressive outreach, which
436 appeared to be effective in increasing the offer of smoking treatment to a greater proportion of
437 the healthcare system patient population. Amongst patients who did not visit their primary care
438 clinic in the past year, or visited their clinic but made no quit plans, about half were reached by
439 phone. Such contacts were consequential in that, of the contacted patients, 1 in every 5-6
440 patients reached made a quit plan, and 1 in 6 patients accepted smoking-cessation medication.
441 This adds to evidence that comprehensive phone outreach meaningfully expands utilization of
442 cessation treatment services [31-32].

443 At post-quit TCOS calls one week after patients' TQD, 1 in 3 reported they were no
444 longer smoking and another 1 in 10 set a new quit date. Four to six weeks after an initial TQD, 1
445 in 5 patients reported no longer smoking and more than 10% made a new quit plan. As such,
446 TCOS outreach appeared to be successful in engaging people in quitting efforts both before and
447 after a TQD was set.

448 In addition to TCOS calls, quarterly outreach by mail or via the EHR patient portal
449 informed patients about cessation resources and how to access them (e.g., via letters,
450 postcards, magnets, a 2-week starter kit of nicotine patches). Of all the patients on the smoking
451 registry, fewer than 5% initiated contact with the TCOS, and it is unclear how many were
452 prompted by the outreach program. However, this approach was relatively inexpensive, and
453 more than 40% of those who initiated contact with a TCOS agreed to cessation medication use.

454 The comprehensive program was especially effective in reaching traditionally
455 underserved populations. When engagement in any form of smoking treatment was analyzed,
456 results revealed that reach rates were especially high for African-American patients, Hispanic
457 patients, and those with Medicaid health insurance coverage. Similar results have been
458 reported with other applications of EHR-enabled smoking interventions in primary care [13, 22,
459 23] suggesting that such approaches reduce disparities in smoking treatment offers and access.

460 When patients from all clinics had access to CTIP, between 15-32% of patients received
461 some form of smoking treatment, depending on the clinic. These engagement rates are
462 substantially higher than rates of quitline treatment engagement in prior studies evaluating
463 closed-loop EHR based referral without enhanced outreach strategies [13, 22, 23]. For instance,
464 a recent pragmatic study [23] of closed-loop tobacco quitline eReferral in 30 clinics implemented
465 by clinic staff during face-to-face encounters over an 8-month period found that only 3.6% of
466 adults eligible for eReferral connected with the quitline.

467 Another distinctive feature of the comprehensive program is that smoking treatment was
468 delivered by healthcare system personnel rather than via quitline referral. The TCOS delivered

469 treatment to receptive individuals who were referred at clinic visits or contacted via outreach,
470 and such treatment involved quit planning, counseling, and coordination of medications with
471 primary care clinicians. Of those who set a quit date, at least 45% completed treatment and
472 follow-up calls [22].

473 This proactive, chronic care cessation program increased the rates of smoking cessation
474 five-fold from the baseline period to the period when all clinics had had the program
475 implemented (from 2.1% of smoking patients to 10.5%). Conversion rates from current to former
476 smoker increased contingently as the comprehensive program was implemented in each set of
477 clinics.

478 Despite the promising results obtained with the comprehensive program there is still
479 need for improvement. For instance, in the last 15 months of this study (Period 4), less than one
480 third of individuals who smoked received any form of smoking treatment. Although expecting
481 100% of patients who smoke to engage in cessation treatment is unrealistic, engagement rates
482 may be improved by motivational strategies to encourage treatment uptake, such as incentives
483 for treatment engagement [33-34].

484 In addition, there was some variability in the performance of clinics during program
485 implementation. For instance, in the fourth period of the study, when the program was active in
486 all clinics, the rate of provision of medication varied 6-fold across 2 of the participating clinics
487 (from 2.9% to 18.3%). It will be important in future research to attain a greater understanding of
488 the causes of such variability and methods for addressing it.

489 Limitations of this research are that it involved only a single healthcare system, which
490 may limit the generalizability of the findings. The ascertainment of outcomes relied on EHR
491 records which may have introduced error; abstinence was not biochemically verified and the
492 EHR measures did not consistently assess all treated smokers at standard long-term follow-up
493 time points. Also, the introduction of the comprehensive program may have affected both
494 intervention delivery as well as ascertainment of outcomes, which would be impossible to

495 disentangle with the data in hand. This issue argues for future research efforts that include
496 independent means of assessing system-wide program impact beyond EHR records. Finally,
497 the program involved numerous components, precluding identification of prepotent elements.

498 In sum, this research suggests that a comprehensive health system-wide approach to
499 smoking treatment in primary care can effectively address common gaps in smoking treatment
500 delivery in primary care. This program increased the reach of cessation treatment in the adult
501 primary care population, especially amongst traditionally underserved groups, and led to
502 increased rates of cessation across the entire healthcare patient population. These results
503 encourage further research on similar comprehensive smoking treatment programs in primary
504 care that: are EHR enabled, use opt-out strategies for treatment offer, use aggressive outreach
505 efforts that involve personal contact with all individuals who smoke, and deploy health system
506 tobacco care specialists to offer and deliver telephonic treatment.

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Acknowledgements

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The authors thank Epic Systems Corp., Verona, Wisconsin, USA, for their assistance and

511

support in making necessary EHR enhancements that enabled the conduct of this research.

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Fig. 1. Schedule for the introduction of the CTIP in the stepped-wedge design. Each cohort comprised two different primary care clinics.

	Period 1	Period 2	Period 2	Period 4
	(Jan-Dec	(Jan-Jun	(Jul-Oct	(Nov 2018-
Cohort	2017)	2018)	2018)	Feb 2020)
1 (Clinics 1-2)	Baseline	Active	Active ^a	Active
2 (Clinics 3-4)	Baseline	Baseline	Active ^b	Active ^b
3 (Clinics 5-6)	Baseline	Baseline	Baseline	Active

^a Clinic 2 operations affected by remodeling, with some clinical teams relocated to other sites, Jul-Sep 2018.

^b Clinic 3 closed for repairs and renovation, with all clinical teams relocated to other sites, Aug 2018-Oct 2019.

Fig. 2. Expanded CONSORT diagram. Number (and percentage from the previous step) of patients retained in each step are displayed by study period and implementation status (active vs. inactive). Gray shaded boxes show rates of CTIP treatment activities post-implementation (periods 2-4) including: clinician advice to quit smoking (Advice), setting a target quit date (TQD), ordering smoking cessation medication (Meds), clinician referral to the Tobacco Cessation Outreach Specialist (TCOS), proactive calls from the TCOS (Called), and phone contact with the TCOS (Reached). Effectiveness was measured by conversion to former smoking status (Quit) for those on the smoking registry in the EHR in each period.

