Annals of Internal Medicine

Effectiveness of Integrating Suicide Care in Primary Care

Secondary Analysis of a Stepped-Wedge, Cluster Randomized Implementation Trial

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Background: Primary care encounters are common among patients at risk for suicide.

Objective: To evaluate the effectiveness of implementing population-based suicide care (SC) in primary care for suicide attempt prevention.

Design: Secondary analysis of a stepped-wedge, cluster randomized implementation trial. (ClinicalTrials.gov: NCT02675777)

Setting: 19 primary care practices within a large health care system in Washington State, randomly assigned launch dates.

Patients: Adult patients (aged ≥18 years) with primary care visits from January 2015 to July 2018.

Intervention: Practice facilitators, electronic medical record (EMR) clinical decision support, and performance monitoring supported implementation of depression screening, suicide risk assessment, and safety planning.

Measurements: Clinical practice and patient measures relied on EMR and insurance claims data to compare usual care (UC) and SC periods. Primary outcomes included documented safety planning after population-based screening and suicide risk assessment and suicide attempts or deaths (with self-harm intent) within 90 days of a visit. Mixed-effects logistic models

regressed binary outcome indicators on UC versus SC, adjusted for randomization stratification and calendar time, accounting for repeated outcomes from the same site. Monthly outcome rates (percentage per 10 000 patients) were estimated by applying marginal standardization.

Results: During UC, 255789 patients made 953402 primary care visits and 228255 patients made 615511 visits during the SC period. The rate of safety planning was higher in the SC group than in the UC group (38.3 vs. 32.8 per 10000 patients; rate difference, 5.5 [95% CI, 2.3 to 8.7]). Suicide attempts within 90 days were lower in the SC group than in the UC group (4.5 vs. 6.0 per 10000 patients; rate difference, -1.5 [CI, -2.6 to -0.4]).

Limitation: Suicide care was implemented in combination with care for depression and substance use.

Conclusion: Implementation of population-based SC concurrent with a substance use program resulted in a 25% reduction in the suicide attempt rate in the 90 days after primary care visits.

Primary Funding Source: National Institute of Mental Health.

Ann Intern Med. doi:10.7326/M24-0024 Annals.org For author, article, and disclosure information, see end of text. This article was published at Annals.org on 1 October 2024.

ore than 40% of persons who die by suicide see a primary care clinician in the month before death and more than 75% in the year before suicide death (1-5). Therefore, primary care teams may have important opportunities to engage at-risk patients in early intervention efforts to prevent suicide attempts and deaths. As suicide rates continue to increase, the urgency to improve identification of suicide risk has intensified over the past decade (6, 7). In 2012, the U.S. Surgeon General and the National Action Alliance for Suicide Prevention put out a "call to action," galvanizing health care systems in enacting innovative, system-wide suicide prevention approaches, like the Zero Suicide model (6, 8). Key functions of this model include suicide risk identification, followed by engagement in risk mitigation, evidence-based treatment, and supportive care transitions (8, 9).

Integration of suicide care (SC) practices in mental health specialty settings has shown positive outcomes. A large public mental health service in Australia showed a reduction in repeated suicide attempts among patients engaged in a suicide prevention pathway that included suicide risk screening and risk assessment and mitigation via collaborative safety planning–individualized warning signs, coping strategies, social contact, personal and professional support, and strategies for limiting access to lethal means (9-12). A large cross-sectional study of community-based mental health clinics in New York State found positive associations between observed reductions in suicide attempts and self-reported Zero Suicide practice fidelity, including screening, assessment, and safety planning (13). Most recently, a quasiexperimental, interrupted time series study among 6 large U.S. health care systems (serving more than 300 000 per month) showed population-level decreases

See also:

Web-Only Supplement

in suicide attempts and deaths after the implementation of a systematic SC pathway, including suicide risk screening, assessment, brief intervention, and behavioral health treatment (Ahmedani B, Penfold R, Frank C, et al. Zero Suicide model implementation is associated with reductions in suicide attempt and death rates. In preparation.) (14, 15). Relatedly, the national Recovery Engagement and Coordination for Health-Veterans Enhanced Treatment (REACH VET) program, designed to identify (via predictive analytics) and coordinate SC among at-risk veterans, has also shown increases in safety planning in combination with mental health care utilization and decreases in nonfatal suicide attempts (16-18).

Although these studies are encouraging, data on integration of SC practices in primary care settings are limited. Nonetheless, routine primary care increasingly includes population-based screening for depression, as recommended by the U.S. Preventive Services Task Force (19, 20). Depression questionnaires often include questions about suicidal thoughts, which can accurately help predict subsequent suicidal behavior (21-24). However, how primary care teams should respond when patients report frequent suicidal thoughts is unclear (25).

Therefore, the objective of this study was to analyze the outcomes of integrating SC in primary care, beginning with population-based screening for depression, followed by suicide risk assessment and collaborative safety planning. The findings from this study will provide vital evidence for health care teams considering how to respond to patient-reported suicidality during routine primary care encounters, as well as for organizational leaders considering the value of integrating clinical practices in primary care to support suicide prevention.

METHODS

Design Overview

This study is a secondary analysis of a steppedwedge, cluster randomized implementation trial (ClinicalTrials.gov: NCT02675777) (26, 27). The original trial was funded to evaluate the integration of alcohol-related care in primary care. However, at the request of care delivery leadership as previously described (26), population-based SC was implemented at the same time as care for substance use (alcohol, cannabis, and other drug use) as part of a behavioral health integration initiative (detailed below). Before this initiative, the health system had no population-based screening or systematic follow-up for these conditions in primary care. In preparation for this steppedwedge trial, implementation teams partnered with care delivery teams from 3 primary care practices (excluded from this analysis) to pilot the intervention (28-30). The Kaiser Permanente Institutional Review Board approved this study and waived informed consent because of minimal risks to the patients whose data were analyzed.

Setting and Patient Sample

The trial was done at Kaiser Permanente Washington, a large integrated health care system providing insurance coverage and care for approximately 700 000 persons.

Inclusion Criteria

Inclusion criteria were all adult patients (aged ≥18 years) with primary care visits between 1 January 2015 and 31 July 2018, approximately 1 year before the first sites implemented SC through the last wave of implementation (Figure 1).

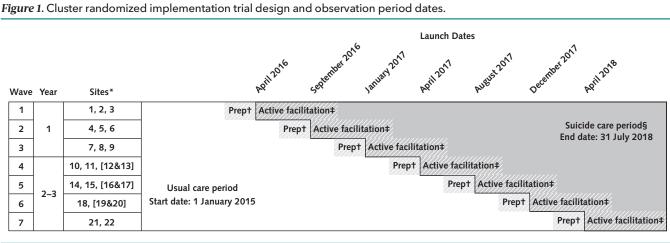
Exclusion Criteria

Exclusion criteria were visits by patients younger than 18 years because the intervention implementation was designed for adult patients. Visits to the 3 clinics that participated in the SC pilot were also excluded.

Randomization and Interventions

Twenty-two primary care practices were randomly assigned to implementation of SC in combination with substance use care in 7 mutually exclusive groups (that is, "waves") (Figure 1); 3 pairs of nearby practices were randomly assigned in pairs to support the logistics of practice facilitation (described below), resulting in 19 distinct primary care sites. As previously described (26, 27), randomization was stratified by year, with 9 sites randomly assigned to 3 implementation waves (3 sites per wave) in year 1, and 10 practices randomly assigned to 4 implementation waves (2 waves with 3 sites and 2 waves with 2 sites) in years 2 and 3. Year 1 sites were randomly assigned to waves on 22 January 2016, and year 2 and 3 sites were randomly assigned on 7 October 2016. In year 1, sites were randomly assigned to each wave with a probability of 0.333. In years 2 and 3, each site had the same probability of being assigned to each wave: 0.2 probability for wave 4 (restricted to have 2 sites) and 0.267 for waves 1 to 3. The random allocation sequences were generated by the original study biostatistician after all sites were identified (see the statistical analysis plan, available at Annals.org). Blinding was not possible due to the nature of the SC intervention.

The SC intervention (Figure 2) was designed to support implementation of population-based care for depression and suicidality, in combination with care for substance use (27, 29, 30). As previously described (26), this included administration of a 7-item annual screening, including the 2-item Patient Health Questionnaire (PHQ-2) for depression (31), the 3-item Alcohol Use Disorders Identification Test-Consumption (32, 33), a cannabis use frequency question (34), and a question about illegal drug or nonmedical use of prescription medications frequency. Symptom assessment using Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria "checklists" helped clinicians diagnose alcohol and drug use disorders (27, 29, 30, 35) (Supplement Figure 1, available at Annals.org). Depression symptom assessment followed when



Prep = preparation.

* Three pairs of nearby practices, indicated in brackets, were randomly assigned in pairs to support the logistics of practice facilitation

† Preparation phase: Practice facilitators conducted two 2-hour meetings with local implementation teams at each participating site. Meeting goals were to build team cohesiveness and engage team members in sharing how providing integrated care for depression, suicidality, and substance use will benefit their patients and support the organization's mission, as well as for practice facilitators to develop a deeper understanding of the clinic's mission, patients, staff, communication practices, and workflows. Weekly practice facilitator meetings with local implementation teams followed. Meeting goals were to iteratively adapt the core workflow to fit with the clinic's local culture, develop job aids and clinical tools, and develop communication plans for the rest of the primary care site personnel.

‡ Active facilitation phase: Started on the launch dates (randomly assigned) when electronic medical record-based clinical decision support tools began functioning. Practice facilitators began meeting weekly with the local implementation team for 3 mo, and then every other week meetings for the last month. These Plan-Do-Check-Adjust meetings use performance feedback data to help teams identify gaps in clinical care and test solutions. One meeting per month is replaced with a larger Plan-Do-Check-Adjust meeting with local and/or regional leaders.

§ Implemented in parallel with population-based care for depression and substance use.

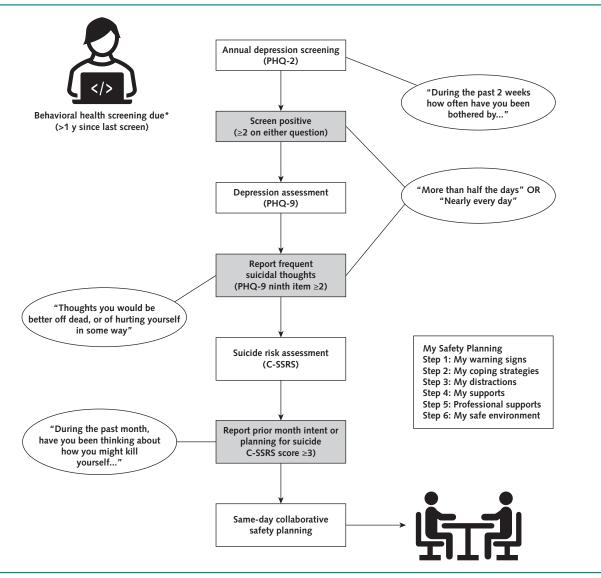
the PHQ-2 was positive (score of 2 or 3 on either item) using the remaining 7 items (Patient Health Questionnaire-9 [PHQ-9]) (36), which was followed by a self-administered version of the Columbia-Suicide Severity Rating Scale (C-SSRS) (37, 38) among patients who endorsed relatively frequent thoughts about self-harm (that is, score 2 to 3 on PHQ-9 item 9). When patients reported some level of prior month intent or planning for a suicide attempt on the C-SSRS, primary care clinicians were instructed to connect patients with designated members of the care team for same-day safety planning (9). Licensed independent clinical social workers, who had previously functioned as medical social workers doing case management, were trained to function as integrated mental health clinicians, specifically to prioritize engaging at-risk patients in safety planning, as well as provide short-term counseling and linkage to specialty mental health and substance use treatment (26, 29, 30).

Intervention implementation was supported by 3 key strategies (39): practice facilitation (40), electronic medical record (EMR) clinical decision support, and performance monitoring (that is, audit and provide feedback). Practice facilitators supported primary care implementation teams, including clinicians, medical assistants, registered nurses, and clinical social workers at each site, beginning 2 months before randomly assigned implementation dates ("preparation phase") and 4 months after implementation (6 months total) (26) (Figure 1). Facilitators conducted formal trainings and helped troubleshoot workflow concerns using Plan-Do-Check-Adjust cycles, often regarding the time and resources required to address depression, suicidality, and substance use in the context of a primary care visit (26-30). All sites participated in formal trainings; implementation team meeting adherence was not formally tracked, but attendance records (available for 65% of meetings) were used to estimate implementation costs (previously reported) (41). Electronic medical record-based clinical decision support and performance monitoring began on the launch dates (assigned at the time of randomization) at all study sites. Clinical decision support consisted of previsit screening and assessment (for example, PHQ and C-SSRS) reminders for primary care teams, as well as prompts to support suicide risk identification and risk mitigation during visits (Supplement Figure 1). Performance monitoring measured rates of screening and assessment for depression and suicidality (in combination with substance use) weekly for implementation teams at each site and monthly for health system leaders during the implementation period (Supplement Figure 2, available at Annals.org).

Suicide Care Outcomes and Covariates

Clinical process and patient outcomes relied on EMR and insurance claims data. All outcome measures were defined using a denominator of all patients who had a visit with a primary care clinician each month (consecutive 28-day periods), which was selected to mitigate issues with potential identification bias (42, 43).

Figure 2. Suicide care workflow.



PHQ-2 = Patient Health Questionnnaire-2; PHQ-9 = Patient Health Questionnnaire-9; C-SSRS = Columbia-Suicide Severity Rating Scale. * Seven questions included PHQ-2 (2 questions), Alcohol Use Disorders Identification Test-Consumption (3 questions), cannabis use frequency (1 question), and illegal drug use frequency (or nonmedical use of prescription medications) (1 question).

Intermediate Outcomes

Intermediate outcomes were rates of process and patient outcomes during primary care visits, including risk identification (via PHQ-2, PHQ-9, and C-SSRS), and new psychotherapy within 30, 60, and 90 days of the visit defined using CPT (Current Procedural Terminology) codes (44).

Primary Outcomes

Primary outcomes were safety planning after population-based screening and suicide risk assessment (process outcome) and suicide attempts (nonfatal) or deaths, with self-harm intent, within 90 days of a visit (patient outcome). Specifically, safety planning was measured among patients reporting some level of suicide attempt planning or intent in the past month (that is, answering "yes" to C-SSRS question 3 or higher), using distinctive phrases from EMR-based templates documented in the text of clinical notes (Supplement Table 1, available at Annals.org). Nonfatal suicide attempts within 90 days of a primary care visit were ascertained from EMR diagnostic codes derived from a systematic assessment of self-harm coding: International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes E950 through E958, International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) poisoning codes in the range T36 through T65 with modifiers indicating self-harm intent, ICD-10-CM code T14.91, and ICD-10-CM injury codes in the range X71 through X83 (Supplement Table 2, available at Annals.org) (45). Fatal suicide attempts were ascertained from Washington

State death records using ICD-10 underlying cause of death codes U03, X60 to X84, and Y87.0 (46), consistent with common recommendations (47, 48). Suicide deaths and nonfatal attempts were combined because the study sample size was not large enough to separately evaluate fatal suicide attempt outcomes. Ninety days was selected to maximize the likelihood of observing a suicide attempt soon after a health care visit based on prior research (1, 22), but suicide attempts (nonfatal and fatal) within 30 and 60 days of the primary care visit were also measured.

Covariates

Demographic and clinical characteristics associated with suicide attempts were used to describe the patient sample, including age; sex; race and ethnicity; insurance type; and diagnoses for substance use disorders, mental health conditions, and cancer in the prior year to the visit date, using ICD-9 and ICD-10 diagnosis codes.

Statistical Analyses

Descriptive analyses summarized the study flow consistent with guidelines for cluster randomized trials (49), and demographic and clinical characteristics of the patient population in the SC and usual care (UC) periods, using the first and last visit in the study periods. The UC period consisted of the time before the launch date, including the 2-month preparatory period (described earlier); the SC period consisted of the time after the launch date, including the 4-month period of active practice facilitation. Following prespecified analysis plans (see the statistical analysis plan), informed by the original trial focused on alcohol-related outcomes (27), primary analyses compared outcome rates during 1-month intervals in the UC and SC periods across all 19 sites. Specifically, binary indicators for whether a patient seen in primary care at a site during a particular month had an outcome in that month were modeled using mixed-effects logistic regression models (26). The models included an indicator for whether the site was in the UC or SC period in that month, adjusted for stratification (years 2 and 3 versus year 1) to account for possible differences in the outcome across the 2 years of sites, and calendar time (indicator variable for each 4 months) to allow for secular trends across time. In addition, site-level random effects accounted for correlation of persons from the same site. The marginal predicted probability of each outcome during the UC and SC periods as well as their difference (SC - UC) was estimated by applying marginal standardization (50) to the average over the observed covariate distribution and the estimated random effects (51). Ninety-five percent CIs were obtained assuming normality and applying the delta method. Monthly outcome rates are reported as percentages or per 10000 patients. Results were interpreted cautiously, so as not to overinterpret intermediate process outcome findings given multiple comparisons (52-54). All statistical

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models were estimated in R, version 4.0.2 (R Foundation), via RStudio, version 1.3.1056 (Posit Software), with the *Ime4*, *dfoptim*, and *optimx* packages. Marginal risks and risk differences along with corresponding 95% CIs were obtained in R, version 4.4.0, via RStudio, version 1.3.1056, using the *emmeans* package.

Statistical Power

Power calculations for the 2 primary outcomes of interest were done using a 2-sided test for 2 proportions in a stepped-wedge, cluster randomized design with a type I error rate of 0.05 and 19 sites across 7 study waves staggered at 4-month intervals (55). The intraclass correlation coefficient was assumed to be 0.001, and the number of visits at each clinic per month was set to 1690. Estimated power was greater than 80% (>90% in parentheses) to detect a change in suicide attempts in the 90 days after a visit of 2.18 per 10 000 visits (2.52 per 10 000 visits) and change in safety planning (with a recorded intervention indicator at the visit or in the following 14 days) of 4.77 per 10 000 visits (5.52 per 10 000 visits).

Sensitivity Analyses

Predefined sensitively analyses explored differential outcome ascertainment following diagnostic coding changes after the transition from ICD-9-CM to ICD-10-CM in October 2015 that occurred during the first year of the study period (see the statistical analysis plan) (56).

Supplemental Analyses

Proportions of patient visits identified at risk for suicide who also received alcohol care were summarized to describe overlap between SC and alcohol care workflows, as high-level patient-reported use is known to be associated with short-term risk for suicide attempt (57, 58), and brief alcohol counseling may have positively affected SC outcomes.

Role of the Funding Source

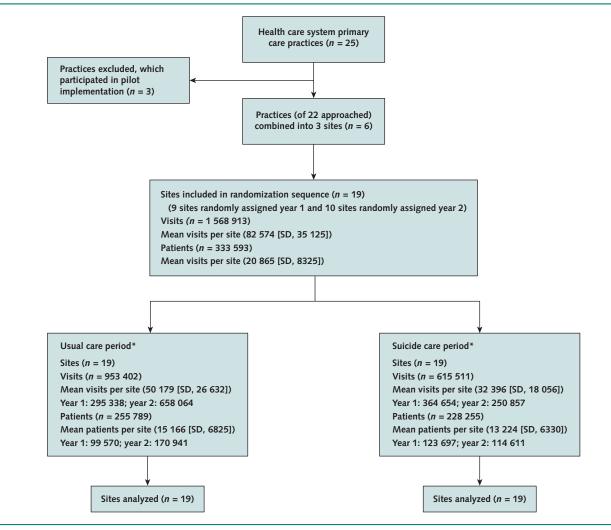
The National Institute of Mental Health had no role in the design or conduct of this study; collection, management, analysis, or interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication.

RESULTS

Sample Characteristics and Visits

During the study period, 333593 patients made 1568913 visits to participating primary care practices during the study period. Overall, 255789 and 228255 patients were seen during UC and SC intervention periods, respectively (**Figure 3**). Patient characteristics at the first visit during the UC and SC periods were overall similar (**Table 1**), with slightly lower rates of commercially insured patients in the SC period (61.0% and 56.4%, respectively) and higher private pay patients

Figure 3. Stepped-wedge implementation trial CONSORT flow diagram.



CONSORT = Consolidated Standards of Reporting Trials.

* Number of patients in both periods = 150451 (see the statistical analysis plan [available at Annals.org] for additional information about crossover).

(9.4% and 13.5%, respectively). Descriptive comparisons of demographic and clinical characteristics at the last visit in each period led to similar findings (**Supplement Table 3**, available at Annals.org). The median number of visits (total across UC and SC periods) for persons reporting frequent suicidal thoughts (during any visit) was 3 (IQR = 1 to 6) and for persons reporting no suicidal thoughts was 2 (IQR = 1 to 4).

Suicide Care and Suicide Attempts

Comparing the UC and SC periods, all intermediate screening and assessment process outcome rates were significantly higher in the SC period after adjustment for randomization stratification and calendar time (as prespecified) (Table 2). However, rates of new psychotherapy within 90 days of primary care visits were slightly lower during the SC versus the UC periods (by 8.5 encounters per 10 000 visits).

Nevertheless, our primary outcomes of rates of safety planning and documented suicide attempts

were more favorable during the SC than UC periods (Table 2). Rates of safety planning were significantly higher by 5.5 plans per 10 000 visits and documented suicide attempts were significantly lower in the 90 days after primary care visits by 1.5 events per 10 000 visits in the SC period. Sensitivity analyses exploring differential outcome ascertainment following diagnostic coding changes after the transition from ICD-9-CM to ICD-10-CM led to similar findings (Supplement Table 4, available at Annals.org).

Overlapping Care for Alcohol Use

Overall, 84.5% in the SC and 19.9% in the UC were screened for alcohol misuse via the Alcohol Use Disorders Identification Test-Consumption; 21.7% versus 19.9% screened positive, 0.67% versus 0.79% received an alcohol use disorder (AUD) diagnosis, and 0.51% and 0.14% received brief alcohol counseling, respectively. Supplement Table 5 (available at Annals.org)

Table 1. Demographic and Clinical Characteristics of the Patient Population, at the Time of the First Visit in Each Study Period

Characteristic	Usual Care (<i>n</i> = 255 789)	Suicide Care (<i>n</i> = 228 255)
Mean age (SD), y	49.3 (18.1)	50.2 (18.1)
Sex, n (%)*		
Female	149 561 (58.5)	135 414 (59.3)
Male	106 227 (41.5)	92839(40.7)
Dees and other sites in (9/)th		
Race and ethnicity, n (%)† American Indian or Alaskan Native	4502/1 0)	272/ (1 /)
American Indian or Alaskan Native Asian or Asian American	4583 (1.8)	3736 (1.6)
Black or African American	27 886 (10.9)	27 896 (12.2)
	17 076 (6.7) 15 239 (6.0)	14 575 (6.4)
Hispanic or Latinx	8224 (3.2)	13 647 (6.0) 7091 (3.1)
Multiple races Native Hawaijan or other Pacific Islander	3859 (1.5)	3279 (1.4)
Other race	10 137 (4.0)	9398 (4.1)
	183 620 (71.8)	160 354 (70.3)
White non-Hispanic/Latinx	11 574 (4.5)	12 329 (5.4)
No race or ethnicity recorded	11574 (4.5)	12 329 (3.4)
Needs interpreter, n (%)	7912 (3.1)	7848 (3.4)
Insurance type, <i>n</i> (%)		
Commercial	156019(61.0)	128 711 (56.4)
Medicaid	9267 (3.6)	7054 (3.1)
Medicare	58 093 (22.7)	54 559 (23.9)
Other	8350 (3.3)	7082 (3.1)
Private pay	24 060 (9.4)	30 849 (13.5)
i mate pay	21000(7.1)	00017(10.0)
Conditions, past year, n (%)‡		
Alcohol use disorder	4868 (1.9)	4045 (1.8)
Cannabis use disorder	1885 (0.7)	1701 (0.7)
Drug use disorder	1161 (0.5)	718 (0.3)
Opioid use disorder	1662 (0.6)	1489 (0.7)
Stimulant use disorder	488 (0.2)	482 (0.2)
Depression	43 358 (17.0)	40 087 (17.6)
Anxiety	32 666 (12.8)	32 420 (14.2)
Serious mental illness	5707 (2.2)	4265 (1.9)
Cancer	7266 (2.8)	7059 (3.1)

* Unknown sex: 1 patient in the usual care period and 2 patients in the suicide care period.

† Patient-reported race and ethnicity categories, including "other" category (i.e., patients self-identified as "other" in this category). "Multiple races," or multiracial, was not an option for patient self-report, but patients could report up to 5 races. Patients with multiple races or >1 race indicated were included in this category. Because patients could be included in multiple race and ethnicity categories, the sum of percentages across all racial and ethnic categories will be greater than 100%.

‡ All conditions in the year before each patients' initial primary care visit defined via International Classification of Diseases, Ninth Revision, and International Classification of Diseases, 10th Revision, diagnosis codes in the prior year. Alcohol, cannabis, drug, opioid, and stimulant use disorders include only active use disorders (excluding remission). Cancer includes any malignancy. Additional publicly available information regarding diagnosis variable definitions available here: https://github. com/MHResearchNetwork/Diagnosis-Codes.

presents the proportion of patient visits in the UC and SC groups that included overlapping care for alcohol use and suicidality as part of the behavioral health integration initiative.

DISCUSSION

This randomized stepped-wedge trial showed that the implementation of population-based suicide

ORIGINAL RESEARCH

care implemented concurrent with a substance use care program resulted in a 25% reduction in the suicide attempt rate in the 90 days after primary care visits (1.5 documented events per 10000 visits). This study suggests that the key functions of the Zero Suicide model (14), including risk identification via depression screening and suicide risk assessment followed by safety planning, effectively reduced risk for suicide attempt among adult primary care patients.

These findings provide evidence to support prevention and clinical care strategies implemented by primary care teams, and for organizational leaders considering primary care-based practices to support suicide prevention. Findings from this study are aligned with prior Zero Suicide model research, including an 8-year study in 6 U.S. health care systems showing reductions in suicide attempts and deaths after implementation among patients receiving mental health specialty care (Ahmedani B, Penfold R, Frank C, et al. Zero Suicide model implementation is associated with reductions in suicide attempt and death rates. In preparation.). These findings are also consistent with prior Zero Suicide evaluations among patients receiving care from communitybased mental health specialty care organizations in the United States (New York) and Australia (Queensland) (10, 11, 13), and efforts to identify and engage high-risk veterans in supportive suicide care, including safety planning and follow-up (16).

Clinical implications of these findings support use of primary care-based practices for suicide preventionspecifically, population-based suicide risk identification followed by collaborative safety planning. These findings also underscore the importance of using robust implementation strategies. Specifically, the combination of skilled practice facilitators, EMR-based clinical decision support, and routine performance monitoring supported this integration over a 2-year period (26, 27). This effort required resources and active participation of primary care leaders and teams, including registered nurses and integrated clinical social workers, who were responsible for engaging patients at risk for suicide in collaborative safety planning (28). Although this implementation required resources, particularly to support the practice facilitators, costs were well within the range for commonly used diagnostic assessments in primary care (41). Moreover, initiation of new psychotherapy seemed to decrease slightly in the SC period, suggesting that the intervention, including short-term counseling provided by clinical social workers, may have offset demand for mental health specialty care. Findings from the present study, therefore, also support and extend the empirical evidence for national and international efforts over the past 2 decades to integrate care for mental health and substance use in routine primary care (19, 59-62).

The study has several limitations. First, suicide care was implemented in combination with care for substance use disorders at the request of clinical leaders,

Outcomes	Usual Care (95% CI)*	Suicide Care (95% CI)*	Difference (95% CI)†
Intermediate process outcomes‡			
Screened for depression (PHQ-2)	2923.7 (2787.6 to 3059.8)	8278.8 (8184.5 to 8373.1)	5355.1 (5306.4 to 5403.8
Screened for suicidal ideation frequency (PHQ-9 question 9)	2594.7 (2445.0 to 2744.5)	3763.8 (3579.4 to 3948.1)	1169 (1124.5 to 1213.5)
Reported frequent suicidal ideation	199.9 (184.9 to 214.9)	224.9 (207.7 to 242.1)	25 (16.9 to 33.2)
Assessed for suicide risk (C-SSRS) (within 14 d)	146.2 (135.6 to 156.8)	189.6 (175.3 to 203.8)	43.4 (35.9 to 50.8)
Reported prior-month suicide attempt intent/planning	59.6 (53.9 to 65.3)	70.5 (63.5 to 77.5)	10.9 (6.5 to 15.3)
Safety plan documented (within 14 d) (primary outcome)	32.8 (29.7 to 35.8)	38.3 (34.6 to 41.9)	5.5 (2.3 to 8.7)
New psychotherapy within 30 d	111.4 (104.6 to 118.2)	106.9 (99.9 to 113.9)	-4.5 (-9.9 to 0.9)
New psychotherapy within 60 d	168.6 (158.2 to 179.0)	163.3 (152.6 to 174.0)	-5.3 (-12.5 to 1.9)
New psychotherapy within 90 d	216.0 (204.1 to 227.8)	207.5 (195.3 to 219.8)	-8.5 (-16.6 to -0.4)
Suicide attempt outcomes‡			
Within 30 d of visit	2.7 (2.2 to 3.2)	2.2 (1.7 to 2.8)	-0.5 (-1.3 to 0.4)
Within 60 d of visit	4.5 (3.8 to 5.2)	3.4 (2.7 to 4.1)	-1.1 (-2.1 to -0.1)
Within 90 d of visit (primary outcome)	6.0 (5.2 to 6.8)	4.5 (3.7 to 5.3)	-1.5 (-2.6 to -0.4)

PHQ-2 = Patient Health Questionnnaire-2; PHQ-9 = Patient Health Questionnnaire-9; C-SSRS = Columbia-Suicide Severity Rating Scale.

* Marginal predicted probabilities were estimated from the primary logistic mixed-effects model using marginal standardization and then multiplied by 10 000 to obtain monthly outcome rates per 10 000 patients seen in the cluster.

† Difference = suicide care – usual care absolute difference in marginal predicted rates.

‡ See the statistical analysis plan (available at Annals.org) for detailed outcome measure definitions. Primary outcomes included documented safety planning after population-based screening and suicide risk assessment and suicide attempts or deaths (with self-harm intent) within 90 d of a visit.

which resulted in modest but statistically significant increases in brief alcohol counseling and new AUD diagnoses (27). However, a low proportion of patient visits with documented suicide risk also included brief alcohol counseling, likely because safety planning was prioritized above addressing substance use. Nevertheless, independent effects of these practices cannot be estimated in this study-findings reflect the effectiveness of implementing suicide care in combination with care for substance use. Addressing alcohol use may have been impactful due to the high prevalence of co-occurring depression, suicidality, and AUDs (63, 64); additional research is needed to evaluate how care for AUDs may enhance care for suicidality. Second, SC implementation occurred before the COVID-19 pandemic, which permanently shifted how health care is delivered (65). Virtual screening and assessment are now commonplace; additional research is needed to define best practices for virtual warm handoffs and engagement in safety planning. Third, screening for suicidality is known to miss patients at risk for suicide who either may not be experiencing suicidal thoughts at the time of their visit or choose not to report suicidality due to fears of overreaction and loss of autonomy (66, 67). Additional research is needed on how to implement tools designed to augment risk identification practices relying on patient-reported suicidality, such as predictive analytics used in REACH VET and other settings (16, 68, 69). Fourth, the sample was not large enough to separately evaluate documented fatal and nonfatal suicide attempt outcomes and may not be generalizable to the U.S. population-the study population was older, with a higher proportion of women, Asian, Pacific Islander, White, and insured persons. Finally, time-varying confounding, even with adjustment for calendar time, is a particular limitation

of the stepped-wedge design. Effectiveness estimates in this study may be conservative given that suicide attempt rates seem to have been higher in the SC period than the UC period (70).

In summary, results from our stepped-wedge, cluster randomized implementation trial suggest that strategies to improve suicide risk identification and mitigation in primary care implemented alongside a substance care program are effective in reducing suicide attempts. Future work might consider examining both the independent and bundled effects of clinical practices supporting care for depression, suicidality, alcohol, cannabis, and other drug use.

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Acknowledgment: The authors acknowledge the following persons who contributed to the design and analysis of the original stepped-wedge cluster randomized evaluation trial, which supported and informed this secondary analysis: Jennifer F. Bobb, PhD; Carol E. Achtmeyer, ARNP, MN; Evette Ludman, PhD; Malia Oliver, BA; Ryan M. Caldeiro, MD; Rebecca Parrish, LICSW, MSW; Paula M. Lozano, MD, MPH; Gwen T. Lapham, PhD, MSW, MPH; Emily C. Williams, PhD, MPH; Joseph E. Glass, PhD, MSW; and Katharine A. Bradley, MD, MPH. In addition, the

authors acknowledge the patients who receive care from Kaiser Permanente Washington and staff who care for them; without them this research would not be possible.

Financial Support: By the National Institute of Mental Health (U01MH114087).

Disclosures: Disclosures can be viewed at www.acponline.org/ authors/icmje/ConflictOfInterestForms.do?msNum=M24-0024.

Data Sharing Statement: The authors have indicated they will not be sharing data. Additional context: In keeping with safeguards required by the Health Insurance Portability and Accountability Privacy and Security Rules, and special protections required by Title 42 of the Code of Federal Regulations Part 2, we are not able to make this data set publicly available due to risk of reidentification and breach of patient confidentiality. However, per our usual institutional research practices, we will assist third-party researchers in using the data sets from our analyses with obtaining institutional review board approval and access to appropriate data sets through data use agreement. Our goal for this project, consistent with the mission of our organization, is to support public domain research collaborations balanced with respect for our patients and the laws designed to protect their privacy.

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