ORIGINAL RESEARCH

Low-Intensity Intervention Supports Diabetes Registry Implementation: A Cluster-Randomized Trial in the Ambulatory Care Outcomes Research Network (ACORN)

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Background: **Previous research demonstrated that registries are effective for improving clinical guideline adherence for the care of patients with type 2 diabetes. However, registry implementation has typically relied on intensive support (such as practice facilitators) for practice change and care improvement.**

Objective: **To determine whether a remotely delivered, low-intensity organizational change intervention supports implementation and use of diabetes registries in primary care.**

Design: **Cluster-randomized controlled effectiveness trial of providing limited external support leveraging internal practice resources and problem-solving capacities for driving diabetes registry implementation in 32 practices in Virginia.**

Intervention: **All practices identified local implementation champions who participated in an in-person education session on the value and use of diabetes registries, while intervention practices were also paired with peer mentors and had access to a physician informaticist, who worked remotely to assist practices with implementation.**

Main Measures: **Practice champions reported progress on registry implementation milestone achievement, and reported practice-level organizational capacity by using a modified version of the Assessment of Chronic Illness Care (ACIC).**

Key Results: **Intervention practices were significantly more likely to have implemented a registry (44% vs 6%, $P = .04$) and to have achieved more implementation milestones (5.5 vs 2.6, $P < .0001$) than control practices. Baseline ACIC scores indicated room for organizational improvement with regard to chronic illness care (overall median, 6.4; range, 3.8 to 10.8) and clinical information systems use (median, 6.0; range, 0 to 11) with no significant differences between intervention and control practices.**

Conclusions: **Remotely provided guidance paired with limited in-person assistance can support rapid implementation of diabetes registries in typical primary care practices. (J Am Board Fam Med 2020;33:728–735.)**

Keywords: **Chronic Disease, Electronic Health Records, Guideline Adherence, Mentors, Type 2 Diabetes, Organizational Innovation, Practice-Based Research, Primary Health Care, Registries, Virginia**

Introduction

Primary care practices account for an estimated 42% of diabetes-related office visits in the United States, with most adults with type 2 diabetes mellitus (T2DM) seeking their care from primary care physicians.[1] However, previous studies have shown room for improvement in meeting diabetes care guidelines in these settings,[2] which, if realized, could have a

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large effect on reducing diabetes-related excess morbidity and mortality while helping to control the costs of diabetes. A key first step to ensure appropriate diabetes management in these settings is the identification of gaps in care with tools such as patient registries. Once these gaps are identified, primary care practices can focus additional attention on population health needs as well as efforts to address clinical inertia in treatment[3,4] to achieve improved control of glycemia, hypertension, and dyslipidemia.[5]

The chronic care model (CCM) suggests that a prepared, proactive team, when paired with an informed, activated patient with the knowledge, skills, and willingness to manage their own health, will lead to productive interactions and improved clinical outcomes in chronic illnesses, such as diabetes.[6,7] Recent research has demonstrated that even modest levels of CCM implementation in primary care are associated with improvements in diabetes care and that improvements focused on supporting continuity of care and treatment intensification in primary care settings are more effective than the use of more expensive outside resources, such as disease management programs.[8] A key tool for team-based chronic illness care is the use of population health tools, such as patient registries, which we define as a care delivery approach focused on integrating data systems into clinical work processes to track and improve care across all patients with diabetes in a specific practice. Effective use of patient registries can prepare the primary care team for productive interactions with patients and enable proactive efforts that improve patient care. For example, an effectively used diabetic patient registry can help identify patients in need of treatment intensification, plan diabetes visits, and identify patients who fail to make appropriate follow-up appointments. Practice-level interventions, including registries, are associated with improved diabetes care, but implementing such system-level changes can be difficult and costly, deterring private practices from implementing them.[9–13] Despite these known advantages, previous research has shown that fewer than half of primary care practices currently use registries for supporting their efforts to improve diabetes care for their patients.[14,15]

One potential barrier to keeping practices from developing registries is limited or inadequate implementation resources. External support from peers at practices that have successfully implemented diabetes registries, which are provided remotely, may help overcome this barrier. Supporting Practices to Adopt Registry-based Care (SPARC) is a cluster-randomized controlled trial designed to test the effectiveness of a low-intensity external support intervention to support diabetes registry implementation in primary care practices.[16] These registries, once enabled, will support our ultimate goal of improving health outcomes related to diabetes care and adherence to evidence-based diabetes management guidelines.

Methods

Participants and Setting

From February to November 2014, we recruited 32 primary care practices throughout the commonwealth of Virginia. Each participating practice was invited to join the Ambulatory Care Outcomes Research Network (ACORN), a practice-based research network of internal medicine and family medicine practices in the commonwealth of Virginia.[17] We excluded practices if they reported that they already used a disease registry to support care of patients with diabetes or if they did not have an electronic health record (EHR) system at the time of recruitment. Funding from the National Institute of Diabetes and Digestive and Kidney Diseases (R18DK091810; PI: JCC) provided all participating practices with an incentive payment of $1,500. Each practice was followed for 2 years. The institutional review boards (IRBs) of the Virginia Commonwealth University and the New England Institutional Review Board approved this study. This study was also registered as a trial (number NCT02318108).

Allocation

Stratified randomization was used to achieve balanced allocation between intervention and control groups across practice settings (rural or urban) and sizes (fewer than 3 clinicians and 3 or more clinicians). Practices were divided into 4 strata formed by the combination of these characteristics and were randomized with equal probability between intervention and control by using a random number generator. This was all done by the study biostatistician (RTS).

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Table 1. Type 2 Diabetes Mellitus Registry Implementation Milestones*

Milestone	Action	Description
1	Identify practice champions	The practice identifies two implementation champions (one lead, one alternate)
2	Set practice-level goals	Stakeholders identify goals, set achievement targets, and share goals with everyone in practice
3	Define content	Practice identifies specific measures to track
4	Build	Practice selects software and populates the registry
5	Plan for use	Registry management tasks defined and practice workflows assessed to integrate registry use into care
6	Implement workflow changes	Practice workflows modified to accommodate registry use and staff are trained in use
7	Begin use	Use of the registry goes live
8	Sustainable use	Ongoing maintenance and monitoring of the registry to ensure continued usefulness

*Each intervention practice established their own timeline for achieving these milestones.

Intervention

We have described the SPARC intervention in detail elsewhere[16]; the protocol is available on request. Briefly, practices identified local implementation champions who attended in-person education sessions (separately for intervention and control practices to avoid possible contamination) in March 2015 about the value and use of diabetes registries, primary care practice workflow redesign, and general principles of population-based care delivery for patients with chronic conditions. Practice champions reconvened approximately 15 months after the first meeting and shared challenges they faced during registry implementation, solutions they developed to meet those challenges, how their practices changed during registry implementation, and their plans to achieve subsequent milestones or sustain and expand existing registries. At the first education session, champions received a copy of the 2015 American Diabetes Association's Standards of Medical Care in Diabetes (including a rating of the strength of evidence for each of the recommended standards)[18] along with instruction in the use of a practice self-assessment tool designed for this study to assist practices in identifying registry goals and planning workflow changes. Champions from intervention practices also received a list of implementation milestones (see Table 1), met their assigned peer mentor and physician informaticist, and heard implementation success stories. Table 2 provides a brief review and comparison of support activities offered to control and intervention practices.

Note that the groups differed only in that intervention practices had access to peer mentors and the physician informaticist, all who were local practicing primary care clinicians. Mentors had successfully implemented and maintained a diabetes registry in their practices. The physician informaticist had expertise in primary care data systems and was available to guide practice champions through populating registry systems, ensuring structured data entry of specific fields needed to populate integrated registry systems, and discussing implementation options with EHR vendors. Peer mentors visited each intervention practice at least twice during the first study year. Between visits, peer mentors maintained mostly virtual contact with practice champions via telephone or e-mail to monitor implementation progress, offer assistance, and help practices connect with the physician informaticist as needed. The physician informaticists was present at the first champions meeting and was available through e-mail and telephone thereafter.

Data Collection

At each of the first education sessions, practice champions from both intervention and control practices completed a practice-level assessment of organizational capacity by using a version of the Assessment of Chronic Illness Care (ACIC) survey modified to focus on diabetes care in primary care settings.[19,20] The ACIC for primary care consists of 7 domains (organization of health care system, community linkages, self-management support, decision support, delivery system design, clinical information systems, and integration of CCM components), each with several questions. For each question, respondents indicated that their practice had limited (0 to 2), basic (3 to 5), good (6 to 8), or fully developed support in the assessed area (9 to 11). We calculated composite scores for each of the

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Table 2. Comparison of Support Activities Offered to Control and Intervention Practices

Support Activity	Received by Control Practice	Received by Intervention Practice
Identification of practice champions	X*	X
Support identifying T2DM patient population	X	X
Kick off 3-hour educational meeting/champion meeting	X	X
Basic instruction regarding creation and use of registries	X	X
Demonstration of potential software options for registry use	X	X
Provision of updated ADA guidelines for T2DM care	X	X
Tool to facilitate practice self-assessment for registry adoption	X	X
Document describing 8 milestones for registry adoption	X	X
Interim champion meeting 15 months after kick off	X	X
Connection to area clinician peer mentor (in person and via phone)		**X**
Access to area clinician informaticist for additional support		**X**

*X, activity offered.
ADA, American Diabetes Association; T2DM, type 2 diabetes mellitus.
Bold indicates support activities only provided to intervention practices.

7 domains by averaging responses within each domain and then calculated an overall ACIC score by averaging the domain scores. At the baseline meeting, practice champions completed a Practice Information Form detailing practice size and location.

Following the initial education session, 4 (of 32) practices dropped out of the study (1 in the intervention arm and 3 in the control arm). In the remaining 28 practices, we retrospectively reviewed the medical records of 100 randomly selected patients with T2DM and established baseline patient demographics and quality-of-care indicators by using aa article-based, structured audit instrument focusing on the 12 months before March 2015. If practices could not identify the requisite 100 patients diagnosed with T2DM, we reviewed all records of patients with this diagnosis. Reviewers documented the date and value for the most recent laboratory measurements of hemoglobin A1c, systolic blood pressure, diastolic blood pressure, low-density lipoprotein (LDL), high-density lipoprotein, and body mass index. To ensure the accuracy of the medical record reviews, a second reviewer examined 20% of the records. A threshold of greater than 85% agreement between first and second medical record review was established as sufficient. A review of these chart reviews revealed an agreement equal to our threshold. In addition, reviewers called each practice champion (in both intervention and control practices) once a month from the start of the study through August 2016 and asked a series of questions designed to assess milestone achievement and progress toward registry implementation. We designed the milestones, listed in Table 1, to be sequentially achievable so that practices could easily track their progress toward implementation.

Statistical Analysis

Practice-level analyses

We compared practice-level frequencies and percentages (location and size) between groups by using Fisher's exact test, used binary logistic regression to examine the effect of the intervention on registry implementation (defined as achievement of milestone 7 or 8, as a registry must be implemented before it can be used [step 7] or maintained [step 8]), and used binomial logistic regression to examine the effect of the intervention, practice size, and location on the percentage of milestones achieved. Using an intent-to-treat analysis, we used the last recorded milestone as the outcome measure for each practice; for those dropping out before any measurement was taken, we used a milestone value of zero. We report median ACIC scores (with minimum and maximum values) and used the Wilcoxon rank sum test to compare between groups.

Patient-level analyses

We summarized baseline patient-level data with means (with standard deviations) and frequencies (with percentages) both overall and for treatment and control groups, and we compared means for these measurements between by groups by using generalized linear mixed effect models with a fixed

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Table 3. Baseline Practice and Patient Characteristics

Baseline Characteristic	All Practices (n = 28)	Intervention Practices (n = 15)	Control Practices (n = 13)	*P* Value
Patients*				
Baseline, N	2,798	1,501	1,297	
Age in years, mean ± SD	63.5 ± 12.8	63.4 ± 12.9, N = 1,500	63.8 ± 12.7, N = 1,297	.7824
Women, % (N)	59 (1,636/2,795)	62 (933/1,499)	54 (703/1,295)	.0686
Body mass index, mean ± SD	33.8 ± 7.9	33.5 ± 7.7, N = 1,446	34.1 ± 8.1, N = 1,260	.1478
Hemoglobin A1c, mean ± SD, %	7.4 ± 1.8	7.4 ± 1.9, N = 1284	7.5 ± 1.8, N = 1117	.8969
Systolic BP, mean ± SD, mm Hg	131.2 ± 17.3	131.7 ± 17.7, N = 1,486	130.7 ± 17.0, N = 1,296	.6074
Diastolic BP, mean ± SD, mm Hg	76.5 ± 10.6	77.0 ± 10.7, N = 1,486	76.0 ± 10.4, N = 1,296	.3635
Low-density lipoprotein level, mean ± SD, mg/dL0.0465	95.6 ± 36.8	97.8 ± 39.5, N = 1,175	93.0 ± 33.3, N = 1,021	.0465
High-density lipoprotein level, mean ± SD, mg/dL	49.0 ± 15.9	50.2 ± 16.7, N = 1,194	47.6 ± 14.7, N = 1,029	.0015
Practices,†‡ % (n)				
Rural	69 (22/32)	63 (10/16)	75 (12/16)	.7043
<3 clinicians	50 (16/32)	56 (9/16)	44 (7/16)	.7244
Baseline practice-level ACIC score, median (min., max.); range 0 to 11†				
Organization of healthcare system	7.5 (4.5, 11.0)	7.3 (4.8, 11.0)	7.5 (4.5, 11.0)	.5366
Community linkages	6.5 (2.3, 11.0)	5.3 (2.3, 11.0)	7.5 (4.0, 8.8)	.2542
Self-management support	7.0 (3.0, 11.0)	6.8 (3.0, 11.0)	8.7 (4.0, 11.0)	.5371
Decision support	6.5 (4.3, 11.0)	6.5 (5.3, 11.0)	7.8 (4.3, 9.5)	.8773
Delivery system design	6.6 (2.8, 10.4)	5.9 (3.0, 10.4)	6.6 (2.8, 9.6)	.6888
Clinical information systems	6.0 (0, 11)	6.1 (0.0, 11.0)	6.0 (3.8, 10.3)	.5377
Integration of chronic care model	6.0 (2.2, 10.7)	6.1 (3.0, 10.7)	6.0 (2.2, 9.8)	.7815
Total ACIC score	6.4 (3.8, 10.8)	5.9 (4.0, 10.8)	(3.8, 9.4)	.4237

ACIC, Assessment of Chronic Illness Care; BP, blood pressure; SD, standard deviation.
*Patient information obtained from chart audits of electronic health records, with inclusion dates April 1, 2014 to March 31, 2015.
†32 practices enrolled and 4 dropped out; 28 provided baseline characteristics; 23 provided ACIC scores.
‡Practice Information Form completed by practice champions at first education meeting; ACIC surveys completed by practice champions after first education meeting.

treatment group indicator and a random practice effect to account for practice-level heterogeneity; patient was the unit of analysis for these comparisons.

We used SAS (version 9.4; Cary, NC, USA) FREQ, NPAR1WAY, and GLIMMIX procedures for these analyses. A 5% significance level was used for all analyses.

Sample size determination

The planned sample size for this project was determined based on the original patient-level primary outcome of comparing mean patient hemoglobin A1c between groups, which required 12 practices per group assuming 100 patients per practice, or 15 practices per group to allow for anticipated drop-out. The primary analysis reported in this manuscript (difference in rate of milestone achievement between intervention and control groups) is at the practice level and as such is relatively underpowered compared with the hemoglobin A1c analysis used to power the study. With 15 practices in each of 2 groups, the minimal detectable difference between groups with 80% power (at 5% significance) was a 53% difference in the rate of milestone achievement.

Results

We recruited 32 practices (16 in each group), of which dropped out (3 in the control group and 1 in the intervention group) before chart reviews were conducted. Two practices dropped out before the start date, 1 practice dropped out when the local practice champion left the practice, and another practice was forced to close due to an emergency.

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There were no significant differences between intervention and control practices with regard to size or location of practice, and the patients with diabetes evaluated across the 2 groups were similar with respect to demographic and severity of disease measures, with the exception that mean low-density lipoprotein and high-density lipoprotein cholesterol were somewhat lower in control group practices than in intervention practices. Baseline ACIC scores indicated significant room for organizational improvement across both groups of (median, 6.4; range, 3.8 to 10.8) and no significant differences between intervention and control practices of any of the 7 domains on the overall score (see Table 3).

In our intent-to-treat analysis, we found that, at follow up, intervention practices were more likely to have implemented a registry (44% vs 6%, $P = .04$) and to have achieved more implementation milestones than control practices (5.5 vs 2.6, $P < .0001$) (see Table 4). In addition, practices in urban locations achieved a significantly ($P = .0322$) higher number of milestones (4.9 ± 0.4) than rural practices (3.7 ± 0.3). We conducted sensitivity analyses excluding practices with incomplete data and our findings did not meaningfully change.

Table 4. Highest Registry Implementation Milestone Achieved by End of Year One

Milestone*	No. (%) of Intervention Practices†	No. (%) of Control Practices†	*P* Value
0	6 (1)	25 (4)	
1		31 (5)	
2			
3	19 (3)		
4	13 (2)	6 (1)	
5	13 (2)	31 (5)	
6	6 (1)		
7	6 (1)		
8	38 (6)	6 (1)	
Milestone 7 or 8	44 (7)	6 (1)	.0408
Milestones Achieved, mean ± SE	5.5 ± 0.3	2.6 ± 0.3	<.0001

*Milestones are defined in Table 1.
†n = 16 total each for intervention practices and control practices.
SE, standard error.

Discussion

Targeted and remotely provided external resources can support the implementation of diabetes registries in typical primary care practices. This is important because although Medicare and other payers use payment reform and technical assistance to drive practice change, many practices in which patients receive diabetes care might not have the administrative capacity to adapt to those changes on their own. Practices not part of large federally or payer-supported programs and demonstrations could benefit from care improvement options that do not require intensive external resource use. The remotely provided approach described here supports practices in drawing on local assets so that they can work collaboratively to implement registry adoption.

As most outpatient care for patients with diabetes continues to be provided in primary care settings, implementation and use of diabetes (and other chronic disease) registries in these settings has great potential for reducing the burden of this disease on patients, their families, and the health system.[21] Our implementation approach targets primary care practices rather than focusing specifically on patients. Our findings here lend support to prior research indicating that a systems-oriented approach can be particularly effective in improving care in rural settings.[22]

In a prior analysis of qualitative data collected to examine barriers to implementation in this study[23] staff in practices that did not complete the registry implementation process reported several common implementation barriers. Specifically, staff reported persistent and insurmountable challenges coordinating this work with their EHR vendor and a lack of sufficient staff resources to enter data or make changes to existing systems of care. Our own qualitative analysis of barriers and facilitators to implementation will follow in a separate manuscript. Based on our results from Table 4, it does seem that control practices had difficulty getting beyond initially identifying practice champions (milestone 1), and for those that made it past this initial stage, they had difficulty with planning for registry use (milestone 5). This may be because moving from identifying practice champions to formally setting goals (milestone 2) required substantially more time and deliberation than milestone 1. The second drop-off point, transitioning from planning (milestone 5) to implementing changes (milestone 6), also coincides with a substantially increased level of practice-level time and effort. Because we did not

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see similar drop-offs at these points among intervention practices, it may be that the peer support and other intervention resources helped these practices overcome this barrier.

Our study is limited in that we did not select the practices as a representative sample of primary care practices more broadly. For these practice-level analyses, we also have a relatively small sample size. However, the practices include a wide variety of practice types in terms of size and rural versus urban location. Furthermore, although the cluster-randomized design of our trial helps to ensure that the differences we observed between the 2 groups of practices are the result of the intervention, unobserved confounding variables could play a role in the results, and further studies of similar remotely provided implementation supports are needed. For example, we did not collect information on provider characteristics, practice type, or affiliation, which could have been relevant to understanding the success of the intervention. Because the implementation process was self-directed, we did not track practice use of many components of the control and intervention conditions, which is a limitation. However, we are able to note that all but 1 of the intervention practices were able to identify a champion, which was 1 of the 2 criteria that separated the control and intervention groups. Our chart review process relied on manual extraction of patient-level information from medical records. Although there is opportunity for error in this process, our validation efforts showed greater than 85% concordance for all data elements. In our intent-to-treat analysis, we used the last recorded measurement for practices that dropped out, meaning that we recorded zero milestones achieved for practices dropping out early. Although those practices could have achieved some milestones after dropping out, the prospects of doing so were unlikely, and we view this as a minor limitation. We suggested a single order of sequential and unambiguous implementation activities (Table 1) for practices to follow, which was designed so that practices could track their performance and successes. It is possible that other milestones or milestone orders could help promote implementation, although we leave their investigation to other researchers. Finally, because our focus is on practice-level implementation factors, we are unable to comment on how these changes affected patient-level health outcomes; our future analyses will explore these effects.

Our findings indicate that, with a relatively small amount of dedicated support resources offered remotely by physician peers, primary care practices can make self-directed process improvements connected to improved clinical outcomes for patients with diabetes.

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