
Adoption and Implementation of Mandated Diabetes Registries by Community Health Centers

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Background: Innovations adopted by healthcare organizations are often externally mandated. However, few studies examine how mandated innovations progress from adoption to sustained effective use. This study uses Rogers's model of organizational innovation to explore community health centers' (CHCs') mandated adoption and implementation of disease registries in the federal Health Disparities Collaborative (HDC).

Methods: Case studies were conducted on six CHCs in North Carolina participating in the HDC on type 2 diabetes mellitus. Data were collected from semistructured interviews with key staff, and from site-level and individual-level surveys.

Results: Although disease registry adoption and implementation were mandated, CHCs exercised prerogative in the timing of registry adoption and the functions emphasized. Executive and medical director involvement, often directly on the HDC teams, was the single most salient influence on adoption and implementation. Staff members' personal experience with diabetes also provided context and gave registries added significance. Participants lauded HDC's technique of small-scale, rapid-cycle change, but valued even more shared problem solving and peer learning among HDC teams. However, lack of cross-training, inadequate resources, and staff turnover posed serious threats to sustainability of the registries.

Conclusions: The present study illustrates the usefulness of Rogers's model for studying mandated innovation and highlights several key factors, including direct, personal involvement of organizational leadership, and shared problem solving and peer learning facilitated by the HDC. However, these six CHCs elected to participate early in the HDC, and may not be typical of North Carolina's remaining CHCs. Furthermore, most face important long-term challenges that threaten routinization.

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Introduction

A principal concern in health services research is to understand how innovations, such as practice guidelines or point-of-service diagnostic testing, progress from the decision to use them to their effective and sustained use.^{1–3} Frequently innovations are complex in that they require coordinated use by multiple individuals to achieve desired outcomes.⁴ Furthermore, many innovations in health care are mandated by external agents,⁵ such as state mandates of minimum ratios of nurses to patients⁶ or performance measures required by an accrediting agency.⁷ In mandated innovation, the decision to adopt an innovation

originates external to the organization charged with implementing it. This entails processes different from voluntary innovation,^{8–11} but little research has expressly examined how mandated innovation progresses in organizations.

The present study examines a complex innovation that is externally mandated: diabetes registries adopted by community health centers (CHCs) participating in the federal Health Disparities Collaborative (HDC). Rogers's model of organizational innovation⁵ is used as a conceptual framework to organize factors influencing adoption and implementation processes. This study also provides more detail than previously available of the assimilation of diabetes registries by HDC participants.

Background

In 1998, the United States Bureau of Primary Health Care, which conducts oversight of CHCs, launched the HDC to reduce disparities in care of patients with six priority conditions including type 2 diabetes mellitus (referred to in this report simply as "diabetes").¹² CHCs are not-for-profit clinics subsidized by the federal govern-

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Table 1. Five key registry functions promulgated by HDC

Innovation
An electronic disease registry, comprising software, training, and technical support provided by HDC
Purpose
To track data on patients with diabetes and processes of clinic care, to achieve systematic management of diabetes
Key functions
1. Identifying subsets of patients at high risk for complications of diabetes (e.g., patients with hyperlipidemia)
2. Creating lists of patients who need specific services (e.g., due for semiannual measure of hemoglobin A1c concentrations)
3. Developing a system for feedback to healthcare providers, such as reporting average concentrations of hemoglobin A1c for providers' patients along with overall clinic averages for concentrations (i.e., a benchmark)
4. Generating reminders for physicians (e.g., in advance of visits of patients due for referral to ophthalmologist for eye examination)
5. Generating reminders for patients (e.g., automatic mailings to patients due for physician visit for diabetes checkup)

HDC, Health Disparities Collaborative.

ment to provide health care to disadvantaged populations. HDC engages teams from CHCs in a collaborative learning process to implement Wagner's chronic care model,¹³ using the Institute for Healthcare Improvement's "breakthrough" method of rapid-cycle change.¹⁴ Every CHC must participate in at least one HDC project by 2006.¹⁵

One of the six components of the chronic care model is a clinical information system.¹³ Participating CHCs focus on one medical condition and must maintain a registry (or database) that is used to generate monthly and quarterly reports. Accordingly, HDC provides free registry software and technical support.¹⁵ However, an evaluation of CHCs in the Midwest that participate in HDC indicates that implementation of the registries is frequently difficult.¹⁶ The CHCs' adoption and implementation of diabetes registries as part of HDC provides an excellent opportunity to study how mandated innovation progresses.

Methods

Qualitative case studies were conducted at six CHCs.¹⁷ The case unit was the CHC implementing a diabetes registry through HDC. Although HDC entailed many mandated changes, the registry served as a **tracer innovation**, or common frame of reference for interviews and comparison of cases.¹⁸ Registries were selected after consultation with regional HDC staff, who identified five key registry functions promulgated by HDC (Table 1), providing a basis for assessing the extent of implementation.

Each HDC comprises two phases. Phase 1 is an intensive first year in which teams file monthly reports and attend three national or regional meetings to receive expert instruction

and share experiences among participants. Phase 2 is an indefinite follow-up period in which CHCs file quarterly reports and collaborate by e-mail and ad hoc meetings.

The sampling frame comprised eight federally qualified CHCs in North Carolina that had participated in phase 1 of the HDC on type 2 diabetes by 2003. Six agreed to participate. The remaining two CHCs did not respond after three attempts to recruit them and were assumed to decline. The two nonstudy CHCs participated in the HDC in 2000 and 2001, and were similar to the other six in number of clinics operated and geographic area, one being urban, the other rural.

Data Collection

Data were collected between May and September 2004. Medical directors completed an advance survey detailing staffing mix, registry functions, and key staff involved in implementation (Table 2). Information on adoption and implementation processes was collected from semistructured interviews with key staff (See Appendix A).

Interviews followed a three-part interview guide comprising 12 items. The first consisted of six questions covering the innovation adoption processes of agenda setting and matching.⁵ Agenda setting involves identifying problems and opportunities and deciding on their prioritization for action. Matching involves assessing the fit between problems or opportunities and an innovation. The second part of the interview guide comprised four questions covering the innovation implementation processes of restructuring/redefining and clarifying/routinizing. Restructuring/redefining involves the mutual adaptation of the innovation and organization to ensure that their structure and processes are congruent with one another. Clarifying/routinizing involves the integration (or not) of the innovation into standard organizational maintenance processes, such as performance measurement, personnel training, and budgeting. The third and final part of the interview guide comprised two questions about overall lessons learned and any issues missed by the interview team.

Questions were broad and open-ended to elicit diverse responses. For example, one adoption item asked, "Have you expanded the register beyond the original provider team and/or clinic? If so, what were some of the driving factors that led your practice to expand/not expand the register to other sites/teams?" One implementation item asked, "What key events took place to actually put the register into practice?" Follow-up questions then elicited details about who took specific decisions or actions, what they entailed, and how they occurred and when (See Appendix B).

One researcher conducted the interview while another took notes. Immediately following site visits, the research team reviewed their notes and entered them into a study database.¹⁹ Documents pertaining to the registry were also analyzed. These included templates for patient self-management goals, and encounter forms used to record information during patient encounters and then to update the registry.

After the interview, participants filled out a survey assessing five attributes of the registry based on Rogers's diffusion of innovations model⁵: (1) relative advantage, (2) compatibility, (3) complexity, (4) trialability, and (5) observability. For example, the survey asked, "To what extent is the registry easy for you to use?" (assessing complexity) and "To what extent is the registry better than what your clinic did before?" (relative advantage). The survey also assessed implementation out-

Table 2. Characteristics of six CHCs and diabetes registries in North Carolina participating in federal Health Disparities Collaborative for type 2 diabetes, 2004

	CHC 1	CHC 2	CHC 3	CHC 4	CHC 5	CHC 6
Participants interviewed	Medical director, director of patient services, ^a PA-C, lead RNs (2)	CEO, FNP, ^a RN, LPN	Medical director, nurse coordinator, ^a RN, clinical secretary	Physician, ^a PA-C, nutritionist, IT technician	Medical director, ^a social worker, CMA	Medical director, ^a laboratory director, medical records supervisor, LPN
CHC attributes						
Physician FTEs	6	2	2	6	9	4
Other clinical FTEs	22	5	7	19	1	5
Nonclinical FTEs	21	5	17	2	14	3
Urban/rural setting	Rural	Rural	Rural	Urban	Rural	Rural
Number of clinic sites	4	1	1	1	2	1
Registry attributes						
Current/original	PECS/CV-DEMS	PECS/PECS	PECS/PECS	PECS/Other	CV-DEMS/CV-DEMS	PECS/DEMS
Duration of implementation (years)	>2	1–2	1–2	>2	>2	>2

^aCHC's collaborative team leader.

CEO, chief executive officer; CHC, community health center; CMA, certified medical assistant; CV-DEMS, Cardiovascular/Diabetes Electronic Management System; DEMS, Diabetes Electronic Management System; FNP, family nurse practitioner; FTEs, full-time equivalents; IT, information technology; LPN, licensed practical nurse; PA-C, physician assistant-certified; PECS, patient electronic care system; RN, registered nurse.

comes in terms of the degree to which the registry was used to accomplish five key functions identified by HDC staff. Items were assessed on a 5-point Likert scale. The survey was developed to buttress interview data and its psychometric properties were not formally assessed (See Appendix C).

Data Analysis

Two researchers coded interview data using a shared codebook and reconciled differences. Coded data were abstracted into individual-level checklist matrices of themes represented by the codes, and subsequently were aggregated to the site level by using a set of explicit decision rules.²⁰ For example, in completing the site-level data displays (Tables 3 and 4), codes were based on at least two mentions of a particular theme by interview participants who, in principle, possessed pertinent knowledge. The analysis was completed from August through December 2004.

Results

The six CHCs varied in staffing, number of clinic sites, and duration of participation in HDC (Table 2). CHC 4 was urban, and the other five were in rural communities. All CHCs served large minority populations, including African Americans, Hispanics, and Native Americans. Estimates of diabetes prevalence at individual CHCs were not available, but public data suggest a prevalence of 7.9% for diagnosed diabetes at CHCs in North Carolina in 2003 (Uniform Data System, www.bphc.hrsa.gov/uds/data.htm). Three CHCs completed Phase 1 of HDC before 2001, and initially used different registry software,

Diabetes Electronic Management System or Cardiovascular and Diabetes Electronic Management System (U.S. Bureau of Primary Health Care, Washington DC, www.cpcpa.org/healthcollabs/documents/CVDEMS%20USER%20MANUAL.pdf). All sites except CHC 5 now use the most current software, Patient Electronic Care System (U.S. Bureau of Primary Health Care, Washington DC, www.cpcpa.org/healthcollabs/documents/PECS_Info_Packet.pdf) (Table 2).

Adoption

Agenda setting. Table 3 provides an overview of the factors that participants reported influencing two major phases of registry adoption: agenda setting and matching. All sites reported routine forums where the agenda was set for when to participate in HDC and how to use the registry. Forums included meetings of existing teams, such as diabetes management and clinical leadership teams. Teams for diabetes care and quality improvement were typically led by a physician, but included nursing and medical support staff. The process of identifying and assessing ideas for new practices was collective, with nursing and support staff often proposing ideas to physicians or medical directors, who then presented those ideas at team meetings. However, decision making was uniformly centralized. Typically, a medical director, chief executive, or executive team decided on practice changes, sometimes after consultation with a board of directors.

Table 3. Factors contributing to adoption of diabetes registries in six CHCs in North Carolina participating in federal HDC for type 2 diabetes, 1998–2004

	CHC 1	CHC 2	CHC 3	CHC 4	CHC 5	CHC 6
AGENDA SETTING^a						
Organizational attributes						
Routine forum	+	+	+	+	+	+
Nonphysician staff involvement	+	+	+	+	+	+
Decision process	+	+	+	+	+	+
Information sources						
Opinion leader	+	–	–	+	+	+
Published literature	+	–	–	+	–	+
Promulgated care guidelines	+	+	+	+	–	+
Research study of patients	–	–	–	+	+	–
Personal practice experience	+	+	+	+	+	+
Linking Agent^b	+	+	+	+	+	+
Conduit^c	+	+	+	+	+	+
MATCHING^d						
Motivation						
New evidence—external	+	–	+	+	+	+
New evidence—internal	+	+	–	+	+	+
Acceptable to physicians	–	–	–	+	+/-	+
Acceptable to staff	–	–	–	+/-	+	+
Effectiveness in practice	–	–	–	+	+/-	+
Role of patient	–	–	–	+/-	+/-	+/-
Regulatory issues	–	+	–	+	+/-	+
Federal HDC mandate	+	+	+	–	+/-	+/-
Resources						
Reimbursement available	+	–	–	–	–	–
Registry installation and use	–	–	–	–	+/-	–

^aAgenda setting is the process of identifying problems and opportunities and deciding on their priority for action.

^bA linking agent is a third-party individual or organization that links the resource system which produces an innovation (e.g., diabetes registry experts and software producers) and the user system that adopts, implements, and maintains the innovation (e.g., CHCs).

^cA conduit is a medium such as an education program, website, or pamphlet that links the resource system that produces an innovation and the user system that adopts and implements it.

^dMatching is the process of assessing the fit between problems or opportunities and an innovation.

+, factor present and favorable to registry adoption or implementation; –, factor absent or not favorable; +/-, factor present but neither favorable nor unfavorable; CHC, community health center; HDC, Health Disparities Collaborative.

The regional HDC staff members, who were largely drawn from state CHC associations, were the linking agents²¹ who helped provide CHCs with information and technical support for the registries. For example, an important linking agent at CHC 1 was the HDC team leader, who also served on the HDC regional staff. He was active in the state community health center association and was known informally as a registry expert. He was also a midlevel manager, which some research indicates affords an ideal mix of positional authority and frontline experience.²²

Matching

Perception of the degree to which the diabetes registry met the needs of the CHC depended on a range of factors (Table 3). CHC leadership cited “the literature,” national guidelines, and practice experience as evidence for the need for a registry. Physician and staff opinion was mixed but generally favored the registry. Several interview participants reported that colleagues were at times lax in using it, but only CHC 1 described a physician refusing to use the registry. Where staff acceptance was strongest, they frequently had a per-

sonal connection with diabetes. For example, staff at two CHCs had husbands with diabetes; one staff member noted that her husband was a CHC patient and would soon be entered in the registry.

You see a lot of your own family members coming in, and you want the best for your family. It’s a small community. [Colleague name] has been here a lot of years, and she knows everybody. The people here know everyone in the community, and they want the best for them.

—Participant at CHC 1

Prior experience with disease tracking or population-based care, such as community smoking cessation, increased self-assurance with the registry and expectations that it would ultimately improve care. For example, one CHC formed the HDC team from an existing team for diabetes care, which in turn was based on an intervention team that was highly successful in engaging patients who had human immunodeficiency virus (HIV) and improving their self-management habits.

Demand by patients for better or additional services for diabetes care was anticipated as a possible contributing

Table 4. Factors contributing to implementation of diabetes registries in six CHCs in North Carolina participating in federal Health Disparities Collaborative for type 2 diabetes, 1998–2004

	CHC 1	CHC 2	CHC 3	CHC 4	CHC 5	CHC 6
RESTRUCTURING/REDEFINING^a						
Policies/practices						
Planning	+	+	+/-	-	+	+
Staff involvement	+	+	+	-	+	+
Pilot testing	+	-	-	+	+	+
Training/education	+	+	+	-	+	-
Reward/recognition	-	-	-	+/-	+	+
Monitoring	+	-	+	+	+	+
Other facilitators/barriers						
Management support	+	+	+	+	+	+
Physician acceptance	+/-	-	-	+	+/-	+/-
Innovation champion(s)	+	+	+	+	+	+
Experience with innovation	-	+/-	-	+	-	-
Organization–innovation fit	-	-	-	+	+	+
Data/information systems	+/-	-	-	+	-	+/-
Equipment/space issues	-	-	-	+	-	-
Staffing levels and turnover	+	-	-	-	-	+/-
CLARIFYING/ROUTINIZATION^b						
Policy and procedure changes	+	+	+	+	+	+
Routine monitoring	+	-	-	+	+	-
Budgetary support	+/-	+/-	-	+	-	-
Personnel allocation	+/-	-	-	+/-	+/-	+
Training and education	+	-	-	-	-	+/-
Infrastructure for information technology	+	-	-	+	-	-

^aRedefining and restructuring involves the organization and the innovation adapting to one another in an effort to maximize the benefits of the innovation to the organization

^bClarifying and routinizing is the process by which the innovation, once it is implemented, either spreads beyond its base of first users to become an accepted part of organizational processes or it falls into disuse.

+, factor present and favorable to registry adoption or implementation; -, factor absent or not favorable; +/-, factor present but neither favorable nor unfavorable; CHC, community health center.

factor in the matching process, but no such evidence emerged. Asked about patients' input or influence in adoption of the registry, interview participants indicated that they played an important role insofar as patients' needs and the profound burden of diabetes on communities was the CHC staffs' central motivation, particularly at CHCs 4, 5, and 6. However, patients did not actively demand changes to diabetes care delivery.

Community health center leadership acknowledged that the federal HDC mandate drove adoption of the diabetes registry. Clerical and support staff, who did much of the data entry, and some nursing staff, who were among the intended users of registry data, generally recognized that the registry was being promoted by an external agency but seemed largely unaware of the federal mandate. Some thought it might be a recommendation of the Joint Commission on Accreditation of Healthcare Organizations. A few expressed skepticism about the benefit of the registry. One participant at CHC 5 reported, "I doubt that we would have done the collaborative [HDC] if it weren't mandated." The staff member later added that their CHC declined to participate in an HDC on HIV/AIDS because HDC staff were perceived as less knowledgeable than the CHC staff: "We know more about HIV than they do."

Even though free software, training, and technical support were provided, resources related to registry installation and use were barriers. The registry increased perceived workload and need for human resources to do data entry and extraction. While participants thought that registries improved quality of care, they did not believe registries improved efficiency or generated new revenues or resources. Although two CHCs used registry data to negotiate more favorable contracts with private ophthalmologists for their patients, these cost savings accrued to patients. This improved critical access to specialty care for patients, but did not mitigate the increased work burden on CHC staff.

Implementation

Redefining and restructuring. Table 4 provides an overview of the factors that participants at the six sites reported as influencing two major phases of registry implementation: redefining/restructuring and clarifying/routinizing. The HDC "collaborative" approach encouraged use of cross-disciplinary teams engaged in rapid, small-scale change, and provided technical training and shared problem solving among participants.

Participants at all CHCs lauded the shared problem solving. None mentioned the clinical and change-management experts who lectured at the national and regional HDC meetings, except one participant who noted that the peer learning was superior to what was learned from the experts.

By design, HDC called for pilot testing and regular monitoring, both widely hailed by participants, although used to varying degrees among the CHCs (Table 4). Processes for collecting data for the registry were the clearest beneficiary of pilot testing and evaluation. At all sites, multiple revisions were made to the complex standard encounter forms used to collect data on patients for the registry. As a result, most CHCs said that they significantly streamlined their forms to make them more user-friendly for the clinicians.

The CV-DEMS form is pretty busy, and the PECS form is even worse. Physicians would just flip the page over and write their notes on the back. . . . Now we have redesigned the form to strip it down to the bare minimum of things we need.

—Participant at CHC 5

Existing data and information systems were generally rudimentary. Only CHC 1 and 4 previously used information systems to collect clinical data, although not on diabetes. CHCs 2, 3, and 5 all kept their registry on a single computer, not on a network.

Participants reported few formal incentives, but did describe informal monitoring and feedback on registry implementation, which they took seriously. For example, at CHC 6 use of the registry was not a formal part of nurses' performance evaluations, but there was a perception that if nurses did not update the patient encounter forms for the registry, they would hear about it. Interview subjects had a positive view of performance feedback on clinical care, facilitated by the registry, although it initially highlighted substandard care. In particular, participants found it rewarding to track declining hemoglobin A1c concentrations—an indicator of reduced risk for complications of diabetes, such as amputation.

Support from management and the presence of an innovation champion (the latter frequently being a manager) were key facilitators (Table 4). All CHCs except CHC 4 reported involvement of medical or executive directors on HDC teams, and the executive director of CHC 4 was described as extremely supportive. Key barriers included insufficient human resources and staff turnover (Table 4). Only CHCs 1 and 6 added personnel expressly for data entry and maintenance of the registry. CHC 1, with two staff members dedicated to data entry, was the only CHC to report having data on all patients entered in the registry. But even at CHC 1, staff turnover threatened implementation because of the time required to achieve proficiency in use of the registry. Although training through HDC was effective, typically only one or two persons at a CHC became

proficient at both data entry and report generation. Only CHCs 1 and 6 cross-trained staff to ensure redundancy. Data on staff turnover were limited, but CHC 1 reported that 10 healthcare providers left in the previous year and only three of 28 clinical staff had been there more than 3 years.

Participants also identified time constraints as a major barrier to implementation, although there were also indications that the underlying issue was lack of routine. For example, a participant at CHC 1 suggested that data entry never became less time consuming, but did nonetheless become less onerous as it became routine.

Clarifying and routinizing. All CHCs reported one or more of six organizational changes (Table 4) that suggest an innovation is becoming institutionalized,^{22,23} but in each CHC, additional changes were needed. All CHCs adapted organizational policies to accommodate the registry, such as changing protocols for patient encounter and making modifications to employee training. Although all six CHCs monitored measures of clinical care, only three reported monitoring registry use after implementation. None assessed patient or provider satisfaction, implementation costs, or cost-effectiveness of the registry.

All sites reported needing additional funding or personnel (Table 4), while few changed budgetary or personnel allocations. With the exception of CHC 1 and CHC 4, infrastructure for information technology was weak. Technical support from HDC was perceived as inadequate. Participants reported that HDC technical support staff were often difficult to reach and that subordinate technical support staff were loath to make software fixes without the express consent of their supervisor. Consequently, technical glitches, albeit rare, could take days or weeks to remedy.

Implementation Effectiveness

Four of the six CHCs characterized their registries as "fully implemented" (Table 5). CHCs 1, 2, 3, and 5 all reported that 100% of anticipated personnel were using the diabetes registry, although only CHC 1 reported having entered 100% of their estimated population of patients with diabetes. Of the two CHCs reporting incomplete implementation, CHC 4 had an existing information technology system and was in the process of adopting a full-fledged electronic medical record system that would replace the registry. Both CHCs (CHC 6 being the other) reported high usage of some functions, such as feedback to healthcare providers.

Usage levels of the five key registry functions varied, although generating provider feedback was universally high (usually or always used) and, except for CHC 1, generating patient reminders was universally low (rarely or never used). CHCs reported as benefits of the registry evaluating staff performance, identifying areas

Table 5. Components of effectiveness of implementation of diabetes registries in six CHCs in North Carolina participating in federal Health Disparities Collaborative for type 2 diabetes, 2004

	CHC 1	CHC 2	CHC 3	CHC 4	CHC 5	CHC 6
Registry fully implemented^a	Yes	Yes	Yes	No	Yes	No
Number of current vs. expected users^a						
Total	38/38	5/5	6/6	2/11	24/24	3/6
Physicians	6/6	3/3	2/2	1/7	7/7	1/4
Physician e-tenders	8/8	1/1	2/2	1/2	1/1	—
Nurses	14/14	1/1	2/2	0/2	14/14	1/1
Other staff	10/10	0/0	0/0	0/0	2/2	1/1
Benefits realized^b	Benchmarks based on BPHC measures (5)	None identified	Management of hemoglobin A1c concentrations (4)	Identify patients with diabetes (5)	Measure progress of management of diabetes (4)	Assess clinical outcomes (3)
	Evaluation of staff performance (4)		Increased eye examinations (3)	Track care of patients with diabetes (3)	Determine number of patients with diabetes (4)	Improve quality of life for patients by improved tracking of checkpoints (3)
	PI measures for quality of clinical care (5)		Increased foot examinations (4)	Determine areas of diabetes care that need improvement (5)	Develop productivity tool to track foot and retinal examinations (4)	
	Clinical measures for grant (5)			Identify needs of patients with diabetes (2)		
				Track progress on meeting needs for education of patients with diabetes (1)		
Use of key registry functions^c						
Identify subsets of patients at high risk for complications of diabetes	5.0	3.7	3.7	4.3	4.0	3.5
Generate lists of patients needing specific services	4.8	3.7	3.7	3.5	4.0	3.3
Generate feedback to healthcare providers	4.3	4.0	4.0	5.0	4.3	4.0
Generate reminders to physicians	5.0	4.0	3.0	2.5	3.3	3.0
Generate reminders to patients	4.3	2.7	2.0	1.0	2.7	2.5

^aBased on advance survey sent to key contact at each site, either medical director or collaborative team leader.

^bBased on advance survey sent to key contact at each site, either medical director or collaborative team leader. Items were rated on Likert scale as follows: 5 = great improvement and 1 = no improvement.

^cBased on follow-up survey of all interview participants on degree to which diabetes registry is used for each of five anticipated key functions. Items were rated on Likert scale as follows: 5 = registry always used for function, and 1 = registry never used for function. Mean scores are reported.

BPHC, Bureau of Primary Health Care; CHC, community health center; PI, process improvement.

of care that needed improvement, and improving management of hemoglobin A1c concentrations.

Discussion

The purpose of this study was to examine the implementation of an externally mandated innovation using Rogers's model of organizational innovation⁵ as a conceptual framework. Generally, both favorable and unfavorable factors varied among the six CHCs across the adoption and implementation processes of agenda setting, matching, restructuring/redefining, and clarifying/routinizing. This is consistent with hypotheses advanced by Klein et al.²⁴ that organizational determinants of innovation implementation are equifinal, compensatory, and cumula-

tive, meaning that various combinations of factors may result in similar levels of innovation implementation in different organizations. This makes direct comparison among CHCs more difficult because with few exceptions (discussed below) there are not many patterns across CHCs to suggest that particular factors are necessary or sufficient conditions for implementation effectiveness. Meaningful comparison was also limited because there was relatively little variation in the outcome. Of the two CHCs reporting that their registries were not yet fully implemented, CHC 4 was in the process of adopting an electronic health record system that would render the registry obsolete, and CHC 6 (as well as CHC 4) still reported high levels of use of some key registry functions by some staff. Consequently, a certain level of effective

implementation was achieved by all CHCs, with CHC 1 providing the only exceptional case by virtue of having already entered their full known population of patients with diabetes.

In spite of these constraints, three factors were salient across the six CHCs and help indicate both what may be necessary conditions for effective registry implementation and what pitfalls remain. First, participants at all CHCs reported a high degree of support from executive and medical directors. In all but CHC 4 (where innovation effectiveness was arguably lowest), either the executive or medical director were personally involved with the HDC team, and at CHC 1 (where implementation effectiveness was arguably highest) the medical director was heavily involved and the HDC team leader was also on the HDC staff. Participants at all CHCs also identified “champions” that took a lead in promoting implementation of the registries, again with CHC 1 perhaps providing the exemplar champion. Thus, direct involvement of executive leadership and the emergence of a champion may be necessary conditions for effective implementation of mandated innovations.

Second, participants cited shared problem solving and peer learning among HDC teams as essential to their success. Some indicated that it was superior to support from HDC experts. This study did not explore what kinds of information exchanges were better from peers than experts, and it is not clear to what degree the difference was in the utility of the content or the way it was communicated. This study is also unable to comment on the relative contribution of the face-to-face regional meetings, telephone conferences, and web-based communication that the HDC uses to enable shared problem solving. Whatever the answers to these questions, participants judged the peer group support highly effective.

Third, although indicators of implementation were strong, there were some indicators that sustainability remains in jeopardy. Across the CHCs few changes were made in personnel allocation, budgetary support, or information system infrastructure. Specifically, there was inadequate cross-training, a lack of dedicated staff for data entry and registry maintenance, and information systems at most CHCs remained rudimentary. These pose the greatest obstacles to achieving long-term “routinization” of data entry and reporting. Unfortunately, while the registries may contribute to more effective diabetes care, they did not reduce workload for CHC staff or generate new revenues, either of which might help offset the need for additional personnel and budgetary support. These factors were not particular to any one CHC, but appear to be common conditions related to the current funding environment and social mission of this type of healthcare organization.

The present study builds on research conducted of CHCs in the Midwest.¹⁶ These authors also concluded that a frontline champion and senior management

support were key facilitators, and that inadequate staffing, time, technical support, and supplies presented barriers. However, this study provides much greater detail and examples, and places the findings within a conceptual framework.

There are two study limitations that warrant particular note. First, qualitative case study methodology is useful for providing rich descriptive details about how processes unfold and for presenting the perspectives of individuals involved, but provides a poor basis for quantifying comparisons or drawing externally generalizable conclusions. One particular issue is whether an “early adopter” bias exists. One should not be surprised if later HDC participants lack the uniformly strong leadership support and ultimate receptiveness among staff seen in these six CHCs that elected to participate in early HDC cohorts. Potential differences in later HDC participants provides an important topic for future research, because HDC itself is intended as a linking system or conduit to facilitate both matching, by reducing uncertainty about the registry, and restructuring, by providing technical training and shared problem solving among participants. It may be that these qualities attenuate the expected disparities between early and later HDC cohorts.

A second limitation is that qualitative case studies are at particular risk of participant reactivity (i.e., the presence of researchers influencing how participants answer questions) and of investigator-introduced bias in pursuing particular lines of questioning and interpreting results. To minimize the risk of bias, a semi-structured interview guide was used and at least two investigators participated in every interview. In addition, a common coding manual was used to code interview data and two investigators coded all data. Nevertheless, one cannot discount the possibility that interview participants were selective in what they reported—for example, emphasizing activities or outcomes that reflected well on them and their organizations. Similarly, the interview guide was developed from Rogers’s model, and this line of questioning may have simply failed to elicit key contributing factors not congruent with the model.

Conclusion

Although innovation is often initiated externally, limited research has examined the process of mandated change. The present study illustrates the usefulness of Rogers’s model as a conceptual framework and highlights key factors that may shape effective implementation. Notably, the six CHCs in North Carolina participating in HDC on diabetes between 1998 and 2004 benefited from the direct, personal involvement of organizational leadership and the efforts of registry champions. Additionally, they gained from shared problem solving and peer learning facilitated by HDC. However, these CHCs—although obligated to participate—elected to participate earlier

rather than later, and it remains to be seen whether their experience is typical of North Carolina's remaining CHCs. Furthermore, all six face important long-term challenges in terms of adequate personnel, cross-training, and information system infrastructure. These represent major constraints that are largely related to the overall organizational environment that all CHCs in North Carolina operate under.

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Appendix A

UNC/CDC Collaboratively Managing the Public's Health Project

Thank you for allowing us to visit [insert group practice name] on [insert date] to understand how your community health center has put into practice the diabetes registry. Please take a few minutes to answer the following questions. Your answers will help us make the most of our time together during our upcoming visit.

If you have questions regarding the questions on this survey, feel free to contact _____. **Please fax your completed survey to _____ at _____ by _____.** Thank you for your assistance.

1. Please describe the size and staffing mix of your practice. FTEs
- (a) Number of physician FTEs _____
 - (b) Number of physician assistant FTEs _____
 - (c) Number of nurse FTEs _____
 - (d) Number of non-clinical staff FTEs _____
 - (e) Number of other FTEs (please specify: _____) _____

2. What percentage of patients in your practice belong to managed care plans? (check one)
- < 5% 5-10% 11-25% 26-50% > 50% Unsure

3. In general, are decisions to adopt new strategies or protocols for diabetes patients made by individual physicians or by the practice as a whole? (check one)
- By individuals By the clinic as a whole By the CHC (if multiple clinics) Varies

4. Which registry did you initially implement? DEMS CVDEMS PECS Other

5. Which registry do you currently use? DEMS CVDEMS PECS Other

6. Did your clinic have clear expectations of what information you wanted to capture with the registry when you first began implementing it? Yes..... No..... Unsure

7. To the best of your memory, what clinical information did you intend to record in the registry, and what have you actually ended up recording?

	We intended to record:		We actually record:	
	Date of service	Level/ results	Date of service	Level/ results
a. glycosylated hemoglobin or hemoglobin A1c measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. cholesterol screening.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. microalbuminuria screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. blood pressure exams	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. dilated eye exams.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. foot exams.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. date of last PCP visit	<input type="checkbox"/>		<input type="checkbox"/>	
h. diabetes related dietary counseling	<input type="checkbox"/>		<input type="checkbox"/>	
i. date of last referral to DM related physician specialist.....	<input type="checkbox"/>		<input type="checkbox"/>	
j. influenza vaccines with appropriate indications.....	<input type="checkbox"/>		<input type="checkbox"/>	
k. smoking cessation counseling.....	<input type="checkbox"/>		<input type="checkbox"/>	
l. referrals to mental health providers	<input type="checkbox"/>		<input type="checkbox"/>	

Check all that apply

		We intended to record:	We actually record:
Check if "yes"	m. type of diabetes	<input type="checkbox"/>	<input type="checkbox"/>
	n. insulin use	<input type="checkbox"/>	<input type="checkbox"/>
	o. oral agent use	<input type="checkbox"/>	<input type="checkbox"/>
	p. ACE Inhibitor use	<input type="checkbox"/>	<input type="checkbox"/>

8. Did your clinic have clear expectations of what activities or functions you wanted to use the registry for? Yes
 No Unsure

9. Which of the following did you intend to use the registry for, and which have you actually ended up using?
(check all that apply)

- a. Identify high-risk subset of diabetic patients for targeted interventions Intended Actual
- b. Generate lists of patients needing specific services at specific times Intended Actual
- c. Generate and feedback provider reports on quality of care Intended Actual
- d. Generate physician reminders for diabetes-specific services, e.g., attaching the registry-generated patient encounter forms to charts Intended Actual
- e. Generate patient reminders (e.g., to produce mailings) Intended Actual
- f. Other: _____ Intended Actual

10. How long ago did your clinic decide to adopt the registry? *(check one)*
 Less than 1 year ago 1 – 2 years ago More than 2 years ago

11. Has [insert clinic name] fully implemented the registry? *(check one)*
 No → Expected date of full implementation _____ (month and year)
 Yes → Date of full implementation _____ (month and year)

12. What is the current extent of use of the registry at [insert clinic name]?

	Number of current users	Number of expected users
(a) Physician	_____	_____
(b) Physician assistants (or other physician extenders)	_____	_____
(c) Nurse	_____	_____
(d) Non-clinical staff	_____	_____

13. Please identify the benefits that [insert clinic name] expected from the registry and the extent to which the registry has delivered those benefits.

Not at All		To Some Extent		To a Great Extent	Don't Know or Too Early
1	2	3	4	5	DK

Expected Benefit <i>(please write-in as many benefits as you need)</i>	Extent to Which Benefit Delivered <i>(Please use the scale above)</i>					
(a) _____	1	2	3	4	5	DK
(b) _____	1	2	3	4	5	DK
(c) _____	1	2	3	4	5	DK
(d) _____	1	2	3	4	5	DK
(e) _____	1	2	3	4	5	DK

14. Has [insert clinic name] investigated how much it cost to implement the registry?

- No → Any reason why? _____
- Yes → What did you do? _____
- What did you find? _____

15. Has [insert clinic name] assessed the impact of the registry on key intended benefits such as patient outcomes, patient satisfaction, employee productivity, or the like?

- No → Any reason why? _____
- Yes → What did you do? _____
- What did you find? _____

During our visit we would like to complete 3-4 key informant interviews (each approximately 30 minutes long) with members of your practice who are instrumental in the adoption and/or implementation of the diabetes registry to help us learn more about how it has been adopted, implemented and institutionalized.

Please identify by name those staff members who have detailed knowledge about the diabetes registry. Please indicate if they are members of the Collaborative Team.

Administrative Staff

Name	Position	Collaborative Team
_____	_____	<input type="checkbox"/>
_____	_____	<input type="checkbox"/>
_____	_____	<input type="checkbox"/>
_____	_____	<input type="checkbox"/>

Clinical Staff (both physician and non-physician)

Name	Position	Collaborative Team
_____	_____	<input type="checkbox"/>
_____	_____	<input type="checkbox"/>
_____	_____	<input type="checkbox"/>
_____	_____	<input type="checkbox"/>

Thank You!

**Key Informant Interview for SIP 17-00
“A Model for Collaboratively Managing the Public’s Health”**

Adoption and Diffusion of Diabetes Register

1. In general how do you make decisions about the adoption of new technology or new practices for managing the care of your diabetes patients?
2. Could you tell me about the history of your decision to participate in the Health Disparities Collaborative on Diabetes and your adoption of the diabetes register? For example, what was the source of the idea and what were the key events that led to the decision to participate?

2(a): If this were not a mandated program, would you still do it?

(Probe about what determined the timing – early vs. later entry)

(Probe about overall impression of the Collaborative prior to their entry, e.g., did they know about other clinics that were already involved?)

3. Have you expanded the register beyond the original provider team and/or clinic?

3(a): What were some of the driving factors that led your practice to expand/not expand the register to other sites/teams?

NOTE TO INTERVIEWER. Did he or she mention... (check all that apply)

- New evidence
- Changes in physician expectations about state-of-the-art care?
- Changes in patient expectations about state-of-the-art care?

4. What types of information or evidence do you (or the group) consider when making decisions to change your practice in treating diabetes patients?

NOTE TO INTERVIEWER. Did he or she mention... (check all that apply)

- Recommendations by respected colleague or opinion leader
- Consensus of practice partners
- Reported research study in the literature (evidence based)
- Promulgated care guidelines by a respected source
- Research study of own patients
- Recommendation by professional organization
- Recommendation by managed care organization
- Own practice experience

5. What role, if any, did your patients play in your decision to expand/not expand the register to other provider teams/sites?

6. What were some concerns or anticipated problems that your practice considered in making the decision to expand/not expand the register to other provider teams/sites?

NOTE TO INTERVIEWER. Did he or she mention...

- Effectiveness of best practice under “real life” conditions?
- Cost of acquiring or implementing best practice?
- Ease of use?
- Acceptability by physicians and clinical staff?
- Acceptability by patients?
- Adequacy of existing infrastructure and human resources?
- Feasibility or ease of reimbursement?

Implementation of Strategies or Protocols to Improve Care

7. How did your practice implement the diabetes register? For example, what key events took place to actually put the register into practice?

7(a): Was there a formal process?

- How often do you do data entry?
- Do you have a process for quality control of register data?
- Did a dual system exist side-by-side with the register?
- Formal orientation of staff on-site?

8. What challenges arose in implementing the register?

8(a): How did availability of resources affect implementation?

- Time
- IT expertise
- Personnel, in terms of sufficient FTEs
- Computer/hardware resources
- Office space

8(b): Were any other important activities or initiatives taking place at the clinic at the same time?

9. What factors supported the implementation of the register?

9(a): How much did team members expect each other to use the register initially? And now?

9(b): Were specific policies or activities used to help implement the register?

- Training, incentives, or procedures to identify/reduce barriers
- Do you use the Patient-Encounter Forms?

9(c): What role did clinic or CHC management play?

- Clinic level
- CHC level
- Goodwill among staff?
- Cohesive staff?

9(d): How did the register fit with the way your staff feels care should be provided?

- Do they have clinical integration and a team-care approach?

Institutionalization of Strategies or Protocols for Improving Care

10. Is the register a routine and accepted part of the way diabetes care is done in your group practice?

a. If not, why do you think that is the case?

b. If so, what changes have had to make in your practice in order to make the register a routine and accepted part of the way diabetes care is done?

NOTE TO INTERVIEWER. Did he or she mention... (check all that apply)

- Changes in staffing
- Changes in training and user support
- Changes in information systems
- Changes in policies (including reward and compensation systems)
- Changes in relationships with other organizations

Lessons Learned

11. Did your practice learn any important lessons from its decision to adopt and implement the register? If so, does your organization [group] do things differently now?
12. Is there anything else that we ought to know about how your practice adopted and implemented the register? Did we miss anything?

Thank you. If we have any follow-up questions, may we contact you by e-mail or telephone?

Email address: _____

Telephone number: _____

Thank you again for your time and help.

INTERVIEWER _____

KEY INFORMANT _____

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Appendix C

Key Informant Interview

ID #: _____

Thinking about the electronic diabetes registry, please complete the following items by circling the best response. Please respond in terms of your own perceptions.

1. To what extent is the registry easy for you to use?

1 2 3 4 5 Don't Know/
Difficult Easy Not Applicable

2. To what extent is the registry better than what your clinic did before?

1 2 3 4 5 Don't Know/
Worse Better Not Applicable

3. To what extent is the registry compatible with values and experiences of the clinic?

1 2 3 4 5 Don't Know/
Incompatible Compatible Not Applicable

4. To what extent does the registry meet your needs?

1 2 3 4 5 Don't Know/
Does Not Meet Meets Needs Not Applicable
Needs

5. To what extent can the registry be experimented with on a limited or trial basis?

1 2 3 4 5 Don't Know/
With Difficulty Easily Not Applicable

Page 1 of 2

6. To what extent are the benefits of the registry visible to you?

1 2 3 4 5 Don't Know/
Not Visible Readily Visible Not Applicable

7. To what extent are the benefits of the strategy or intervention visible to patients?

1 2 3 4 5 Don't Know/
Not Visible Readily Visible Not Applicable

Please indicate how frequently the diabetes registry is used for the following purposes.

(Please circle one response for each.)

	Never	Sometimes	Always	Don't Know		
a. Identify high-risk subset of diabetic patients for targeted interventions	1	2	3	4	5	99
b. Generate lists of patients needing specific services at specific times	1	2	3	4	5	99
c. Generate and feedback provider reports on quality of care	1	2	3	4	5	99
d. Generate physician reminders for diabetes-specific services, e.g., patient-encounter forms	1	2	3	4	5	99
e. Generate patient reminders, e.g., mailings	1	2	3	4	5	99
f. Other: _____	1	2	3	4	5	99

Please answer the following questions regarding the climate of your group practice.

	Strongly Disagree	Disagree	Neither Disagree Nor Agree	Agree	Don't Know
Innovation is encouraged without fear of punishment if the innovation does not work	1	2	3	4	5
Creativity is rewarded	1	2	3	4	5
Physicians are receptive to new ways of providing care	1	2	3	4	5
Nurses are receptive to new ways of providing care	1	2	3	4	5
Managers are receptive to new ways of providing care	1	2	3	4	5
Employees are receptive to new ways of providing care	1	2	3	4	5
Employees are given training when new ways of providing care are introduced	1	2	3	4	5
New ways of providing care are encouraged	1	2	3	4	5

Thank You!