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Collaborative Development of a Randomized Study to Adapt a Diabetes Quality Improvement Initiative for Federally Qualified Health Centers

Rachel Gold, PhD, MPH,
Assistant Investigator at Kaiser Permanente Northwest Center for Health Research in Portland Oregon

John Muench, MD,
Oregon Health and Science University (OHSU) Richmond Clinic and is Director of Behavioral Health in the OHSU Department of Family Medicine

Christian Hill, MD, MPH,
Lead Clinician at the Virginia Garcia Memorial Health Center in Beaverton, Oregon

Ann Turner, MD,
Co-Medical Director, Virginia Garcia Memorial Health Center

Meena Mital, MD,
Assistant Medical Director of the Multnomah County Health Department in Portland, Oregon

Christina Milano, MD,
OHSU Richmond Clinic

Amit Shah, MD,
Medical Director of the Multnomah County Health Department

Christine Nelson, PhD, RN,
Senior research associate at OCHIN and Affiliate Instructor, OHSU Department of Family Medicine

Jennifer E. DeVoe, MD, DPhil, and
Associate Professor in the OHSU Department of Family Medicine and Research Director, OCHIN

Gregory A. Nichols, PhD
Investigator at the Kaiser Permanente Northwest Center for Health Research

Summary

This case study describes how we are translating a diabetes care quality improvement initiative from an insured (HMO) setting into federally qualified health centers (FQHCs). We outline the innovative collaborative processes whereby researchers and FQHC providers adapted this initiative, which includes health information technology tools, to meet the FQHCs' needs.

Keywords

Translational research; practice-based research; quality improvement; electronic health record

Please address correspondence to: Dr. Gold at Kaiser Permanente Northwest Center for Health Research; 3800 N. Interstate Avenue; Portland, OR 97227; (503) 528-3902; rachel.gold@kpchr.org.

Many quality improvement (QI) strategies that use health information technology (HIT) have been shown to improve care quality in clinical settings with insured populations.[1–8] Strategies that use electronic health records (EHRs), such as clinical decision support and panel management tools, show increasing promise as EHRs are more commonly used.[9] However, HIT-based QI initiatives proven effective in private care systems are rarely disseminated beyond such settings. Thus, federally qualified health centers (FQHCs) and other settings that provide care to underserved, underinsured, and socioeconomically vulnerable patient populations often have not benefited from these evidence-based QI strategies. This dearth of dissemination is a missed opportunity for sharing HIT tools and resources across settings, and potentially for addressing socioeconomic disparities in care quality and health outcomes.[10–13]

There are several explanations of why HIT-based QI initiatives, proven effective in private care systems, are rarely disseminated to FQHCs. For example, until recently few FQHCs had the HIT resources needed to support such tools. Others did not have the institutional resources needed to conduct the adaptation, testing, and evaluation required to implement QI tools in settings different from those in which they were developed. Such testing is critical before FQHCs can adopt and implement HIT-based QI strategies, because FQHCs differ from private care settings in many ways, including different populations, care philosophies, staffing structures, standards of care, availability of ancillary services, and payment structure. Because of these differences, it cannot be assumed that QI programs developed in private or integrated care settings can be implemented in FQHCs through similar processes, nor that these strategies, once implemented, will be equally effective in FQHCs. Understanding how QI strategies can be effectively implemented into FQHCs requires *practice-based research*—evaluations conducted in partnership with providers from the new care settings.

This Report from the Field describes one such researcher-clinician collaboration in a study of the translation and implementation of a diabetes care QI initiative, originally developed and tested in the Kaiser Permanente (KP) integrated care setting of insured patients, into 12 FQHCs in Oregon. The study is a partnership between primary care clinicians from the Safety Net West Practice-based Research Network (PBRN), and academic researchers from the KP Northwest Center for Health Research and the Oregon Health & Science University. It is supported by a National Institutes of Health/National Heart, Lung and Blood Institute R18 research grant, awarded in 2010 (1R18HL095481). We describe the collaborative processes used in designing and initiating the study, including how we worked together in our first study year to adapt the original QI initiative to meet the needs of the participant FQHCs.

The A.L.L. Diabetes Quality Improvement Initiative at Kaiser Permanente

The Kaiser Permanente (KP) QI initiative being adapted for implementation in FQHCs is called the A.L.L. (Aspirin, Lisinopril, Lovastatin) Initiative. It was designed at the Care Management Institute, KP's national center for QI development, to ensure that patients with diabetes who, according to current evidence, are indicated for aspirin, statins, and angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), are taking these medications. This initiative was developed to be efficient, low-cost, and minimally disruptive to clinic workflow, while having the greatest impact on health outcomes among people with diabetes. As implemented at KP nationally starting in 2003, the initiative includes electronic reminders for care providers, tailored panel management tools, and targeted outreach to patients.[14,15] At Kaiser Permanente North-west, the EHR-based functions supporting the A.L.L. Initiative are integrated into KP's Panel Support Tool, which includes two main functions: point-of-care summaries of patient data, with

highlighted 'care gaps' and suggested actions, and a 'panel view' panel management tool that supports targeted outreach and flexible reporting.[1,2] For images of these tools and more information, see Zhou et al. 2011[1] and Feldstein et al. 2010.[2]

An internal review estimated that implementation of the initiative was associated with a greater than 60% reduction in heart attacks and strokes among KP patients with diabetes; another study showed a 24% reduction in myocardial infarctions, and a 62% reduction in the relative incidence of serious infarctions, among 46,000 KP members.[14–16] As a result of these achievements, the A.L.L. Initiative won the prestigious national James A. Vohs award for care quality.[15]

Our community-based QI study: Setting and data sources

Our team of researchers and physicians received federal funding to evaluate the implementation of the A.L.L. initiative in 12 FQHCs in the Portland, Oregon metropolitan area. These FQHCs are all members of OCHIN, a 501(c)(3) collaboration of safety-net clinics, which includes most of the FQHCs in Oregon as well as clinics from many other states; OCHIN provides a comprehensive Epic© EHR infrastructure for its member clinics. Clinics in OCHIN share this linked EHR, and patients have a single health record number across all sites. The EHR data, including both practice management data and a full electronic medical record, are stored centrally at OCHIN. Changes to the EHR are implemented centrally, and the data are regularly cleaned and validated, and maintained in OCHIN's central repository. Electronic searches of the OCHIN data are possible both directly and through Solutions™, a sophisticated panel management tool. Solutions pulls data from multiple sites across the EHR including practice management data, the medical record, laboratory test results, prescriptions, and other orders. These data are then presented in an aggregated form, with multiple filtering and sorting options and a wide range of roll-up options for grouping (e.g., by provider panel, clinic, and service area/clinic group).

In addition to OCHIN's powerful data resource, this project was further enabled by the existence of Safety Net West, a PBRN which was registered with the Agency for Healthcare Research and Quality in 2007.[17] Members of the PBRN include clinicians from OCHIN member clinics and academic researchers. The trust built between individuals from these groups, many of whom have met monthly since 2005, was essential to the successful conception and development of this project.

Our community-based QI study: Design and study components

The first phase of the study was the adaptation of the QI tools and strategies, primarily conducted between September 2010 and August 2011, with additional adaptations implemented as needed throughout the study period. Through the collaborative process described below, we developed QI tools broadly modeled after those used at KP, but adapted for implementation in the FQHCs (Box 1). We randomized six clinics to *early implementation* and six to *late implementation*. The adapted QI intervention was launched in September 2011 in the six early clinics; we implemented the tools in the six late FQHCs in September 2012. The final phase of the study will involve a mixed-methods evaluation of the implementation process and of the intervention's effectiveness, reach and impact.

Our community-based QI study: The clinician-researcher collaborative process

Development of the research protocol

From its inception, this project has been driven by researcher-clinician collaboration (Box 2). The idea for the project was conceived at a PBRN meeting when an FQHC physician suggested adapting the well-respected KP A.L.L. Initiative for use in FQHCs and studying the feasibility of such dissemination. Researchers worked with clinicians from the 12 study clinics to develop the proposed work and study design. The FQHC clinicians provided insight into the clinics' existing diabetes care processes, and suggestions for how to make the proposed work amenable to the clinics' workflows. Clinicians from each service area (clinic group) volunteered to be champions of the project. The research team led the writing of the proposal and navigation of the NIH submission process, consulted with the KP leaders who developed the original initiative, identified and recruited other investigators with diabetes expertise, and fine-tuned the proposed methods.

Development of the study tools

After the project was funded in 2010, the researcher-clinician collaborators began a multi-step process to adapt the A.L.L. Initiative for implementation into the study clinics.[18] We started with a review of the components of the initiative as implemented at KP, a lengthy discussion of which of these elements could fit into the study clinics' workflows and organizational culture, and what additional elements would be helpful. The study FQHCs wanted the same *overall functions* as those of the KP tools—e.g., flagging patients in need at the point of care, and supporting targeted outreach. To meet this need, the panel support tool functions were re-created in an adapted form using OCHIN's Solutions panel management tool, and the automated, EHR-based clinician reminder tool, based on the same Epic© functionality as KP's, was also adapted.

However, substantial revision was often required for the tools' *specific content*. To that end, we engaged in a highly iterative process of specifying every component of the adapted QI initiative to meet the clinics' needs. This included making collaborative decisions about factors such as inclusion criteria (i.e., which people would be considered indicated for statins and/or ACE-Inhibitors/ARBs, and thus would trigger the best practice alert, and be identified in the panel support tools); the content of the patient education materials; and the content of the best practice alert. For example, because the FQHCs' standards of care differ from KP's, the definition of which patients were considered 'indicated' for the medications was revised to target not just patients with DM at especially high risk of CVD (as at KP) but any adult patients with DM, and language was added to the BPA to alert providers if the patient was a woman of childbearing age, regardless of pregnancy status. The study clinics' outreach workflows differed from KP's, so the panel management tools' content was revised substantially to better fit these workflows.

Through this process, we built a 'menu' of tools to support the QI initiative, and each clinic was free to choose which tools to integrate into their workflow. This 'menu' includes: I. Automated panel management tools that identify (a) patients scheduled to be seen the next day who appear to be 'missing' one of the indicated medications; (b) patients who have not had a visit in the last 3–12 months and appear to be missing one of the medications; and (c) patients who recently received a prescription and might benefit from a follow-up call. II. Automated 'best practice alerts' that fire at the start of encounters with patients who are missing an indicated medication. III. Pre-programmed order sets that enable quick prescribing. IV. Patient education materials including handouts, exam room posters, and pre-set after-visit summary text to accompany prescribed medications. V. Staff training

materials to orient clinic staff to these tools. We plan to iteratively refine the tools throughout the study, to allow ongoing adaptation of the tools targeting the clinics' specific needs.

The researchers' role in this process involved: 1) facilitating discussions about creating the tools; 2) working with OCHIN's programming staff to determine the feasibility of the desired elements of the intervention; 3) reporting back to the clinic teams and brain-storming about how to create the desired tools within the limitations of the functional abilities of the EHR and Solutions tools; 4) providing first drafts of patient education materials, coordinating the editing process, producing the required materials; and 5) overseeing the IRB and other legal processes. Throughout the process of developing and pilot testing the electronic tools, communication between the programmers and clinic staff was facilitated by designated research staff liaisons.

As of December 2011, all aspects of the adapted QI initiative had been implemented at the six early clinics. In the next phase, the research team will continue to meet regularly with clinic staff, including Site Coordinators hired to oversee implementation of the intervention. The research team will also work with OCHIN's data managers to regularly abstract EHR data related to the study. These ongoing data analyses will be presented to the clinics monthly, to show the clinics' progress over time in increasing the proportion of patients with active prescriptions for the indicated medications, and to quantify the use of the QI tools. The study sites report that they are generally happy with the tools and the process through which the tools were adapted. Preliminary reports suggest that many of the tools are being used regularly, and are positively impacting the percentage of patients taking the indicated medications.

Lessons learned

The most important lesson learned thus far was that EHR-based QI tools developed in private care settings *can* feasibly be adapted to FQHCs through researcher-clinician partnership. Researchers seeking to conduct similar work should solicit clinician input in every step of study design and implementation; further, this complex work often impacts clinic workflows, and so may have a greater chance of success if implemented by established, trusting collaborators. Certain challenges should also be anticipated. For example, providers may be skeptical about suggested changes to care standards and workflows, especially if the changes are perceived to be 'dictated' by the original QI developers. A flexible, iterative adaptation process is needed to assure providers that the QI tools truly meet their needs; in our study, despite extensive revisions and multiple quality checks conducted in response to provider feedback, we still face skepticism among some FQHC staff regarding the accuracy of the adapted tools.

Implications and conclusion

There is great potential for implementing and disseminating established QI initiatives into FQHCs and other settings where underserved populations receive care. Previous research has shown the need for adapting interventions when translating them between practice settings.[18] This innovative project is a model of how practice-based research networks and academic-community partnerships can facilitate and evaluate such efforts, and demonstrates how researchers are working with primary care providers to bridge public health and primary care quality improvement, using state-of-the-art EHR-based tools. For the participating clinics, this process has demonstrated how involvement and collaboration in research can lead to improved care. This case study also highlights the importance of researcher-clinician collaboration in every step of the process to ensure successful adaptation and translation of established QI initiatives to meet the unique needs of FQHCs.

Notes

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Box 1

ELEMENTS OF THE ADAPTED QUALITY IMPROVEMENT INTERVENTION

Tool	Function	Purpose	Location
Automated panel management tools	Inreach	Identify patients on the day's schedule who are indicated for, but not actively taking, statins or ACE-inhibitors/ARBs.	Solutions PST
	Outreach	Identify patients on a given panel who have not been seen recently, and are indicated for but not known to be taking statins or ACE inhibitors/ARBs, for targeted outreach.	Solutions PST
	Follow-up	Identify patients on a given panel who were recently prescribed one of these medications, for follow-up on medication adherence.	Solutions PST
Automated best practice alerts	Inreach	Alerts in the EHR notify providers at the point of care when a patient is 'missing' an indicated medication, and include hyperlinks to the Order Sets and After-Visit Summary text tools.	Epic EHR
Order Sets	Support	Pre-programmed forms enable quick prescribing of ACE-inhibitors/ARBs and statins.	Epic EHR
Patient education materials	Support	Exam room posters and patient informational handouts orient patients to the potential benefits of taking statins and ACE-inhibitors/ARBs.	Point of care
(English and Spanish)	Support	Standardized text can be added to patients' After-Visit Summary from the EHR using 'SmartPhrases.'	Epic EHR
Site Coordinators	Support	Study staff work in the clinics to oversee the implementation of the Quality Improvement initiative; they also meet regularly with the research team and share ideas.	—
Staff training materials	Support	Training materials to orient staff to the study tools and the associated changes to practice and standards of care.	—

PST = Panel Support Tool

EHR = Electronic Health Record

ACE = Angiotensin-converting enzyme

ARB = Angiotensin receptor blocker

Box 2

PARTICIPATING ORGANIZATIONS AND STUDY FQHCS, AND ROLES PLAYED IN ADAPTING THE INTERVENTION

		OCHIN[a]			
			Safety Net West[a] (AHRQ-registered Practice-based Research Network)		
	Organizations		**Primary care clinics (12 FQHCs from 3 community health center service areas in Portland, OR)**	**Center for Health Research, Kaiser Permanente Northwest**	**OregonHe Science University, Department of Family Medicine**
	Project Staff	**Researcher Co-Is, programmers**	**Provider Co-Is, site coordinators**	**Research Co-Is, biostatistician, data analyst**	**Research Co-Is**
	Tasks	**Partnering on project tasks**			
Proposal development	Proposal concept		L		
	Proposal writing	S	S	L	S
	Proposal submission			L	
Intervention logistics	IRB and legal processes		S	L	
	Identify clinic champions		L		
	Hire site coordinators		L	S	
Intervention development	Study and randomization design	S	S	L	S
	Adapt original tools	P	P	P	P
	Define inclusion parameters		L	S	
	Bridge between clinic staff and programmers		S	L	
	Build adapted tools	L	S	S	
	Adapt workflows to include new tools		L		
	Draft, edit patient education materials		S	L	
Intervention implementation	Print, distribute patient education materials		S	L	
	Share ideas/best practices		L	S	
	Implement adapted tools		L	S	
	Train clinic staff		L	S	
Analysis	Data analysis and reporting		S	L	

[a]Representatives from OCHIN, the KP Northwest Center for Health Research, and the OHSU Department of Family Medicine all participate in the Safety Net West PBRN (Practice-based Research Network). OCHIN is also the insitutional ‘home’ of the PBRN.

S = Support

L = Lead

P = Full Partnership

AHRQ = Agency for Healthcare Research and Quality

FQHC = Federally Qualified Health Center