Grant Final Report

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Improving Quality through Decision Support for Evidence-Based Pharmacotherapy

Inclusive project dates: 09/01/07 - 08/31/11

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Abstract

Purpose: To improve adherence to evidence-based pharmacotherapies (EBP) using clinical decision support in the context of a regional health information exchange.

Scope: None provided.

Methods: We created two interventions to detect evidence-based indications for nine classes of medications based on the presence of diabetes, hypertension, asthma, congestive heart failure, ischemic vascular disease or stroke. The clinic-directed intervention generated reports displaying a one-year list of filled prescriptions along with numerical and graphical summaries of adherence and recommendations for missing EBP. Patient-specific reports were sent to primary care clinics one day prior to a scheduled appointment. The population-oriented intervention sent weekly notices to care managers assigned to patients who appeared to be nonadherent to EBP and had no record of contact with their primary care clinics. To evaluate these interventions, 2219 Medicaid beneficiaries with at least one priority condition receiving care at one of the 16 study clinics were randomly assigned to usual care, reports alone, or reports plus care manager notices.

Results: Neither the reports alone nor the reports plus notices improved adherence to EBP compared to usual care. No improved adherence was detected for any individual class of medication or for any individual condition. The group randomized to receive notices had significantly increased contact with care managers demonstrating the potential to address EBP nonadherence at the population level. Site visits, contextual evaluation and user surveys suggested that the failure to improve adherence to EBP resulted from insufficient capacity to address medication adherence issues by clinicians in the context of the clinical encounter.

Key Words: clinical decision support; evidence-based pharmacotherapy; population health management; computers in healthcare; Medicaid; healthcare utilization; healthcare costs; healthcare quality

Final Report

Purpose

Clinician use of Health Information Technology (HIT) has been identified as a promising strategy for improving the quality and safety of health care. However, little is known of the specific benefits of using HIT to increase adherence to EBP. The purpose of this project was to increase knowledge and understanding regarding the use of clinical decision support (CDS) for increasing adherence to EBP within a vulnerable population and for assessing the impact of this technology on service utilization and costs; and to demonstrate a generalizable approach in a community setting that can be replicated at other sites.

Objectives of Study

This project was conducted over four years in accordance with four specific aims (Table 1) that explicitly reflect the project objectives (Table 2).

Table 1. Original project specific aims

#	Specific Aim
1	Expand the functionality of an existing decision support system in use within a regional health information exchange network for Medicaid beneficiaries to incorporate EBP and to promote medication adherence.
2	Implement and evaluate the impact of two complementary interventions for medication management on adherence to EBP among Medicaid beneficiaries in ambulatory care settings through a three-arm randomized controlled trial.
3	Compare resource utilization and assess the economic attractiveness (cost-savings or cost-effectiveness) of the interventions to promote medication adherence and EBP.
4	Disseminate information regarding the development and the impact of the interventions through Web teleconferences, professional meetings, educational lectures and peer review journals.

Table 2. Project objectives to achieve specific aims

#	Objective
1	*Augment Available Data.* Import scheduling and registration data from practice management systems from primary care practices in the Northern Piedmont Community Care Network (Aim 1)
2	*Enhance Decision Support System.* Demonstrate the ability to produce medication management reports and medication alert notices in the context of a HIE network (Aim 1)
3	*Implement Medication Management Decision Support.* Provide medication management reports to clinicians at the point of care and alerts to care managers (Aim 2)
4	*Evaluate Clinical Impact of Medication Management System.* Assess the impact of decision support for medication management on adherence with EBP (Aim 2)
5	*Stakeholder Satisfaction.* Determine clinician satisfaction with and use of medication management report and alerts (Aim 2)
6	*Evaluate Economic Impact of Medication Management System.* Assess the economic attractiveness of the medication management system (Aim 3)
7	*Dissemination.* Disseminate the approaches used in this project as well as the results of the analyses, so as to promote broader use of decision support for medication management (Aim 4)

Scope

Background

Misuse of medications results in thousands of serious adverse events and deaths, and costs an estimated $290 billion for unnecessary medical services in the United States annually.[1-4] For example, the adjusted risk of death was found to be significantly higher in patients with ischemic heart disease who were not taking aspirin, beta-blockers, lipid lowering therapy, or the combination of these drugs as compared to those patients who took these drugs consistently.[5] In another study, decreasing levels of adherence to beta-blockers and statins resulted in a significant increase in mortality in patients followed for a median of 2.4 years after myocardial infarction.[6] Hepke *et al.* found that higher adherence to insulin or oral hypoglycemic drugs among patients with diabetes resulted in an overall reduction in medical care costs, emergency room visits, and hospitalizations once a threshold level of adherence had been crossed.[7]

An estimated 30% to 50% of patients do not take their medications as prescribed.[4] Convincing research has demonstrated that adherence to appropriate pharmacotherapeutic interventions can dramatically reduce morbidity and mortality;[2-4,8] however, effective approaches derived from such research have been slow to be integrated into the process of routine clinical care. In an effort to close this quality and safety gap, new models of care need to be developed that address appropriate use of medications and seamlessly integrate into the care process. Through the proposed project, we assessed the impact of HIT on adherence to EBP guidelines for priority conditions identified by the IOM. The intent of this combined clinic- and population-based effort was to improve the health of a population, and not just the health of the patients who proactively seek care. Thus, in addition to supporting traditional models of clinic-based care, this project also intervened through managing patients by population and by linking to resources in the community through a HIE network.

Context

The Institute of Medicine (IOM) Quality Chasm report identified 20 priority areas for which improvement in the delivery of care would result in substantial overall improvement in the quality of healthcare.[9] For many of these priority areas (asthma, diabetes, depression, heart failure, COPD, hypertension, ischemic heart disease, and stroke), the use of EBP, as embodied in clinical practice guidelines (CPGs), is a central component of the overall care. Despite the proven benefits of EBP, use of these proven therapies in clinical practice is suboptimal. This lack of adherence to EBP constitutes a medication error[10] and is the result of two broad factors: (i) clinicians not following CPGs and prescribing EBP to patients, and (ii) patients not taking their prescribed medications as instructed. This project provides an example of how health information technology can facilitate appropriate pharmacotherapy for IOM priority conditions.

Population-based Care Management. The North Carolina Department of Medical Assistance has divided the state into 14 care management networks for Medicaid beneficiaries.[11] One of these networks, Northern Piedmont Community Care Network (NPCCN), serves 5 adjoining counties in central North Carolina. Care management services are provided through a community-based care management team that is led by a program manager and includes nurses,

social workers, community health workers, nutritionists, and health educators. Approximately 500 individuals are under active care management at any time. Care management services offered through the Network include home assessments, in-home health education and dietary instruction, assistance scheduling and keeping clinic appointments, and support for obtaining and taking medications. Furthermore, these providers routinely interact with other network partners including physicians, nurse practitioners, nurses, and pharmacists.

Development of a Regional HIE. In an effort to support community-based care management, a regional Health Information Exchange (HIE) network was developed. The COACH system (Community-Oriented Approach to Coordinated Healthcare) was initiated in 2000 as a care management documentation tool.[12] Over the ensuing twelve years, the system has been enhanced to facilitate communication between team members collaborating in the care of patients in the Network. Basic demographic and eligibility data for Network enrollees are uploaded to the system from the North Carolina Office of Rural Health and Community Care on a monthly basis, and data transfer protocols are in place to import clinical and billing data from partner sites. The imported data include encounter and pharmacy claims data from the State Medicaid Office, as well as billing data from nine clinics and all five hospitals in the service region. The four types of data collected by the system include: 1) administrative data (demographics and identifiers, services used, provider associations, audit trails); 2) care management data (care management encounters, health risk and environment assessment, socio-economic data, special needs, and care management plans); 3) clinical data (encounters, problems/procedures, appointments, medications, allergies, laboratory results, disease-specific care plans); and 4) data on communications (messages and alerts, referrals, notices of new information).

Clinical Decision Support. To detect nonadherence to EBP, we refined our decision support tool known as SEBASTIAN (System for Evidence-Based Advice through Simultaneous Transaction with an Intelligent Agent across a Network) to support sophisticated population health management activities.[12] SEBASTIAN is a general decision support tool based on an international draft standard (the Health Level 7 Decision Support Service Draft Standard for Trial Use).[13] This system is consistent with the Roadmap for Clinical Decision Support from the Office of the National Coordinator for Health Information Technology.[14,15] SEBASTIAN uses Web service technology to receive patient data from a client application. It then processes these data according to an application independent, pre-programmed set of rules (e.g., clinical algorithms and guidelines) and returns back patient-specific recommendations to the client application.

Settings

The specific partners participating in the Medicaid-focused Northern Piedmont Community Care Network of North Carolina are summarized in Table 3.

Table 3. List of participating study clinic practices and clinic sites at the inception of the project

Care Mgt Network	Administrative Group	Scheduling System	Clinical Site
Durham Community Care Network (DCHN)	Lincoln Community Health Center*	Health Pro	Adult Medicine Clinic
DCHN	Lincoln Community Health Center*	Health Pro	Pediatric Clinic
DCHN	Duke Univ. Health System	IDX	Duke Medical Outpatient Clinic (Int. Med.)
DCHN	Duke Univ. Health System	IDX	Duke Family Medicine
DCHN	Duke Univ. Health System	IDX	Duke Children's Primary Care Clinic
DCHN	Duke Univ. Health System	IDX	Duke Pediatric Primary Care Clinic
DCHN	Duke Univ. Health System	IDX	Durham Pediatrics
DCHN	Duke Univ. Health System	IDX	Duke Gynecology Outpatient Clinic
DCHN	Regional Pediatric Associates†	A4 HealthMatics	Regional Pediatrics-Freedom Lake Drive
DCHN	Regional Pediatric Associates†	A4 HealthMatics	Regional Pediatrics-Highgate Drive
Community Care Partners (CCP)	Beckford Medical Center‡	NueMD® Practice Mgt	Beckford Avenue Medical Center
CCP	Beckford Medical Center‡	NueMD® Practice Mgt	Beckford Warren Medical Center
CCP	Duke Univ. Health System	IDX	Butner-Creedmoor Family Medicine
CCP	Duke Univ. Health System	IDX	Henderson Family Medicine Clinic
CCP	Duke Univ. Health System	IDX	Oxford Family Physicians
CCP	Henderson Pediatric Center§	Misys Tiger®	Granville Pediatric Center
CCP	Henderson Pediatric Center§	Misys Tiger®	Henderson Pediatric Center
CCP	Vance Family Medicine	Misys Tiger®	Vance Family Medicine

* Federal Qualified Health Center ; † Dropped site because of new EHR 03/29/2010; ‡Dropped site because of new EHR 02/12/2010; §Dropped site because of new EHR as of 12/07/2009

Participants

Study participants in this project include Medicaid beneficiaries with at least one IOM priority condition who were continuously enrolled in the NPCCN during the intervention period and their care providers. We elected to study only continuously enrolled patients because we wanted to have the complete dataset of all of the care provided to the individuals included in the analysis. The presence of IOM priority conditions was determined from claims data using algorithms modeled after the Healthcare Effectiveness Data and Information Set (HEDIS) with the exclusion of criteria based on medication claims because the mediation criteria might have biased our subject selection in favor of patients who were already taking medications. Without medication criteria the HEDIS criteria were ineffective at identifying persistent asthma. Therefore, to identify subjects with persistent asthma, we conducted chart audits on all 1,064 subjects who had an asthma ICD9 code in their claims data to find definitive clinical

documentation of persistent asthma in the medical record. We identified 617 cases of persistent asthma, 112 cases of intermittent asthma and 335 cases that were indeterminate.

In place of informed consent, study subjects were sent a letter explaining the study and a response card to allow them to opt out of the study. A total of 155 potential subjects opted out (Figure 1). During the course of the study we had additional subject attrition because three administrative groups representing six study clinic sites installed new electronic health record (EHR) systems. In all instances, after the installation of the new EHRs, these groups were unable to start/resume sending schedule information to the HIE. As a consequence no further medication management reports could be generated. Since these subjects only received partial (or no) exposure to the intervention, they were censored from the analysis (Fig 1). The final source of subject attrition involved subjects who were reassigned to a network clinic site that was not participating in the study (and not sending scheduling data). As a result, these subjects also received a limited exposure to the intervention and were censored from the analysis. Demographic data for the final set of included subjects are summarized in Table 4 by treatment group along with p-values to detect significant differences between groups. Demographic data for study subjects who triggered at least one medication management report and for subjects who triggered at least one care manager notice did not differ by treatment group (data not shown).

Figure 1. Subject inclusion, exclusion and randomization

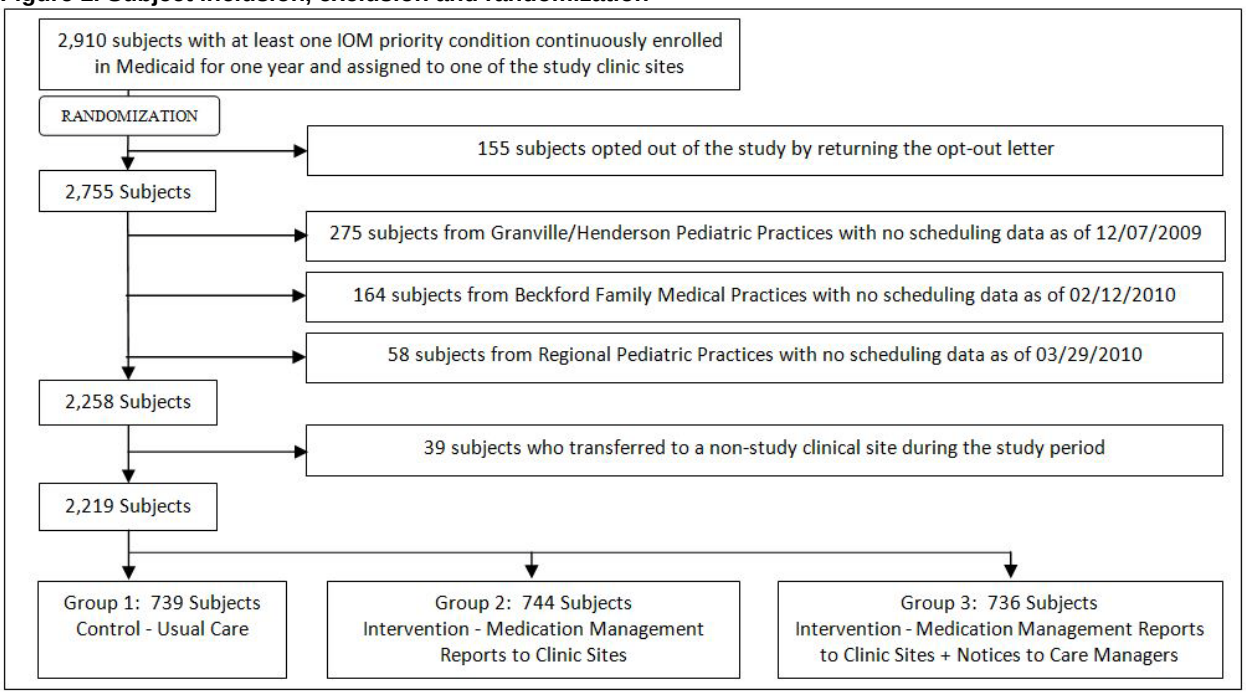


Table 4. Baseline characteristics of subjects randomized to the three treatment groups

	No Interv. (Control) #	No Interv. (Control) %	Info. Interv. Strategies: Reports Sent to Clinics (Reports) #	Info. Interv. Strategies: Reports Sent to Clinics (Reports) %	Info. Interv. Strategies: Reports Sent to Clinics (Reports) p	Info. Interv. Strategies: Reports and Email Notices to Care Managers (Reports+) #	Info. Interv. Strategies: Reports and Email Notices to Care Managers (Reports+) %	Info. Interv. Strategies: Reports and Email Notices to Care Managers (Reports+) p	Total #	Total %
Total	739	33.3	744	33.5		736	33.2		2219	100.0
Gender: Female	440	59.5	433	58.2	0.64	443	60.2	0.84	1316	59.3
Gender: Male	299	40.5	311	41.8		293	39.8		903	40.7
Race: Caucasian	106	14.3	98	13.2	0.56	94	12.8	0.42	298	13.4
Race: Black	479	64.8	488	65.6	0.80	485	65.9	0.70	1452	65.4
Race: Asia	4	0.5	2	0.3	0.68	1	0.1	0.37	7	0.3
Race: American Indian	3	0.4	0	0.0	0.25	1	0.1	0.62	4	0.2
Race: Pacific Islander	0	0.0	0	0.0		2	0.3	0.48	2	0.1
Race: Other	118	16.0	129	17.3	0.52	116	15.8	0.97	363	16.4
Race: Unknown	29	3.9	27	3.6	0.87	37	5.0	0.37	93	4.2
Ethnicity: Hispanic	14	1.9	13	1.8	0.99	18	2.5	0.58	45	2.0
Age: 0 - 2	42	5.7	37	5.0	0.62	45	6.1	0.81	124	5.6
Age: 2 -12	193	26.1	200	26.9	0.78	192	26.1	1.00	585	26.4
Age: 13 -20	105	14.2	96	12.9	0.51	83	11.3	0.11	284	12.8
Age: 21 – 40	113	15.3	149	20.0	0.02	141	19.2	0.06	403	18.2
Age: 40 -64	277	37.5	258	34.7	0.28	267	36.3	0.67	802	36.1
Age: >= 65	9	1.2	4	0.5	0.26	8	1.1	1.00	21	1.0
Condition: Persistent Asthma	202	27.3	204	27.4	1.00	211	28.7	0.61	617	27.8
Condition: Diabetes	172	23.3	205	27.6	0.07	183	24.9	0.51	560	25.2
Condition: Hypertension	290	39.2	286	38.4	0.79	285	38.7	0.88	861	38.8
Condition: CHF	44	6.0	47	6.3	0.85	42	5.7	0.93	133	6.0
Condition: IHD	44	6.0	29	3.9	0.09	42	5.7	0.93	115	5.2
Condition: Stroke	29	3.9	32	4.3	0.81	39	5.3	0.26	100	4.5

Incidence

Incidence in the context of this study represents the generation of the study interventions. In this project, 5,948 medication reports were generated for study subjects with scheduled appointments at their assigned PCP clinic (Table 6). Of these reports, 2061 were withheld for control subjects and 3,887 were prepared for sending to the appropriate clinic site. The distribution of reports generated across the participating clinic sites is summarized in Table 11.

Table 6. Medication management reports generated

	Arm #1 (Control): #	Arm #2 (Reports): #	Arm #2 (Reports): p	Arm #3 (Reports+): #	Arm #3 (Reports+): p	Total: #
Reports to Clinics: Generated	2061	1951	0.44	1936	0.71	5948
Reports to Clinics: Sent	0	1951		1936		3887

The number of care manager notices generated by treatment group is summarized in Table 7. A total of 1,052 notices were generated for 385 unique subjects thus averaging 2.73 notices per subject. Of these notices, 363 were actually sent and 689 were withheld for control subjects. The distribution of reports and notices across the participating clinic sites are summarized in Table 8. The site that generated the most reports and notices was a Federally qualified health center known as the Lincoln Community Health Center.

Table 7. Care manager notices generated

	Arm #1 (Control): # Notices	Arm #2 (Reports): # Notices	Arm #2 (Reports): p	Arm #3 (Reports+): # Notices	Arm #3 (Reports+): p	Total: #
# Notices Generated	353	336	0.69	363	0.55	1052
#Notices Sent	0	0		363		363
# Unique Pts Generating Notices	127	122	0.69	136	0.52	385
Ave # Notices/Patient	2.78	2.75		2.67		2.73

Table 8. Reports and notifications generated during the 12-month study period

Administrative Group	**Clinic Site**	Control (N = 739) Count: **Reports**	Control (N = 739) Count: **Notices**	Report Only Group (N= 744) Count: **Reports**	Report Only Group (N= 744) Count: **p**	Report Only Group (N= 744) Count: **Notices**	Report Only Group (N= 744) Count: **p**	Reports and Notices to Care Managers Group (N= 736) Count: **Reports**	Reports and Notices to Care Managers Group (N= 736) Count: **p**	Reports and Notices to Care Managers Group (N= 736) Count: **Notices**	Reports and Notices to Care Managers Group (N= 736) Count: **p**
LCHC	LCHC Adult Medicine Clinic LCHC Pediatric Clinic	499	76	498	0.75	108	0.50	528	0.86	95	0.40
Duke Univ. Health System	Duke Medical Outpatient Clinic	528	30	518	0.79	26	0.80	483	0.93	53	0.09
Duke Univ. Health System	Duke Family Medicine	316	68	289	0.85	41	0.07	348	0.82	64	1.00
Duke Univ. Health System	Duke Children's Primary Care Clinic	205	58	173	0.13	45	0.19	200	0.40	48	0.25
Duke Univ. Health System	Durham Pediatrics	16	16	10	0.09	14	0.71	14	0.85	4	0.35
Duke Univ. Health System	Duke Gynecology Outpatient Clinic	9	2	4	1.00	0	0.61	5	1.00	5	0.47
Duke Univ. Health System	Butner Creedmoor Family Medicine	12	8	29	0.42	9	0.90	13	1.00	6	0.61
Duke Univ. Health System	Henderson Family Medicine Clinic	77	13	98	0.27	15	0.57	47	0.79	13	0.90
Duke Univ. Health System	Oxford Family Physicians	43	40	50	0.81	23	0.55	40	0.87	15	0.04
Vance Family Med.	Vance Family Medicine	356	42	282	0.22	55	0.26	258	0.41	60	0.10
Total Events Detected		2061	353	1951		336		1936		363	

Prevalence

The prevalence of the six target IOM conditions across the study sites is shown in Table 9. Hypertension was the most prevalent condition with 861cases followed by asthma with 617 cases and diabetes with 560 cases.

Table 9. Prevalence of IOM conditions at study clinic sites

Care Mgt Network	Administrative Group	Clinical Site*	# NPCCN Pts	# Unique Pts w/ Priority Dzs*	Persistent Asthma	DM	Htn	CHF	IHD	Stroke
DCHN	LCHC	Adult Medicine Clinic Pediatric Clinic	596	456	147	166	239	47	35	38
DCHN	Duke Univ. Health System	Duke Medical Outpatient Clinic	364	331	45	133	258	49	41	28
DCHN	Duke Univ. Health System	Duke Family Medicine	252	225	92	71	123	10	12	8
DCHN	Duke Univ. Health System	Duke Children's Primary Care Clinic	418	248	184	28	37	6	0	8
DCHN	Duke Univ. Health System	Durham Pediatrics	48	32	26	2	1	2	0	1
DCHN	Duke Univ. Health System	Duke Gynecology Outpatient Clinic	10	7	1	3	3	1	0	0
CCP	Duke Univ. Health System	Butner-Creedmoor Family Medicine	36	25	11	7	10	0	0	0
CCP	Duke Univ. Health System	Henderson Family Medicine Clinic	91	70	8	31	45	6	9	3
CCP	Duke Univ. Health System	Oxford Family Physicians	97	75	18	30	52	4	4	2
CCP	Vance Family Med.	Vance Family Medicine	307	241	85	89	93	8	14	12
TOTAL			2219	1710	617	560	861	133	115	100

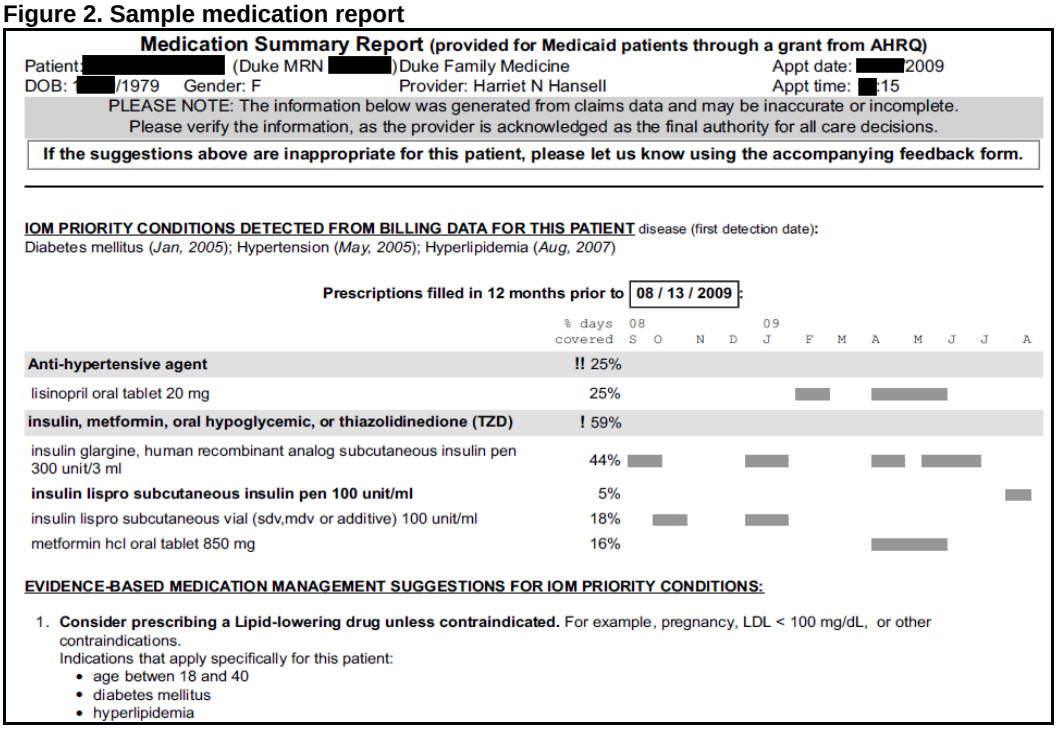
Methods

Study Design

This study was a randomized controlled trial evaluating two interventions against a usual care control. Medicaid beneficiaries who were continuously enrolled in the NPCCN for at least one year were randomly assigned by family unit to one of three groups. Group 1 subjects were maintained with usual care. Group 2 subjects were exposed to an information intervention that consisted of a report containing a summary list of filled prescription claims along with a numeric calculation of medication adherence and a graphical depiction of "days covered" over a one-year period (Figure 2). These reports were delivered to the point of care at the time of a scheduled appointment of a study subject with his/her primary care clinic. The reports also include recommendations pertaining to specific IOM conditions that addressed possible deficiencies in medication therapies relative to EBP guidelines. Subjects assigned to group 3 received the same reports for their primary care clinicians as group 2 subjects and also received notices sent to their assigned care managers (Figure 3) if possible medication deficiencies relative to EB pharmacotherapeutic guidelines were detected and they had not had an appointment with their primary care clinic for the past 6 months and had no scheduled primary care appointments. The

study was registered with ClinicalTrials.gov as NCT00979225 as of August 27, 2009. This study was approved by the Duke University School of Medicine Institutional Review Board.

Figure 2. Sample medication report



Medication Summary Report (provided for Medicaid patients through a grant from AHRQ)

Patient: [redacted] (Duke MRN [redacted]) Duke Family Medicine Appt date: [redacted]2009
DOB: 1[redacted]/1979 Gender: F Provider: Harriet N Hansell Appt time: [redacted]:15

PLEASE NOTE: The information below was generated from claims data and may be inaccurate or incomplete.
Please verify the information, as the provider is acknowledged as the final authority for all care decisions.

If the suggestions above are inappropriate for this patient, please let us know using the accompanying feedback form.

IOM PRIORITY CONDITIONS DETECTED FROM BILLING DATA FOR THIS PATIENT disease (first detection date):
Diabetes mellitus (*Jan, 2005*); Hypertension (*May, 2005*); Hyperlipidemia (*Aug, 2007*)

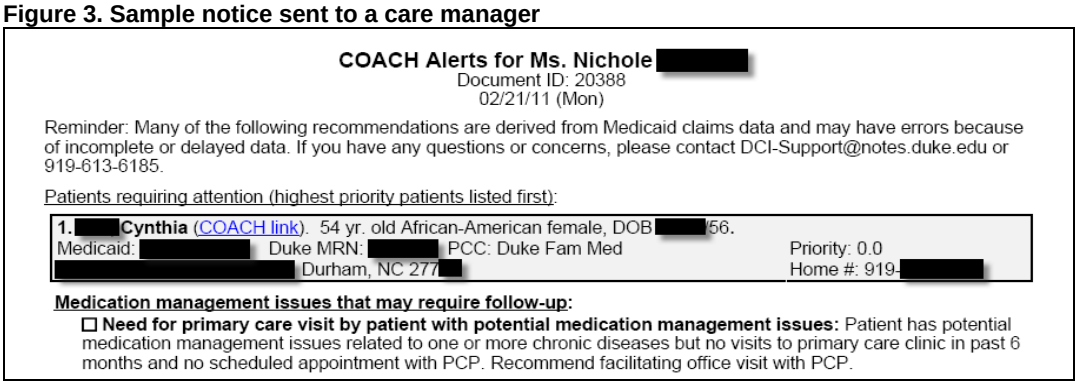
Prescriptions filled in 12 months prior to 08 / 13 / 2009:

	% days covered	08 S	O	N	D	09 J	F	M	A	M	J	J	A
Anti-hypertensive agent	!! 25%												
lisinopril oral tablet 20 mg	25%												
insulin, metformin, oral hypoglycemic, or thiazolidinedione (TZD)	! 59%												
insulin glargine, human recombinant analog subcutaneous insulin pen 300 unit/3 ml	44%												
insulin lispro subcutaneous insulin pen 100 unit/ml	5%												
insulin lispro subcutaneous vial (sdv,mdv or additive) 100 unit/ml	18%												
metformin hcl oral tablet 850 mg	16%												

EVIDENCE-BASED MEDICATION MANAGEMENT SUGGESTIONS FOR IOM PRIORITY CONDITIONS:

1. **Consider prescribing a Lipid-lowering drug unless contraindicated.** For example, pregnancy, LDL < 100 mg/dL, or other contraindications.
   Indications that apply specifically for this patient:
   - age betwen 18 and 40
   - diabetes mellitus
   - hyperlipidemia

Figure 3. Sample notice sent to a care manager



COACH Alerts for Ms. Nichole [redacted]
Document ID: 20388
02/21/11 (Mon)

Reminder: Many of the following recommendations are derived from Medicaid claims data and may have errors because of incomplete or delayed data. If you have any questions or concerns, please contact DCI-Support@notes.duke.edu or 919-613-6185.

Patients requiring attention (highest priority patients listed first):

1.[redacted]Cynthia (COACH link). 54 yr. old African-American female, DOB [redacted]/56.
Medicaid: [redacted] Duke MRN: [redacted] PCC: Duke Fam Med Priority: 0.0
[redacted] Durham, NC 277[redacted] Home #: 919-[redacted]

Medication management issues that may require follow-up:
☐ **Need for primary care visit by patient with potential medication management issues:** Patient has potential medication management issues related to one or more chronic diseases but no visits to primary care clinic in past 6 months and no scheduled appointment with PCP. Recommend facilitating office visit with PCP.

Data Sources/Collection

Data for the primary and secondary outcomes were obtained from pharmaceutical and other claims data from the NC Department of Health and Human Services. Analyses were delayed by at least 6 months after the completion of the study to ensure that the claims dataset was complete and stable.

The integrity of the delivery of the medication management reports to the point of care at study clinic sites was assessed through on-site monitoring visits at study clinics during study

months 1, 3, 6, 9 and 12. These monitoring visits involved tracking whether or not specific reports scheduled to be available for the day of the visit actually arrived at the point of care. They also included four Likert questions for the report recipients to ascertain the perceived usefulness of various components of the reports. The impact of the intervention on the implementation sites was assessed through a contextual evaluation conducted during the sixth month of the study. The contextual evaluation involved observing every interaction that clinic personnel experienced with the intervention reports. After observing the routine processing of the reports, staff who handled the reports were interviewed to collect their impressions regarding how the reports affected the clinic site and the work flow.

Clinician opinions regarding the interventions and their effectiveness were assessed at the completion of the project using validated survey instruments for assessing usability.

The medication management system records, at the level of the individual patient, every point-of-care medication report and every care manager notice that was generated and sent or withheld based on a patient's study group assignment. The volume of reports and notices generated and sent for the twelve-month period from December 7, 2009 to December 6, 2010 was extracted from the event recording database along with patient characteristics including date of birth, gender, race/ethnicity, number of family members in Medicaid, and clinic assignment. The primary study measures are summarized in Table 10.

Table 10. Study measures

Measurement Focus	Measures
Clinical Outcomes	Medication adherence across all drug classes and conditions (all subjects and touched subjects) Medication adherence by drug class (all subjects and touched subjects) Medication adherence by disease condition (all subjects and touched subjects) Outpatient encounters per 100 pt years (all subjects and touched subjects) ED encounters per 100 pt years (all subjects and touched subjects) Hospitalizations per 100 pt years (all subjects and touched subjects)
Care Coordination	Care Manager contacts (all subjects and touched subjects)
Costs/Revenues	Outpatient costs (all subjects and touched subjects) ED costs (all subjects and touched subjects) Hospitalization costs (all subjects and touched subjects) Pharmaceutical reimbursement (all subjects and touched subjects)
Satisfaction	Clinician opinions

Data Analysis

Baseline characteristics and study outcomes were summarized for the two intervention groups and the usual care group using the number (percent) for categorical variables. Estimated treatment effects were based upon generalized estimating equations. The primary comparisons were based on intention-to-treat estimates based on data from all randomized subjects. Primary comparisons were performed for the reports group vs. usual care group and the reports+ group vs. usual care group with p-values reported for each comparison. Subgroup analyses were performed on the subset of individuals who generated an alert (the "touched" cohort). One sample t-tests were used to compare the physician survey responses versus the neutral value for the Likert scales. Statistical significance was set at 0.05 (two-sided) with no correction for multiple comparisons.

Interventions

Identification of Medication Adherence Issues. The team pharmacist (NA-L) conducted an extensive literature search to define appropriate medical therapies for the six study conditions derived from high quality research evidence. She then collaborated with other study investigators to convert this research evidence into discrete clearly defined rules that could be implemented in a computer. Over the course of creating these rules, the team discovered that the recommendations for a specific class of medications could be different for the different IOM conditions resulting in discordant recommendations. As a result, we shifted our rule development from a disease-centric focus to a phamacotherapeutic-centric focus. Thus, instead of creating a rule to ask what medications should this patient with hypertension take, we developed rules that asked if this patient should be taking an angiotensin-converting-enzyme inhibitor medication. The issues considered for each pharmacotherapy-centric rule are summarized in Table 11.

Table 11. Summary list of pharmacotherapeutic-centric rules and the requirement to activate the rules

Medication Class	Conditions Contributing to Rule
Statin	Diabetes + Age > 40 Diabetes + Coronary Artery Disease if Age < 40 Stroke + LDL Cholesterol >=100 (Age>17) Stoke + Diabetes + LDL Cholesterol=70 (Age>17) Prior Myocardial Infarction (Age>17) Stroke + Coronary Artery Disease (Age>17)
ACEI (ARB)	Prior Myocardial Infarction or Coronary Artery Disease + Hypertension (Age>17) Left Ventricular Systoloic Dysfunction (Age>17) Prior Myocardial Infarction or Coronary Artery Disease + Diabetes (Age>17) Prior Myocardial Infarction or Coronary Artery Disease + Chronic Kidney Disease (Age>17)
B-Blocker	Prior Myocardial Infarction (Age>17) Left Ventricular Systoloic Dysfunction (Age>17)
Warfarin	Stroke + Mech Valve (Age>17) Stroke + Valvular Heart Disease (Age>17) Stroke + Afib (Age>17)
Anti-Hypertensive	Hypertension (Age>17) Diabetes+ Hypertension (all Ages) Stroke + Hypertension (Age>17)
Anti-Diabetes	Diabetes (all Ages)
Inhaled Steroid or Montelukast	Persistent Asthma + Age>36 mo
B-Agonist	Persistent Asthma + Age>24 mo

Creation of Reporting Mechanisms for Medication Adherence Issues. We worked with the medical directors and clinicians from the primary care clinics participating in the study to define and develop through focus groups the content and format of the point-of-care medication management reports. We also used focus groups with members of the care management team to develop the content and prioritization of care manager notices related to medication adherence issues.

Development of Standards-Based CDS for Medication Management. We created over 40 rules in the SEBASTIAN knowledge base to detect medical indications, contra-indications and probable medication deficiencies for the six study conditions using the Java programming language. The COACH population health management module uses rule-based knowledge

modules to calculate medication adherence rates by medication and medication class and to detect probable low medication adherence. The accuracy of these rules for correctly identifying medication adherence issues was validated using chart audits. Rules were iteratively modified until a minimum of 90% accuracy was achieved.

Implementation of Clinic- and Population-level Medication Management. SEBASTIAN was used to support medication management in the COACH HIE network at both the clinic and population level. The process for generating point-of-care reports is outlined in detail with sequential numbering of each step in Figure 4. The medication adherence rates calculated by SEBASTIAN are compiled into a graphical and numeric summary table along with recommendations to address probable medication deficiencies and then incorporated into summary reports. Summary medication reports were then sent by secure email or facsimile to participating study sites on the day prior to a study patient's scheduled primary care appointment. Each report was accompanied by a "feedback" form through which the receiving clinician could communicate additional information about medications (e.g., contraindications) that were incorporated into the study subject registry and used to inform future reports. The project coordinator worked with each study site to ensure that delivery of the medication reports to the point of care prior to each patient's arrival occurred consistently. On-site clinic visits were conducted by the study coordinator at 1, 3, 6, 9 and 12 months during the course of the study to ensure that the approaches that had been enacted to ensure delivery of the medication management reports to the point of care were still operational.

In addition to the point-of-care clinical reports that were triggered when a scheduled appointment for a study patient was detected, the SEBASTIAN CDSS was also programmed to conduct weekly surveillance on all study subjects seeking to identify subjects with probable low medication adherence based on their known health conditions who had not been seen at their primary care clinic in over 6 months and did not have any scheduled appointments with their PCP clinic site in the future. Detection of such situations resulted in an email notice being generated for the patient's assigned care manager. The process for generating notices for care managers is outlined in detail with sequential numbering of each step in Figure 5.

Figure 4. Schematic representation of data communication to generate medication management reports

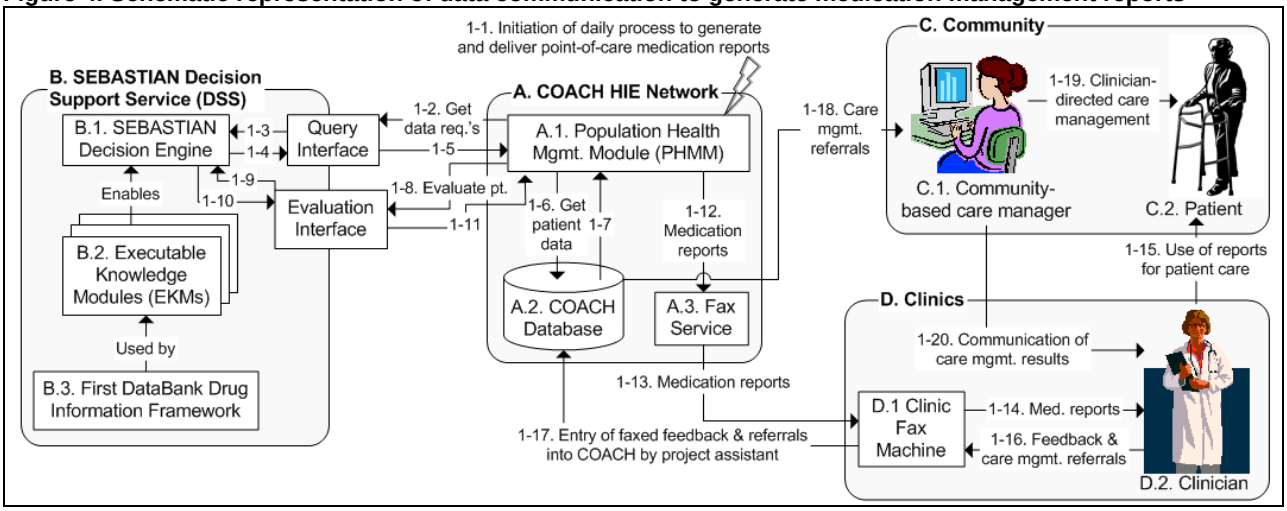
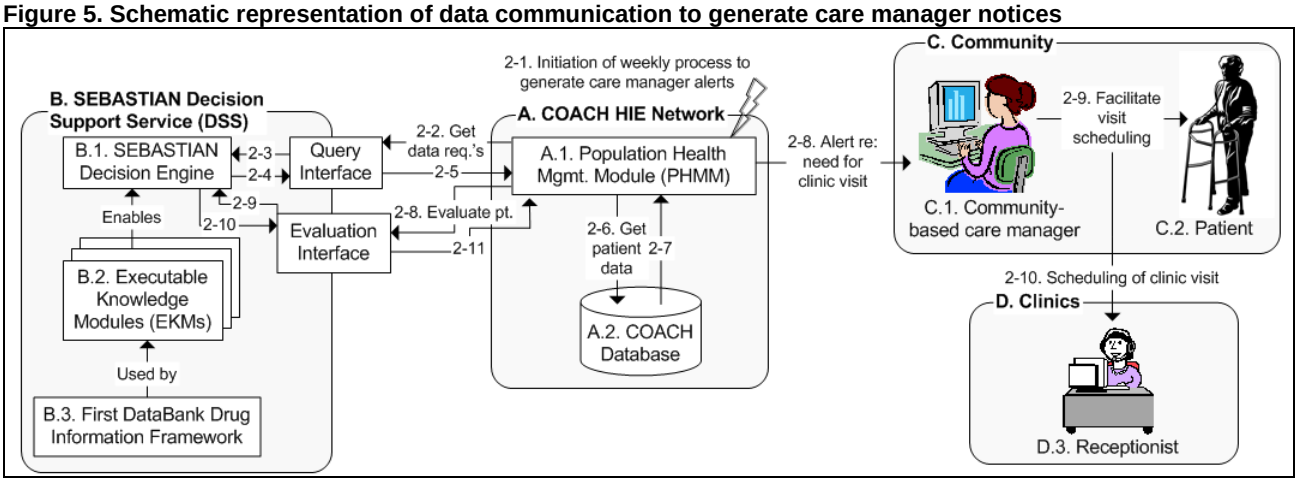


Figure 5. Schematic representation of data communication to generate care manager notices



Results

Principal Findings

Aim 1. We successfully fulfilled the goal of Aim 1 by modifying the SEBASTIAN decision support system to integrate evidence-based pharmacotherapy into the flow of the data within a regional HIE for Medicaid beneficiaries. During the one-year evaluation period the CDSS generated 5,948 medication management reports for the 2,219 study subjects with one or more of the target chronic conditions. We also generated 1,052 notices for care managers to identify subjects with low medication adherence and no contact with the healthcare system for over 6 months.

Aim 2. Aim 2 was fulfilled through the implementation and evaluation of the medication management CDSS from December 7, 2009 through December 6, 2010. We found that the point-of-care medication adherence reports and EBP recommendations did not increase overall adherence to evidence-based pharmacotherapies for the target conditions combined nor for any individual condition or drug class (Group #2 vs. Control). Similarly, we found no increased adherence to evidence-based pharmacotherapies for subjects randomized to receive reports and notices to their care managers regarding low adherence to EBP (Group #3 vs. Control). However, we did detect statistically higher rates of care manager contact with subjects assigned to Group #3 indicating that these notices were effective in mobilizing care management services.

Aim 3. We evaluated the impact of both interventions on utilization of care services and costs. We found no positive or negative impact on outpatient, inpatient or ED service utilization nor on costs of care.

Aim 4. We have disseminated information about this project in 15 presentations in international, national, regional, and local forums including one AHRQ-sponsored Webinar, and in two peer-reviewed publications and one poster abstract that received an award for “Best Poster” at the 2010 AMIA Annual Symposium.

Quantitative Outcomes

The interventions did not significantly increase overall medication adherence relative to controls (primary study measure) (Table 12, Figure 6), nor did we detect an increased adherence for a specific class of medications (Table 12, Figure 6) or for groups of subjects with specific chronic conditions (Table 13, Figure 7). While the primary analysis used an intention-to-treat analytic framework, as a secondary analysis we also evaluated the impact of the interventions by looking selectively at the subjects who actually generated a medication report (i.e., were "touched" by the intervention, or, in the case of the control group, could have been "touched" by the intervention). Unfortunately, we found no statistically significant increase in EBP among "touched" subjects relative to control subjects (Table 14, Figure 8). This lack of impact on touched subjects persisted across drug classes (Table 14, Figure 8) and disease states (Table 15, Figure 9). In contrast to the apparent lack of impact from the point-of-care reports, we did find that the sending of notices (or withholding of potential notices for the control group) significantly increased the extent of care manager contact with study subjects. This effect on care manager contact was detected under both the intention-to-treat (Table 16 and Figure 10) and touched-subject analytic frameworks (Table 17 and Figure 11).

Table 12. Adherence by medication class post intervention: all subjects (intention to treat analysis)

		Arm #1 (Control) Adherence N=739 %	**Arm #2 (Reports) Adherence N=744 %**	**Arm #2 (Reports) Adherence N=744 p**	**Arm #3 (Reports+) Adherence N=736 %**	**Arm #3 (Reports+) Adherence N=736 p**
All Medication Classes		41.3	41.2	0.82	42.9	0.35
Statin	All Conditions (age>17)	54.0	61.0	0.12	56.3	0.63
ACEI (ARB)	All Conditions (age>17)	69.7	68.4	0.85	64.2	0.52
B-Blocker	All Conditions (age>17)	55.2	58.3	0.54	57.1	0.76
Warfarin	All Conditions (age>17)	48.3	56.1	0.54	37.8	0.26
Anti-Htn	All Conditions (age>17)	62.8	61.1	0.88	63.9	0.71
Anti-DM	Diabetes (all ages)	54.3	53.8	0.90	57.1	0.49
Inhaled Steroid/ Montelukast	Persistent Asthma+age>36 mo	36.9	36.4	0.73	41.8	0.23
B-Agonist	Persistent Asthma+age>24 mo	25.4	23.9	0.85	24.7	0.84

Figure 6. Adherence by medication class (intention to treat)

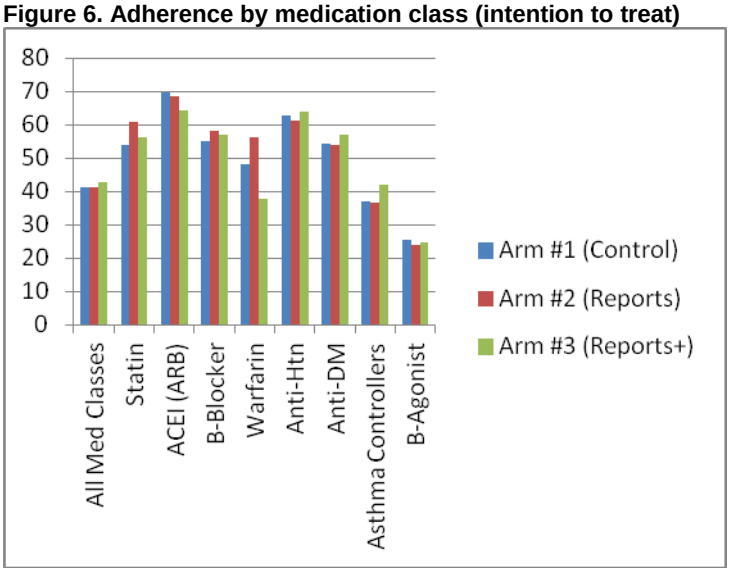


Table 13. Adherence by condition: all subjects (intention to treat)

	Arm #1 (Control) Adherence %	Arm #2 (Reports) Adherence %	Arm #2 (Reports) Adherence p	Arm #3 (Reports+) Adherence %	Arm #3 (Reports+) Adherence p
All Diseases	40.6	39.3	0.77	40.6	0.76
Persistent Asthma	27.7	29.0	0.29	27.2	0.47
Diabetes	49.6	50.3	0.83	51.3	0.62
Hypertension	56.6	53.7	0.29	55.8	0.74
CHF	55.8	62.7	0.32	53.9	0.83
IHD	52.4	51.8	0.92	61.6	0.30
Stroke	61.2	54.1	0.62	50.3	0.22

Figure 7. Adherence by condition (intention to treat)

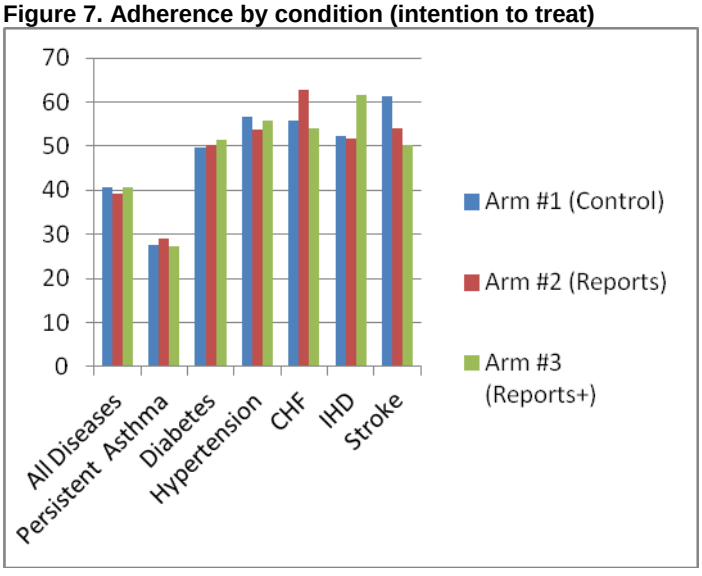


Table 14. Adherence by medication class: touched subjects 6 months after first touch

		Arm #1 (Control) Adherence N=494 %	Arm #2 (Reports) Adherence N=476 %	Arm #2 (Reports) Adherence N=476 p	Arm #3 (Reports+) Adherence N=493 %	Arm #3 (Reports+) Adherence N=493 p
All Medication Classes		50.5	51.3	0.61	52.7	0.35
Statin	All Conditions (age>17)	61.2	67.6	0.18	63.3	0.76
ACEI (ARB)	All Conditions (age>17)	74.7	82.0	0.32	71.0	0.63
B-Blocker	All Conditions (age>17)	58.1	63.8	0.42	64.2	0.45
Warfarin	All Conditions (age>17)	51.9	63.6	0.47	46.8	0.76
Anti-Htn	All Conditions (age>17)	71.2	69.7	0.76	71.8	0.70
Anti-DM	Diabetes (all ages)	63.4	63.0	0.90	66.9	0.33
Inhaled Steroid/ Montelukast	Persistent Asthma+age>36 mo	43.1	43.1	0.63	50.1	0.07
B-Agonist	Persistent Asthma+age>24 mo	31.1	30.1	0.48	29.4	0.74

Figure 8. Adherence by medication class: touched subjects

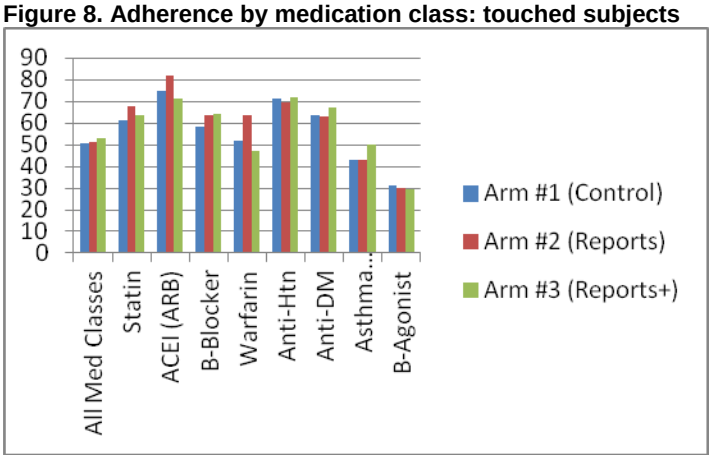


Table 15. Adherence by disease: touched subjects 6 months after first touch

	Arm #1 (Control) Adherence %	Arm #2 (Reports) Adherence %	Arm #2 (Reports) Adherence p	Arm #3 (Reports+) Adherence %	Arm #3 (Reports+) Adherence p
All Diseases	47.5	46.8	0.93	47.7	0.78
Persistent Asthma	33.0	34.6	0.28	32.8	0.51
Diabetes	58.1	57.0	0.72	58.4	0.92
Hypertension	62.2	61.2	0.66	63.0	0.83
CHF	63.7	67.0	0.46	60.8	0.59
IHD	60.1	57.5	0.75	71.1	0.15
Stroke	63.1	60.5	0.97	54.4	0.27

Figure 9. Adherence by condition: touched subjects

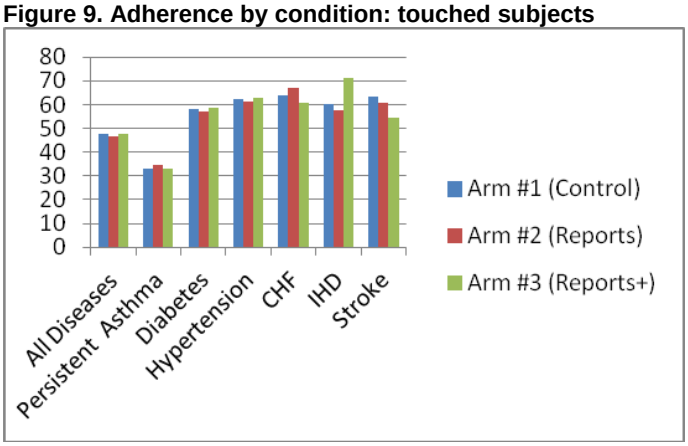


Table 16. Care manager contacts: all subjects (intention to treat analysis)

	Arm #1 (Control) # Contacts	Arm #2 (Reports) # Contacts	Arm #2 (Reports) p	Arm #3 (Reports+) # Contacts	Arm #3 (Reports+) p	Total Contacts
Total	2278	2799	0.12	3548	**<0.0001**	8625
Care mgr f/u in 30 days	161	154	0.50	207	**0.0002**	522
Phone Calls	1084	1328	0.01	1490	**<0.0001**	3902
Letters	306	300	0.65	505	**0.0002**	1111
Home Visits	338	406	0.82	475	0.14	1219
Other	550	765	0.17	1078	**<0.0001**	2393

Figure 10. Care manager contacts: all subjects

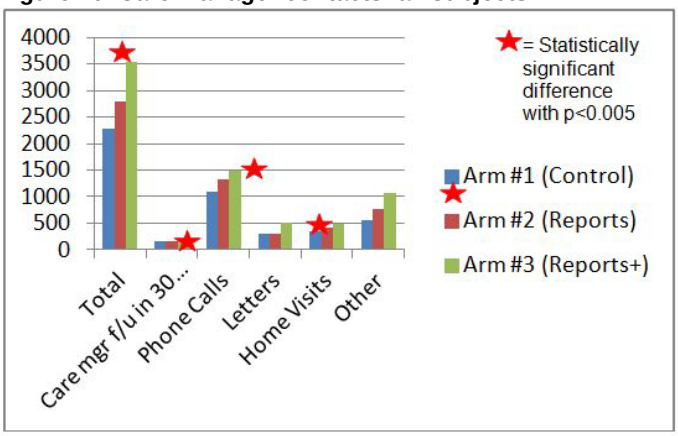
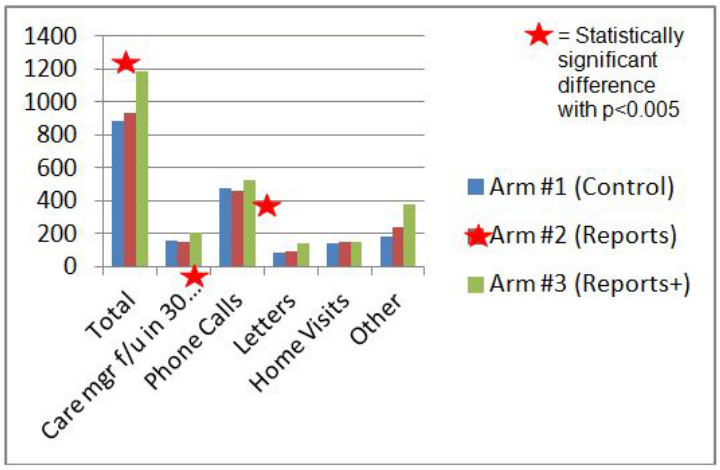


Table 17. Care manager contacts: touched subjects 6 months after first touch

	Arm #1 (Control) # Contacts	Arm #2 (Reports) # Contacts	Arm #2 (Reports) p	Arm #3 (Reports+) # Contacts	Arm #3 (Reports+) p	Total Contacts
Total	882	936	0.11	1188	**<0.0001**	3006
Care mgr f/u in 30 days	161	154	0.33	207	**0.0001**	522
Phone Calls	474	457	0.15	523	**0.002**	1454
Letters	85	90	0.32	139	0.02	314
Home Visits	141	149	0.48	147	0.42	437
Other	182	240	0.25	379	**<0.0001**	801

Figure 11. Care manager contacts: touched subjects



Impact on Stakeholders

In addition to looking for direct effects of the intervention on medication adherence for the study subjects, we also investigated the impact on utilization of health care services and costs. Perhaps not surprisingly because we showed no impact on adherence, we also showed no impact in either a positive or negative direction on outpatient, inpatient or ED utilization (Table 18) nor on costs of care (Table 19). For this analysis to explore the effect of the interventions on the health care system, we used both the intention-to-treat (Tables 18 and 19) and the touched-subject frameworks (Tables 20 and 21).

Table 18. Encounter rates (events per 100 patient years): all subjects (intention to treat analysis)

	Arm #1 (Control) #	Arm #2 (Reports) #	Arm #2 (Reports) p	Arm #3 (Reports+) #	Arm #3 (Reports+) p	Total #
Outpatient	46.0	46.6	0.42	44.5	0.81	45.7
Emergency Department	0.87	0.84	0.77	0.89	0.47	0.87
Hospitalization	0.19	0.21	0.96	0.21	0.92	0.20
Total	47.0	47.7	0.49	45.6	0.81	46.8

Table 19. Costs per patient year: all subjects (intention to treat)

	Arm #1 (Control) $	Arm #2 (Reports) $	Arm #2 (Reports) p	Arm #3 (Reports+) $	Arm #3 (Reports+) p	Total $
Outpatient	4417	5079	0.42	4423	0.75	4641
Emergency Department	423	409	0.58	420	0.07	417
Hospitalization	154	167	0.95	184	0.93	168
Pharmaceuticals	5579	6655	0.15	5703	0.79	5981
Total	10573	12310	0.32	10730	0.76	11208

Table 20. Encounter rates (events per 100 patient years): touched subjects 6 months after first touch

	Arm #1 (Control) #	Arm #2 (Reports) #	Arm #2 (Reports) p	Arm #3 (Reports+) #	Arm #3 (Reports+) p	Total #
Outpatient	52.4	53.4	0.14	48.3	0.98	51.4
Emergency Department	1.04	1.02	0.80	1.16	0.01	1.07
Hospitalization	0.27	0.32	0.82	0.29	0.81	0.29
Total	53.7	54.8	0.20	49.8	0.98	52.7

Table 21. Costs per patient year: touched subjects 6 months after first touch

	Arm #1 (Control) $	Arm #2 (Reports) $	Arm #2 (Reports) p	Arm #3 (Reports+) $	Arm #3 (Reports+) p	Total $
Outpatient	4839	5683	0.05	4813	0.30	5102
Emergency Department	581	515	0.78	551	0.03	550
Hospitalization	226	258	0.88	253	0.46	245
Pharmaceuticals	6518	7688	0.04	6730	0.81	6967
Total	12164	14144	0.08	12347	0.82	12864

Intervention Site Monitoring Visits, Contextual Evaluation and Report Recipient Surveys

As part of our efforts to understand how the medication management interventions function in the field, we assessed the impact of the interventions on clinic sites, support staff and clinicians as well as on care managers through periodic site visits, a contextual evaluation during month 6, and a user survey.

At the periodic site visits we monitored the delivery of reports to the point of care by directly observing whether or not a specific report was available at the time and location of a patient encounter on the same day as the site visit. We observed that the availability of reports ranged from 50% in the earlier months of the study while workflow issues were resolved up to 85% in the latter months of the trial (Table 22). At site visits we also assessed the clinicians' perceived value of the four components of the reports over time. The graphic summary of adherence carried the greatest value followed by the list of filled medications (Table 22). The recommendations from evidence-based guidelines had the least perceived value. The perceived value of the reports peaked during the middle of the trial.

Recurrent themes from the contextual evaluation regarding the impact of the reports on the clinical workflow and practice are summarized in Table 23. While the general sense was that the delivery of reports was not a significant burden or problem, all groups recognized that report "delivery" and access would be improved if the reports were available in the IT systems routinely used by the clinicians. All groups also recognized the potential value of allocating more time and personnel resources to address medication adherence issues after they were identified. Feedback from clinicians was generally positive regarding how the reports uncovered nonadherence and fostered discussions with patients about the importance of adhering to medications as prescribed. In some instances, knowledge of nonadherence influenced clinicians to not increase or change a specific medication because of apparent ineffectiveness when the actual issues was nonadherence to the medication.

Results from the clinician surveys to assess usability and usefulness of the reports are summarized in Table 24. In general, the reports were considered easy to use and understand. In addition, the reports were universally perceived as having a favorable impact on job performance though they were not perceived by clinicians as modifying their style of practice.

Table 22. Perceived value* of the components of the medication management reports over course of the study

Report Component	Month 1	Month 3	Month 6	Month 9	Month 12
List of Filled Pharmacy Claims	3.95	4.30	4.00	4.17	3.33
Numerical Calculation of Days Covered	3.77	4.04	4.11	3.67	3.50
Graphical Chart Illustrating Days Covered	3.68	4.38	4.06	3.83	3.46
Evidence-based Medication recommendations	3.64	3.12	3.30	2.33	2.60
Confirmed Delivery of Reports to the Point of Care	18 of 35 (51%)	15 of 30 (50%)	24 of 33 (73%)	17 of 20 (85%)	14 of 23 (61%)

*Value assessment based on feedback from clinicians using a five-point Likert scale with 1 = not helpful and 5 = very helpful

Table 23. Recurrent themes about interventions from contextual evaluation and site monitoring visits

Issue Addressed	Respondent: Clinic Administrators	Respondent: Clinic Support Staff	Respondent: Clinicians
Support Needs for Using Reports	• Arrange for nurse to assist with medication needs • Continued education to clinicians	• Work flow integration not an issue	• Requires 1 to 2 minute to review report • Need report at start of visit
Changes to Enable Routine Use of Reports	• Allow more time to address adherence issues • Generate higher volume of reports so more familiar to clinicians	• Availability of report in EHR • Integration into existing IT systems	• Have report available for review before visit • Need report always to be available at point of care
Barriers to Using Reports	• Reports not available in practice EHR	• Need more staff support if report volume increases • Report not in practice EHR	• Run out of time to use report • Reports arrive after encounter ends
Suggestions to Enhance Report Effectiveness	• Use nurses to address medication issues • Add reports to practice EHR	• Allow more time during visits to address medication issues • Make available for all payers	• Have reports available for all patients not just Medicaid • Integrate with EHR
Impact of Reports on Practice	[Not Asked]	[Not Asked]	• Use data in report to address adherence issues with patients • Helps identify current medications • Avoid increasing or changing medication because lack of effect due to nonadherence
Impact of Reports on patient - clinician communication	[Not Asked]	[Not Asked]	• Fosters opportunity to educate patients about compliance by showing graph • Enables clinician to directly address compliance issues with patients because of real data • Encourages honest answer from patients about medication adherence

Table 24. Clinician survey responses regarding the usability and usefulness for the medication reports

Table 24a. Category: overall reaction

#	5-point Likert Scale Endpoints			Average	SD
1	Terrible	-----	Wonderful	**3.27***	0.75
2	Difficult	-----	Easy	**3.62***	0.89
3	Frustrating	-----	Satisfying	3.09	0.90
4	Dull	-----	Stimulating	2.84	0.77
5	Slow	-----	Fast	3.24	0.98
6	Rigid	-----	Flexible	2.98	0.64
7	Boring	-----	Fun	2.91	0.56

Table 24b. Category: report organization

#	5-point Likert Scale Endpoints				Average	SD
8	Information on the report is:	Hard to use	-----	Easy to Use	**3.47***	1.10
9	Organization of information is:	Confusing	-----	Very clear	**3.39***	0.95

Table 24c. Category: navigation

#	5-point Likert Scale Endpoints	Average	SD
10	Related tasks can be performed in a straightforward manner: Never ----- Always	**3.47***	0.92
11	My orientation to the report at any given moment was: Never apparent -Always apparent	**3.31***	1.00

Table 24d. Category: user interaction with report

#	Strongly Disagree—Strongly Agree	Average	SD
12	Learning to use the report was easy for me	**3.53***	0.97
13	I find it easy to get the report to do what I want it to do	3.14	0.93
14	My interaction with the report is clear and understandable	3.30	0.76
15	I find the report to be flexible to interact with	2.95	0.71
16	It was easy for me to become skillful at using the report	3.16	0.83
17	I find the report to be easy to use	3.18	0.97

Table 24e. Category: report content

#	Almost Never—Almost Always	Average	SD
18	Does the report provide the precise information you need?	2.93	1.14
19	Does the information content meet your needs?	2.93	1.16
20	Does the report provide information that seems to be just about exactly what you need?	2.80	1.12
21	Does the report provide sufficient information?	3.11	0.91
22	Is the report accurate?	3.09	1.03
23	Are you satisfied with the accuracy of the report?	2.95	1.10
24	Is the output of the report presented in a useful format?	3.09	1.14
25	Is the information clear?	3.25	1.08

Table 24f. Category: impact on job performance

#	Strongly Disagree—Strongly Agree	Average	SD
29	Using the report in my job would enable me to accomplish tasks more quickly	**3.44***	0.99
30	Using the report would improve my job performance	**3.33***	0.90
31	Using the report in my job would increase my productivity	**3.54***	0.86
32	Using the report would enhance my effectiveness on my job	**3.30***	1.01
33	Using the report would make it easier to do my job	**3.39***	0.93
34	I would find the report useful in my job	**3.37***	1.00

Table 24g. Category: workload

#	Yes—No	# Yes (%)	# No (%)	#N/A (%)
35	Was using the medication management report time-consuming?	22(46.8)	24 (51.1)	1 (2.1)
36	Did the medication management report increase your workload?	31 (66.0)	15 (31.9)	1 (2.1)

Table 24h. Category: impact on practice

#	Yes—No	# Yes (%)	# No (%)	#N/A (%)
37	Did you order more tests than you might have done otherwise?	2 (4.3)	44 (93.6)	1 (2.1)
38	Do you think the medication management report made any lasting different to your style of medical practice?	6 (12.8)	40 (85.1)	1 (2.1)
39	Did it help to mold your approach to tackling medical problems?	10 (21.3)	36 (76.6)	1 (2.1)

Table 24i. Category: impact on patient management

#	Yes—No	# Yes (%)	# No (%)	#N/A (%)
40	Did access to the medication management report improve your knowledge of the management of patients?	27 (57.4)	18 (38.3)	2 (4.3)
41	Was your confidence in investigation of patients improved?	17 (36.2)	28 (59.6)	2 (4.3)
42	Did you find the medication management report helpful in patient care?	30 (63.8)	15 (31.9)	2 (4.3)
43	Did the patients receive better care because of the medication management report/ email notice?	22 (46.8)	22 (46.8)	3 (6.4)

* Indicates a p-value of < 0.05 for the average response score relative to a neutral response of 3.0

Power Calculations

In light of the negative results from this study, we conducted power calculations to ascertain what extent of change in medication adherence that could have occurred, but remained undetected based on the limits of the sample size. For the overall study population under the intention-to-treat analytic framework with approximately 740 subjects in each treatment group and a baseline adherence (control group) of 40.6%, we had 80% power to detect an increase in adherence of 7.2% and 90% power to detect and increase in adherence of 8.4%.[16] For the "touched-subject" framework with approximately 490 subjects per group and an overall adherence in the control group of 43.8%, we had 80% power to detect an increase in adherence of 9.2% and 90% power to detect an increase of 10.7%

Limitations

The findings of this study need to be interpreted in the context of the setting in which it was performed. This study focused exclusively on patients with one or more chronic conditions who were enrolled in Medicaid. Accordingly, the study findings may not necessarily be generalizable to other populations. While our initial proposal was to also include dually enrolled Medicare beneficiaries, the Medicare Part D pharmacy benefit started while the project interventions were still under development. As a result, we lost access to pharmacy claims for dually enrolled subjects in spite of significant effort to obtain these claims data and had to drop this cohort from the study (roughly 40% of the original study sample). In the area of pharmacy data, the study was also limited in that we did not have claims data for medications that were not covered by Medicaid reimbursement such as the $4 co-pay programs at many pharmacies. Fortunately, patients were financially incented to use their Medicaid benefit for medications because the copayment was $3 or less. Nonetheless, we have no way to determine what data on filled

medications was missing. A fourth limitation is that our system has functioned primarily by using billing/claims data as opposed to clinical data from an electronic health record system. In addition to the time delay for processing claims (roughly 4 to 8 weeks in our system), this approach represents a minimalist view of what could be possible in terms of population health management if a more comprehensive clinical dataset were available. As the breadth of clinical data available in HIEs increases, the value of proactive population health management is also likely to increase. A fifth limitation was the method of medication report delivery and the variable reliability of this method for consistently providing reports at the point of care prior to patient encounters. Because we worked with independent, geographically dispersed primary care clinics, we had to employ delivery methods that were universally available such as facsimile and email and rely on human participation to deliver reports. As a result, not all reports were available at the point of care which lessened the impact of the intervention. A sixth limitation was that we restricted the care manager involvement for medication adherence to promoting only follow-up appointments with the patients' PCP clinics. A more proactive care management intervention could have had greater impact on medication adherence. Finally, this study did not formally apply a correction factor (e.g. Bonferoni) to the level of significance for the analysis in spite of the multiple comparisons that were made, though only p-values <0.005 were accepted as significant.

Dissemination

The development, methodology and findings from this study have been disseminated through a variety of mechanisms including three peer-reviewed publications, over a dozen presentations including an AHRQ Webinar. The project publications to date are listed below. One of these publications received the award for the best poster at the AMIA Annual Fall Symposium in 2010. Major presentations included a visiting professor lecture in Buenos Aires, Argentina, and CDS panels at the AMIA Annual Symposium 2010 and the Society for Medical Decision Making 2007. In addition, the project has been written up in local newspapers.

Discussion

In this project we have demonstrated significant technical advancement for CDS for promoting medication adherence by intervening at both the level of the PCP clinic and the population. Our clinic-oriented approach advanced the field by using appointment data from an HIE to deliver adherence reports to the point of care at the time of an appointment. Most previous similar projects sent reports to clinicians' administrative offices thus failing to provide useful information in the right setting at the right time. Our project introduced a novel approach for population surveillance by weekly detection of patients with probable nonadherence to EBP who had no record of recent or scheduled contact with their PCP clinics. Through this approach we identified "lost" patients not on EBP such as patients with hypertension receiving no antihypertensive medications and patients with diabetes not on hypoglycemic agents who are potentially destined for negative outcomes. Our population-based approach engaged care managers so that the nonadherent patients could be contacted for follow up.

The findings from this study document that overall adherence to EBP for six IOM priority conditions in a Medicaid population is low and leaves much room for improvement. Unfortunately, even though we introduced technical CDS advancements, the core study

intervention, the delivery to the point of care of patient-specific reports summarizing a one-year history of filled claims numerically and graphically along with evidence-based pharmacotherapy recommendations, failed to increase medication adherence to EBP (the primary outcome for this randomized controlled trial) by at least 7.2% (80% power) across all classes of medications indicated for six common conditions using an intention-to-treat analytic framework. A population management intervention added to the reports, through which care managers were notified about patients who appeared to be non-adherent to EBP and had no recent or scheduled encounters with their PCP clinic also failed to improved adherence to EBP. We did detect that the notifications sent to care managers significantly increased the extent of contact that care managers had with study subjects. One potential weakness of this population-level intervention was that the care manager contact, by design because of licensure issues, was only to encourage patients to arrange follow up with their PCP clinic (where a medication management report would be available). Care managers were instructed not to address medication adherence issues directly because such actions would be beyond their scope of practice. Perhaps a more effectual population-level intervention would have been to engage clinical pharmacists or advanced practice nurses to directly address nonadherence with EBP.

In secondary analyses under the intention-to-treat framework, we did not detect improved adherence for any specific class of medications nor for patients with specific chronic conditions. As an additional secondary analysis designed to assess the impact of the interventions more directly, we identified patients for whom medication management reports were generated and assessed their medication adherence 6 months after their first “touch” with the intervention. Under this intervention-centered analysis we failed to show an increase in medication adherence to EBP of 9.2% (80% power) or greater. No increased adherence was detected by drug class or condition, but we did again observe significantly increased care manager contact specifically for subjects randomized to the reports-plus-care-manager-notice group.

We can conclude from our negative clinical outcome that a printed summary of medication adherence information based on filled claims and delivered to the point of care was insufficient to impact overall adherence for EBP. Three primary points of failure need to be considered: 1) the report content was not useful; 2) the reports were not effectively integrated into the clinical workflow; and 3) the clinical setting was not conducive to addressing medication nonadherence issues effectively. Based on findings from our clinic site visits, the contextual evaluation, and the clinician surveys, we surmise that the failure to impact EBP adherence was not because of report content. Our qualitative data indicate that clinicians found the medication report content helpful for addressing medication nonadherence issues and many anecdotes were provided in which the reports directly led to discussing medication adherence issues with a patient. The usefulness of the medication reports is perhaps most strongly supported by a decision of the leadership of NPCCN to fund conversion of the study interventions to an operational system so that the reports will continue to be available after this research study has ended.

While the qualitative data support the utility of the reports, they indict a breakdown in workflow as a possible point of failure. In spite of carefully analyzing work practices at each clinic site in order to customize an approach for delivering the medication reports to the point of care, we discovered from our site visits that between 15% to 50% of reports were often not available to clinicians at the time they interacted with a patient. Consequentially, patients did not receive the full benefit of the intervention because reports were not always available. As most stakeholders suggested for future effectiveness, reliable report delivery can be enabled by direct integration of the reports into existing practice IT systems. From the qualitative analysis with

regard to the third possible point of failure, we also learned that on many occasions even when reports were available clinicians did not take time to address issues related to EBP nonadherence. Accordingly, we postulate that the many competing demands during the clinical encounter may hinder clinicians from addressing nonadherence issues. As suggested in the contextual evaluation, more resources (time and personnel) and possibly other team members (e.g. pharmacists) and venues outside of the exam room may be more conducive to resolving medication nonadherence issues effectively than the reports provided to clinicians at point of care in this study.

Lessons Learned. We have learned several valuable lessons through the development, implementation and operational support of the medication management system. During development of the interventions we discovered that EBP focusing on specific conditions can lead to conflicting recommendations regarding medication use. Accordingly, we modified our rule development efforts and focused on whether or not a specific individual should receive a certain class of medication based on multiple conditions and demographic parameters. As a second lesson, we learned that conventional technologies of facsimile and email, while ubiquitous and generally available, are not sufficiently reliable to ensure delivery of clinical reports to the point of care. Integration of reports into existing IT systems, as we were able to implement for one clinic site through a document uploading mechanism in the practice EHR, would provide a more reliable mechanism to ensure that report content is available in the right setting at the right time. A third lesson was that population-level care management interventions need to involve more than just arranging for patients to have contact with their PCP clinics. While the care manager notices clearly increased contact with nonadherent patients, these contacts did not materialize into increased adherence to EBP. A final lesson is that clinical data such as clinician-documented problems from an EHR and filled claims from SureScripts™ could improve both the accuracy and the timeliness of medication adherence reports, potentially bolstering the priority of addressing nonadherence amidst the competing demands of the clinical encounter.

Significance

This study demonstrates technical advancements for CDS for detecting and managing low adherence to EBP at both the clinic and population level. In contrast to other CDSSs for medication adherence, our system is integrated into a regional HIE that allows access to clinic appointment information as well as filled medication claims and historical medical problems. The combined use of all three data sources enables us to deliver clinically valuable information to the right *place* (the point of care) at the right *time* (the start of an outpatient encounter). Using these same data sources, we also demonstrate the ability of a CDSS to provide population-level surveillance for EBP nonadherence by proactively identifying patients who are potentially lost to follow-up (no previous PCP encounters in 6 months and no scheduled encounters) and appear nonadherent to EBP relative to their known chronic medical conditions. After identifying a “lost” patient, the system notifies a specific care manager assigned to the patient’s PCP practice so that follow up can be arranged. The CDS advancements in this project are in contrast to previous CDSSs that lack appointment information and do not deliver reports in the right setting at the right time and do not selectively identify EBP nonadherent patients who are not receiving regular care. The advanced methodology of our CDSS should allow more effective and efficient use of healthcare resources. A third advancement of our technology is that the CDS rules are

implemented using Web services that are aligned with emerging national CDS standards. The Web service approach potentially allows other CDSSs to utilize the EBP rules that we created for this project in other environments. Submission of the predefined data elements to the CDS service in the standardized format would allow another system to receive the EBP recommendations.

In addition to the technological innovations, this study is also significant in that we have shown that the delivery of what should have been the right information to the right person in the right setting at the right time failed to improve EBP adherence. This finding raises the question that providing data on medication adherence and recommendations for EBP to clinicians during an outpatient clinical encounter may not be the optimal arrangement for dealing with medication nonadherence. Accordingly, we propose that equipping other care team members with relevant information in a different setting (and time frame) be considered as a potentially more effective approach for improving medication adherence. A final significant observation from this study is that the notification of care managers about EBP nonadherence can significantly increase care manager contact with these patients. While our care manager response was limited to arranging clinic follow up, this finding suggests that decision support-enabled population health management may be an effective alternative approach (given a more aggressive adherence promotion program) for addressing low medication adherence for patients outside of traditional clinic-based models of care.

Conclusions and Implications

From this project, we observed that clinicians consider reports summarizing one-year medication fill histories useful for identifying and addressing nonadherence to EBP. We also observed that population surveillance for EBP nonadherence is effective for mobilizing care managers to respond to medication nonadherence issues. However, the delivery of medication reports to clinicians at the point of care at the start of an encounter via conventional modalities of facsimile and email was not effective for improving adherence to EBP. We postulate that the clinician-driven outpatient encounter may not be the appropriate context for addressing medication nonadherence. Medication nonadherence is a complex, multifaceted problem that cannot easily be addressed in the context of a 15-minute office visit. Instead, CDSS as developed in this project can be used to detect and quantitate nonadherence to EBP. Nonadherence can then be addressed through various members of the care team such as pharmacists or advance practice nurses who are specifically equipped to deal with medication nonadherence in venues other than the clinic exam room.

While our interventions failed to improve medication adherence, we postulate from this project that population-level medication management enabled through decision support is a viable care model that could be expanded to shift care away from the current episodic clinic-based clinician-centered approach to healthcare. Accordingly, expansion of population surveillance and augmentation of the data available through an HIE could allow more extensive patient-focused care management external to clinics in venues such as the patient's home. These new models of care could lower costs and increase accessibility, as they are not dependent on scarce and expensive clinic and clinician resources.

This project has demonstrated an additional context for using the evolving HL7 Decision Support Service as a feasible tool for applied decision support. In this instance, the knowledge rules for detecting nonadherence to EBP guidelines are reusable across other applications

illustrating the portability and flexibility of the DSS approach. DSS has also been used for chronic disease management[17] and breast cancer surveillance.[18]

We suggest that additional resources should be invested to explore how the management of the health of a population enabled through decision support can be extended to improve the coordination, quality, efficiency and even outcomes of healthcare delivery in the United States and abroad.

AHRQ Priority Populations

This project primarily focused on care delivery issues for low-income (Medicaid beneficiaries), minority (65% African American) individuals living in both rural and urban settings in the north and central Piedmont region of North Carolina. Subjects in this study had to have at least one of six priority conditions identified by the Institute of Medicine (asthma, diabetes, hypertension, ischemic heart disease or stroke).

Required Information for AHRQ Improving Quality through Clinician Use of Health IT (IQHIT)

1. Clinical issues addressed by the intervention:
    a. Non compliance with medications
    b. Nonadherence to evidence-based pharmacotherapy guidelines
2. Setting of care:
    a. Ambulatory Primary Care Clinics including a Federally qualified health center
    b. Population health management through IT-enabled care managers
3. Health Professional Roles that Use and Are Impacted by the Health IT System
    a. Primary Care Clinicians (Physicians, Physicians Assistants, Nurse Practitioners)
    b. Care Managers (Registered nurses, social workers, health educators, lay care navigators)

AHRQ IQHIT Outcome Metrics

1. Percent Adoption and Use of Health IT
    a. Sixteen of the 18 originally identified clinical sites received and used the medication management reports generated by the SEBASTIAN CDS System.

b. The two non-participating sites from the same practice group implemented a new EHR system shortly before the study began and were unable to provide the scheduling data to trigger the generation of the medication reports.

c. Two practice groups (with 2 study sites each) adopted EHRs during the study and stopped sending scheduling data, one at 2 months into the study (Beckford Medical Center, 02/12/2010) and the other after 4 months into the study (Regional Pediatrics, 03/29/2010).

d. The use of reports by clinicians at each site was variable and not precisely measured.

2. Utilization of Quality Measurement Reports

a. No quality measurement reports were generated for patients or clinicians through this study.

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List of Publications and Products

Bibliography of Published Works and Electronic Resources from Study

1. Kawamoto K, Allen LaPointe NM, Silvey GM, Anstrom KJ, Eisenstein EL, Lobach DF. Development and evaluation of an improved methodology for assessing adherence to evidence-based drug therapy guidelines using claims data. *AMIA Annu Symp Proc*. 2007; 394-398.

2. Del Fiol G, Kawamoto, K, Allen-LaPointe N, Eisenstein E, Anstrom K, Lobach DF. Improving medication adherence in a regional healthcare information exchange using a scalable, claims-driven, and service oriented approach. *Proceedings / AMIA Annual Symposium.* 2010; 142-146.

3. Wood LL, Del Fiol G; Kawamoto K, Willis JM, Lobach DF. Utility of Point-of-Care Medication Management Reports Generated through a Decision Support Web Service. *Proc / AMIA Annual Symposium.* 2010; 1312. (Recipient of Best Poster Award)

Panels and Invited Presentations

International.

1. Information Technology to Support New Models of Care. Argentina Lecture, Hospital Italiano de Buenos Aires; Oct. 3, 2008.

2. Multinational, Multi-Institutional Clinical Decision Support Using a Common Decision Support Service. 2010 AMIA Annual Fall Symposium, Washington, DC; November 17, 2010

National.

3. Clinical Decision Support for Genomic and Personalized Medicine. SMDM Conference, Pittsburgh, PA. October 23, 2007.

4. Use of Clinical Support in Clinical Practice. AHRQ National Web Conference on CDS; October 27, 2008.

5. Adapting Existing CDS Approaches to Facilitate Personalized Healthcare. CDS Government Collaboratory Quarterly Meeting, Rockville, Maryland; January 15, 2009.

6. Decision Support using Web Services. AHRQ Health Information Technology Conference, Bethesda, MD; June 3, 2010.

State/Regional.

7. Information Technology to Support New Models of Care, Brown University Visiting Scholars, Durham, NC; March 4, 2008.

8. Primary Care Informatics: Supporting Physician and Patient Decision-making. New York City Department of Health and Mental Hygiene; New York City, NY; April 16, 2009.

9. Health Information Technology to Support New Models of Care. Network and Community Partners, Durham Regional Hospital, Durham NC; September 9, 2009.

10. Health Information Technology to Support New Models of Care. State Meeting of Community Care of NC, Chapel Hill; October 6, 2009.

Local.

11. Information Technology to Support New Models of Care. Biomedical Informatics Seminar Presenter, Durham, NC; Nov. 19, 2008.

12. Health Information Technology to Support New Models of Care. DCRI Research Conference, Durham, NC; May 12, 2009.

13. Health Information Technology to Support New Models of Care. Durham Health Innovations Planning Group, Durham, NC; October 14, 2009.

14. Health Information Technology to Support New Models of Care. Family Medicine Conference; December 7, 2009.

15. Health Information Technology to Support New Models of Care. Pathology Grand Rounds, Duke University Medical Center, Durham, NC, April 9, 2010.