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PQA Phase II Demonstration Project: *The Pennsylvania Collaborative*

Principal Investigator: Janice Pringle, PhD
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Sub-Contractors: RTI International and Avatar

Collaborating Organizations: Highmark, Inc.
CECity.com, Inc.
Rite Aid Corporation
Pharmacy Quality Alliance

Objectives:

1. Implement a point-of-dispensing medication adherence intervention in a chain pharmacy (Rite Aid) that is targeted towards patients using chronic medications for heart disease and diabetes (with a focus on statins, ACEI/ARBs, beta-blockers, calcium-channel blockers and oral diabetes medications). This intervention is designed to be implementable in a typical retail pharmacy so that the intervention can be expanded to a national scale after this demonstration project.
2. Evaluate the effect of the intervention on medication adherence using the PQA-endorsed adherence measures (Proportion of Days Covered), as well as the overall healthcare utilization for the Highmark members. The healthcare utilization measures will include hospital and emergency visits as well as medical and drug expenditures. The hypothesis is that improvements in medication adherence for heart disease and/or diabetes will lead to decreased medical expenditures and reduced hospitalization risk.
3. Develop pay-for-performance models for community pharmacies that is based on the findings of the healthcare utilization analyses. These models will identify the appropriate incentives and/or payment to pharmacies for achieving improvements in medication adherence for the target measures.
4. Identify the key facilitators and barriers to successful implementation of the intervention via quantitative and qualitative analyses.
5. Create a dissemination plan for the research findings, as well as a training program for the medication adherence interventions.

Design & Methods:

The study is designed to test the effectiveness and return-on-investment of the adherence interventions. These interventions will be included in the pharmacy performance improvement pathway and tracked for their effectiveness on improving upon the measure. Approximately 270 pharmacists at 120 Rite Aid pharmacies in western Pennsylvania will implement the interventions after participating in a structured training program. A control group of pharmacies in Central Pennsylvania will provide standard care (i.e.,

no adherence intervention). Data on medication adherence will be extracted from Rite Aid databases for all patients who receive the target medications and who visit one of the participating pharmacies. Highmark will provide drug claims and medical claims data for its members on the medications that make up the measures, who visit the intervention and control pharmacies. Highmark has the largest market share of any commercial insurer in western Pennsylvania so it is anticipated that there will be more than enough Highmark members at each pharmacy to provide adequate statistical power (approximately 95,000 eligible members overall).

CECity will prepare the performance reports for each participating pharmacy using the performance scores calculated by Highmark. These reports were developed as part of the Phase I demonstration projects funded by PQA and the pharmacists are familiar with the reports. The performance improvement system will allow the pharmacists to continually track their performance on the medication adherence measures. Rite Aid has also developed information technologies to assist the Rite Aid pharmacists in identifying the specific patients who are not refilling their medications on time.

The researchers from the University of Pittsburgh and RTI will utilize the Highmark data to estimate the change in adherence scores and healthcare utilization for Highmark patients at the intervention and control pharmacies (12 months pre-intervention and 12 months post-intervention). It is hypothesized that the intervention pharmacies will see an increase in adherence scores, and decrease in medical utilization, after implementing the intervention while the control pharmacies will see no change in adherence scores or medical utilization. Statistical analyses will include general linear mixed models (GLMM) and estimation of incremental cost-effectiveness ratios.

Avatar will administer a consumer experience survey to Highmark members who use the target medications and visit one of the Rite Aid pharmacies involved in the study. The survey will be distributed after the intervention period. It is hypothesized that patients who visit the intervention stores will have higher ratings of the quality of the pharmacy as compared to patients who visit the control pharmacies. The consumer experience survey was previously developed by PQA and the American Institutes of Research using questionnaire formats and evaluation techniques that are standard for the CAHPS family of measures. Avatar has experience in administering the survey and was the primary vendor for the survey in the PQA Phase I demonstration projects.

Implications:

This is a unique, and potentially powerful, study in that it examines a point-of-dispensing adherence intervention that could be replicated in almost any community pharmacy. The stakes are high since many studies have estimated that about half of patients are poorly adherent to chronic medication regimens and that poor adherence is associated with higher risk of hospitalization and excess medical spending. The study will also include an assessment of whether increased medication adherence leads to reduced medical spending and better overall value for the healthcare system.

Key elements of this project are the experience, talent, and national visibility of the collaborating partners. Rite Aid and Highmark are nationally-recognized organizations that have demonstrated their commitment to tackling the problem of poor adherence through their prior work with PQA in the Phase I demonstrations. CECity is the national leader in technology platforms for provider performance reports and guided professional development, and Avatar is the most experienced vendor in using the PQA consumer experience survey. The scholars at the University of Pittsburgh and RTI are recognized experts in program evaluation and bring credibility to the project. PQA is the key organization for pharmacy quality measurement and is able to disseminate the findings across a broad spectrum of healthcare organizations and government agencies.

PQA Phase II Demonstration Project: *The Illinois Collaborative*

Principal Investigators: Stephanie Crawford, PhD, MPH
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Collaborators: SUPERVALU (Jewel-Osco) Pharmacies
Humana
Pharmacy Quality Alliance

Background:

The goal of this project is to demonstrate the effectiveness of pharmacist-provided MTM services in improving medication adherence in diverse patient groups. This application will focus on Chicago and surrounding suburban areas. A recent study by Orsi and colleagues revealed that disparities among health status indicators grew wider between non-Hispanic Black populations and non-Hispanic Whites in Chicago from 1995 to 2000. This finding was contrary to the priority goal of reduced disparities (Healthy People 2010) and national trends. The authors speculated that Chicago is worse than other urban cities in efforts toward eliminating health disparities across diverse groups. These profound disparities make Chicago an excellent “laboratory” to assess the ability of pharmacists to reduce medication-related disparities through personalized consultations of patients from many different ethnic and racial groups.

Objectives:

1. Expand an existing pharmacist-provided medication-therapy management (MTM) program beyond Medicare members to commercially-insured members, and evaluate the impact of the MTM program on members’ adherence to chronic medications and subsequent healthcare utilization. The MTM program will be provided by Jewel-Osco pharmacists and the eligible patients will be enrolled in a common health plan (Humana).
2. Measure patient experiences, beliefs, attitudes and self-reported knowledge about medication and assess how these affect the success of the adherence intervention. If patients from different racial/ethnic groups have different beliefs about medications, then these differences will confound the assessment of racial disparities in the impact of the intervention. Therefore, multivariate analyses will be conducted to understand the complex interplay of race, ethnicity, gender, beliefs, and knowledge in modifying the effectiveness of the intervention.
3. Conduct focus groups with patients from different racial/ethnic groups to assess differences in the barriers to optimal medication adherence. Better understanding of the racial/ethnic differences in medication-related beliefs and barriers may help pharmacists optimize their MTM consultations.

Design & Methods:

The design for objectives 1&2 is a prospective, randomized, controlled behavioral intervention trial. The intervention will consist of a face-to-face MTM consultation by a clinical pharmacist at Jewel-Osco. The pharmacists have experience in providing these services to Medicare enrollees, but for this project the

MTM program will be expanded to all Humana members with heart disease and/or diabetes. Jewel-Osco stores in the Chicago metro area will be selected for the project according to census tract to ensure that a diverse group of Humana members will be eligible for the intervention. Within the selected stores, the Humana members taking the target medications will be randomly assigned to the intervention or control groups.

Data for the intervention and control group members will be extracted from the Humana data warehouse for the pre-intervention period (6 months) and the post-intervention periods (6 and 12 month periods). The drug claims will be used to measure patients' adherence to the target medications based on the PQA-endorsed measure of adherence (Proportion of Days Covered), while the medical claims will be used to measure utilization of medical services (hospital, emergency, outpatient). The costs incurred for these services and drugs will also be measured. A survey will also be conducted for both the intervention and control groups to measure the patients' medication-related beliefs, attitudes, knowledge and pharmacy experiences. Multivariate statistical modeling will be used to determine the pre-post change in adherence and healthcare expenditures while controlling for age, gender, race and psychosocial variables. It is hypothesized that the patients who receive the intervention will maintain better adherence to medications, and incur lower post-intervention medical expenses, as compared to the control group. Sub-analyses will focus on racial differences in the effectiveness of the adherence intervention.

For the third objective, the faculty from UIC will conduct focus groups of chronically-ill patients from a diverse set of racial/ethnic groups. This research will supplement the survey data collected in objective 2 to help us understand differences in beliefs, attitudes and experiences across racial/ethnic lines. The focus groups will allow for in-depth discussion of issues/themes related to patients' use of chronic medications and will shed greater light on the interplay of social and medical determinants of health.

Implications:

This project brings together a national health plan (Humana), large pharmacy chain (SUPERVALU, dba Jewel-Osco), academic scholars and the Pharmacy Quality Alliance. This partnership will have high visibility as these national leaders attempt to tackle the issues of medication non-adherence and racial disparities. The project is also likely to get significant interest from federal agencies and national collaboratives that are addressing racial disparities in health and healthcare. In particular, it will be one of the first initiatives to focus on the medication-related issues related to health disparities. If this project can identify ways of enhancing adherence to chronic medications while simultaneously reducing racial disparities in healthcare, it can create a win-win situation for all involved.

PQA Phase II Demonstration Project: *The Wisconsin Collaborative*

Principal Investigators:	David Mott, PhD Sonderegger Research Center University of Wisconsin School of Pharmacy
	James Robinson, PhD University of Wisconsin Center for Health Systems Research and Analysis
Subcontractor:	Pharmacy Society of Wisconsin
Collaborating Organizations:	Wisconsin Pharmacy Quality Collaborative McKesson Corporation Wisconsin Medicaid Unity Health Plan Group Health Cooperative United Health Care—Wisconsin Pharmacy Quality Alliance

Objectives:

The overall objective of this proposal is to examine the impact of the community pharmacist on improving medication use quality as part of a novel collaboration between payors and community pharmacists. Results can inform the future inclusion of pharmacists in community-based, patient-centered medical homes.

1. Test the hypothesis that a novel pharmacist interface with payor medical and prescription drug claims data and historical performance reporting will improve pharmacy performance on selected pharmacy quality measures in community settings.
2. Evaluate the return on investment to payors of paying pharmacists to provide non-dispensing services.
3. Examine community primary care physicians' perceptions of pharmacists providing non-dispensing services related to drug therapy in community settings.

Design & Methods:

We propose to conduct a longitudinal, quasi-experimental, non-equivalent control group trial of an innovative intervention to address medication use quality. To accomplish Objective 1, we first will identify pharmacy quality measures to include in the study. These measures will be drawn from the pool of measures endorsed by PQA as well as other potential measures of medication use quality. Next, we will develop and test an intervention that will provide to pharmacists patient names who should be the subject of quality improvement efforts and pharmacy-level performance reports on the quality measures. Patient names and performance reports will be provided via a secure messaging system and a secure website, respectively.

To test the intervention, the pharmacies will be divided into experimental and control groups. Experimental group pharmacies participate in the Wisconsin Pharmacy Quality Collaborative (WPQC), a novel collaboration between payors and pharmacists that pays pharmacists to provide non-dispensing services to patients. A demonstration of WPQC has been running since March 2008 and evaluations of the

demonstration using pharmacist provided intervention data and payor data are ongoing by our research group. WPQC will expand in 2010 to cover over 1.5 million lives in Wisconsin. Experimental group pharmacies will be exposed to the intervention for 24 months. The intervention will be provided at baseline and will be updated every 3 months (quarterly). Control group pharmacies do not participate in WPQC and will not be exposed to the intervention.. Trends in quarterly pharmacy performance on the quality measures will be examined for 18 months before the intervention and during the intervention for both experimental and control group pharmacies Difference-in-difference models at both the pharmacy and patient level will be used to examine the impact of the intervention. Additionally, mixed effects logistic regression models will be used to explore the impact of pharmacy, patient and prescriber variables on changes in pharmacy performance.

We anticipate having a total of 70 pharmacies participating in WPQC when we begin recruiting pharmacy sites for the proposed intervention. Based on previous studies we have conducted using WPQC pharmacies, we anticipate a pharmacy participation rate of 90% and an attrition rate of 5%. Thus, we anticipate having 63 experimental pharmacies participate at the beginning of the intervention phase of the proposed study and anticipate having 60 experimental pharmacies complete the entire 24 month data collection process.

There are four sources of data for Objective 1: 1) enrollment data, medical claims data, and prescription drug claims data from payors, 2) data provided by pharmacists using the health information technology (HIT) platform used in WPQC related to the validity of each patient name sent to the pharmacy, 3) website utilization data and, 4) a survey of key informant pharmacists. Payor data will be used to calculate the performance measures and track improvement in medication-use quality. The website utilization data and pharmacist survey data will identify opportunities to improve the usefulness of the web-based performance feedback system.

For Aim 2, the payor data will be used to measure the downstream economic impact of the WPQC program. Since the pharmacists will be paid for their interventions (i.e., an investment by the payors), it is important to understand whether this investment had a positive return in the form of reduced medical expenditures. Economic outcomes include changes in drug costs, and costs related to medical care service utilization (e.g. hospitalizations, ER visits, office visits).

Gaining community-based general practitioners' understanding and support of targeted medication use enhancements is important for their success. With input from the Wisconsin Medical Society, a key stakeholder in WPQC, we will conduct interviews with up to 25 community-based general practitioners to obtain their perceptions of community pharmacists providing services to improve medication use quality. The results of the interviews will be disseminated to stakeholders with the intent of expanding patient receipt of pharmacist services.

Significance:

The overall objective of this proposal is to examine the impact of the community pharmacist on improving medication use quality as part of a novel collaboration between payors and community pharmacists that is paying pharmacists for non-dispensing services. Results can inform the future inclusion of pharmacists in community-based, patient-centered medical homes (PCMH). Rather than a physical structure, the medical home is a fundamental rethinking of the way care should be delivered. Endorsed by several medical specialties, two key features of the PCMH are integrated physician-led care, and the use of clinical information systems to support care and to link providers and patients to inform both about care that was provided and by whom, and care that should be provided based on evidence-based guidelines and decision support. A recent report described a community-based medical home concept whereby physicians refer to and collaborate with a network of community-based professionals and agencies for needed services for patients. The linkages created and tested in the proposed study between community pharmacists, payors and physicians can give an early indication of how pharmacists may contribute to improved medication-use quality and better healthcare value in a PCMH.

PQA Phase II Demonstration Project: *The Tennessee Collaborative*

Principal Investigator: Lawrence Brown, PharmD, PhD,
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Co- Investigators: Brad Tice, PharmD,
&
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PharmMD

Collaborators: HealthSpring
eRx Network (an Emdeon Company)
Pharmacy Quality Alliance

Overview:

The goal of this project is to demonstrate the effectiveness of telephonic pharmacist-provided MTM interventions, when triggered by “real-time” clinical rule algorithms, in improving pharmacy quality metric performance and health outcomes in the Medicare Advantage population and quality metric performance in the Stand-Alone Prescription Drug Plan (PDP) population. MTM interventions will be conducted for patients throughout the United States who patron all types of community pharmacies. MTM interventions will be provided for HealthSpring MAPD patients in Alabama, Florida, Illinois, Mississippi, Tennessee, and Texas and for PDP patients nationwide

Background:

Although there is a role for face-to-face MTM services provided by community pharmacists, given the challenges of time-constraints on community pharmacists, there is also a role for person-to-person MTM services provided by a pharmacist telephonically. Telephonic interventions provide a level of patient convenience, since the patient does not have to make an appointment or travel to a pharmacy. Telephonic interventions, when provided by non-community pharmacists, provide a level of efficiency in that the pharmacist is not faced with the need to fit interventions in between filling prescriptions. In addition, when clinical rules run on the pharmacy claims database from a central location are used to trigger the interventions, the interventions are done in a systematic and rational fashion rather than needing to rely on the community pharmacist to notice the need for an intervention.

Objectives:

1. Determine the effectiveness of telephonic MTM interventions, triggered by clinical rules, on improving quality metrics in the Medicare Advantage population
2. Determine the effectiveness of telephonic MTM interventions, triggered by clinical rules, on improving health outcomes in the Medicare Advantage population
3. Develop the specifications for an actuarial modeling of a pay-for-performance model.
4. Evaluate the feasibility of using pharmacy claims data from a switching company compared to health plan provided claims data

Design & Methods:

This project will be an 18-month single group pre-post outcomes-based intervention study of telephonic interventions provided by a network of contract pharmacists throughout the United States. The study will be from the Health Plan perspective in that it seeks to identify improvement in quality metrics and health outcomes for HealthSpring’s MAPD, and quality metrics improvement for those patients enrolled in

HealthSpring's Nationwide PDP. Pre-period data will include Jan 1, 2009 to Dec 31, 2009. Post-period data will include Jan 1, 2010 to Dec 31, 2010.

Inclusion criteria:

1. Continuously enrolled in HealthSpring's MAPD/PDP plan from Jan 1, 2009 to Dec 31, 2010.
2. Eligible for MTM services based on HealthSpring's 2010 eligibility requirements

Exclusion criteria:

1. Patients who did not meet HealthSpring's MTM eligibility requirement in 2009
2. Patients who did not utilize a pharmacy that is contracted with Emdeon in 2009 and 2010

The model for reporting outcomes will be based on actuarial methodology. PharmMD's platform facilitates all of the CMS 2010 Call Letter requirements for MTM and includes a custom-developed documentation system platform that has an appointment and soft-phone system integrated into the system. PharmMD's system will maximize the ability of pharmacists to deliver the services by identifying the patients that need intervention through auto-creating drug therapy problems and interventions that can be standardized.

Clinical rules will be created for each of the 15 NCQA validated PQA measures. On a regular basis each clinical rule will be run on the HealthSpring prescription claims data. Once one or more clinical rule(s) is triggered for a patient, an intervention assignment will be sent to the consultant pharmacist responsible for that patient. The contracted pharmacist will contact the patient for the purpose of resolving the drug therapy problem that triggered the clinical rule, as well as conduct a comprehensive medication review of all of the patient's medications for the purpose of identifying other drug therapy problems that might exist but for which a quality metric does not exist.

The data used to determine clinical and economic outcomes for MAPD patients will be medical and prescription claims data provided by HealthSpring, and additional claims data, provided by Emdeon, which provide medications outside of the claims data. Emdeon claims data will include claims that are outside of the data provided by HealthSpring as well as cash prescriptions (such as \$4 scripts, non-covered scripts, and donut-hole scripts). Quality metrics performance for MAPD and PDP patients will be analyzed using Emdeon prescription data.

Significance:

This study is significant in that it seeks to quantify the improvement in health outcomes and quality metrics that can be achieved via person-to-person telephonic MTM interventions and compare them to the results of the 2009 MTM program that only included prescriber interventions. The intervention process used in this study is significant for several reasons: 1) real-time centralized running of clinical rules will ensure that each opportunity for intervention is identified and forwarded to a contracted pharmacist for action; 2) real-time centralized running of clinical rules allows for daily tracking quality metrics; 3) using contracted clinical pharmacists allows for interventions to be conducted in a more time efficient manner; 4) interventions will not only address the drug therapy problem that triggered the clinical rule, but will also include a comprehensive medication review of all the patient's medications and quarterly follow-up calls; 5) clinical rules will be created so that we can address and measure all 15 NCQA validated quality metrics; 6) having access to medical claims data from HealthSpring will allow for healthcare savings and return on investment analysis; 7) the interventions will be conducted for MAPD patients in six states and PDP patients from around the nation who patron all types of community pharmacies; and 8) using Emdeon claims data will allow us to identify cash prescriptions, such as \$4, non-covered, and donut hole scripts.