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Examining Issues of Cost, Target Populations, and Collaborative Implementation of Medication Therapy Management Services Interventions

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Examining Issues of Cost, Target Population, and Collaborative Implementation of Medication Therapy Management Services Interventions

A dissertation submitted in partial satisfaction of the requirements for the degree of Doctor of Philosophy in Health Services

by

Deborah S. Ling

2012

ABSTRACT OF THE DISSERTATION

Examining Issues of Cost, Target Population, and
Collaborative Implementation of
Medication Therapy Management Services Interventions

by

Deborah S. Ling
Doctor of Philosophy in Health Services
University of California, Los Angeles, 2012
Professor Robert M. Kaplan, Chair

ABSTRACT

This dissertation consists of three studies, each applying a different method, to evaluate the use of pharmacists on the primary care team for people with chronic health conditions, such as high blood pressure and diabetes. Pharmacist interventions, also called Medication Therapy Management (MTM) services, are the subject of considerable current debate in health reform policy. Major associations representing pharmacists are advocating for legislation that will establish reimbursement for MTM services for a wide range of chronic conditions. The studies included in this report address unanswered research questions regarding 1) whether enough evidence exists to conclude that MTM services interventions will result in cost savings and significant

return on investment, 2) which patient populations might benefit most from MTM services interventions, and 3) what are the challenges associated with the implementation of these types of MTM services in collaborative partnerships with public and private community health entities.

The first paper in the trilogy examined the existent literature on the cost-benefits of MTM programs. The findings suggest that existing economic studies of MTM services are lacking in quality and additional high-quality cost-effectiveness research work needs to be completed before there is enough evidence to support reimbursement and policy changes.

The second study considered whether different populations of people who have commercial health insurance, Medicare insurance, or Medicaid insurance who take long-term medications were more or less likely to receive medication monitoring. Presumably, those who take long-term medications but may not be receiving proper monitoring could benefit from interventions such as MTM services. Through quantitative regression analysis, it was determined that for populations on widely prescribed medications, such as angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), and diuretics - those with commercial insurance were almost three times less likely to be monitored than those with Medicare insurance. Also, significant effects on medication monitoring were found for important patient characteristic covariates including gender - females less likely to be monitored, age - older age associated with lower likelihood of monitoring, and income - higher income associated with higher likelihood of monitoring.

The final study examined the efforts of a multi-sector collaborative partnership implementing an MTM services intervention using community pharmacists to assist with treatment of a population of school district employees and their dependents who have diabetes in San Diego, California. Contextual, resource, leadership, and internal conflict factors were evaluated with qualitative analysis to determine their effect on the abilities of the partnership to complete its initiatives. New contributions as a result of this research include developing a cost model to provide MTM services, quantifying relationships between health insurance status and medication monitoring, and revealing practical lessons on implementation of MTM models. This work provides an objective view on these subjects while adding to the growing number of studies on incorporating pharmacists on the primary care team.

The dissertation of Deborah S. Ling is approved.

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Steven Shoptaw

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2012

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"Targeting Hotspots of Poor Diabetes Care for Latinos in Southern California" Ling Grant DS, Presentation, AcademyHealth – National Research Services Award, June 2010.

"Developing a Text Messaging Risk Reduction Intervention for Methamphetamine-Using Men who Have Sex with Men (MSM): Research Note" Reback CJ, Ling Grant DS, Shoptaw S, and Rhode J. (2010) Open Aids Journal, 4, 116-122.

Neuropsychiatry of Alcohol and Drug Abuse. Ling W, Compton P, Rawson R, Wesson DR (2003). In: RB Schiffer, SM Rao & BS Fogel (eds.) *Neuropsychiatry* (2nd ed 893-933); Baltimore, MD: Lippincott, Williams & Wilkins.

Performed extensive literature review and co-wrote sections on stimulant treatment and research

References, awards, teaching experience, additional skills, and other publications/presentations available on request.

INTRODUCTION

The traditional role of the pharmacist has been expanding beyond medication product delivery to include more comprehensive evaluation and counseling, immunization administration, provision of health maintenance and lifestyle information, reduction of adverse drug events, medication management, care coordination, and follow-up patient care. The inclusion of pharmacists on the primary care team has been described as useful to the primary care physician and to patients. This pharmacist-physician team-based care is also known as “Medication Therapy Management” (MTM) services. The use of pharmacists in these expanded roles has been a subject of recent debate in health reform because the official policies and structures for reimbursement for MTM services are not established for non-Medicare beneficiaries. Supporters of MTM services would like to show health policy makers that establish reimbursement rates for procedures (Current Procedural Terminology codes) that these services not only lead to better health outcomes in patients that need better medication monitoring, but also that they lead to cost-savings or significant return on investment. In addition, those that support MTM programs would like to create models for how they might be implemented in applied settings in order to bridge the gap between research on MTM services interventions and their translation into practice. Research is still underway and the evidence-base is still being formed on the cost-effectiveness of MTM services, their impact on health outcomes, and feasible models for implementation in the community.

This dissertation work consists of three preliminary studies that address some of the larger questions relevant to the cost-effectiveness and impact of MTM services on patient outcomes.

The first study is presented in two parts. The first part is a critique of the existing evidence-base on the cost-effectiveness of MTM services. Specifically, articles and pooled analyses that report specific figures on return on investment are evaluated using common criteria. These criteria include strength of the study research design, inclusion of comparison/control groups, sampling methodology and treatment of participants lost to follow-up and attrition, and cost estimation methodology. The second part of this report is the presentation of a cost-model for financing in-physician office MTM services interventions from the payer perspective. The per member per month cost resulting from the model is put into context by comparison to costs for other types of programs to be potentially mandated as part of health insurance coverage programs. This study makes an original contribution by offering a novel cost analysis and the specific, objective critique of existing economic studies of MTM services.

It remains unknown which patient populations are most likely to benefit from more intensive medication monitoring such as that provided by MTM services interventions. More studies must be performed on target populations needing these services to see if a significant improvement in health outcomes results. The second study addresses the question of which target populations might benefit from MTM services by analyzing a large patient dataset consisting of people taking the following long-term medications: angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) used to treat hypertension and diabetes, digoxin used for

cardiovascular conditions, diuretics for heart disease and congestive heart failure patients, and anticonvulsants used to treat neurological disorders. Patients are divided into groups according to each therapeutic agent class and also into an aggregate group of those take ACE/ARB, diuretics, and digoxin and regression analysis is used to determine whether having a specific type of health insurance is significantly associated with being properly monitored on the long-term medication. In addition, the analysis includes bivariate associations and inclusion of patient covariates in the regressions including age, gender, and income. These data have not been described elsewhere and this study provides important new contributions on significant associations between health insurance type and medication monitoring.

The third study is an examination of the efforts of a multi-sector collaborative partnership consisting of public and private partners to implement a medication therapy management (MTM) initiative for people with diabetes in San Diego County in California. A conceptual framework of collaborative implementation is used to form hypotheses about the contextual, resource demands, leadership style, and internal conflict factors that affect this unique community collaboration's potential to implement its initiatives. This study uses qualitative investigation to provide insight into how physician medical groups, health plans, community organizations, and commercial health services providers might work more effectively together to improve quality and produce cost-savings. The nature of qualitative study has allowed for detailed insight into organizational and management challenges over the course of the development of the pilot. Qualitative inquiry allows for collection of specific information on how each partner might deal with these issues and what other potential problems may arise as a

result. Details on negotiation and insight into the working and management style of partners are not easily observed with quantitative study.

These studies together present a cohesive investigation of three important aspects of how MTM services might be practically implemented in real-world settings. It is important to understand how payers will cover the costs of the intervention, which patients will be targeted, and how the intervention will be feasibly implemented into the community. These studies will provide important groundwork for more comprehensive research to be undertaken to bring MTM services into applied settings. Potential future studies are discussed in the concluding section following the presentation of the three studies in the next chapters.

Critique of Cost Effectiveness Analyses of

Medication Therapy Management Services Interventions

INTRODUCTION

The epidemic of diabetes mellitus has had profound effects on the health of populations and the costs of health care. Approximately 8.3% of the U.S. population has received a diagnosis of diabetes (about 25.8 million people) according to the 2011 National Diabetes Fact Sheet by the American Diabetes Association. The fact sheet also reports an additional 7 million people have undiagnosed diabetes and 79 million people have pre-diabetes using both fasting glucose and A1c levels.[1] In 2007, the costs of medical treatment were $174 billion, not including loss of workplace productivity, early disability, or morbidity.[2] These figures illustrate the huge humanistic and economic burden diabetes places on the U.S. Further, there is also evidence that people with diabetes are not receiving the care they should. For example, the Agency for Healthcare Quality and Research (AHRQ) recently released state health care quality snapshots.[3] They estimate the quality of diabetes care processes for people with diabetes in California is “weak” on the baseline year in comparison to other states (Figure 1).

Despite a mature managed care market, abundance of well-trained practitioners, widespread availability of medical technologies, and well-resourced quality improvement initiatives, California health care plans rank relatively poorly on many of the diabetes quality of care measures reported in the Healthcare Effectiveness Data and Information Set (HEDIS) in comparison to the best performing plans in the nation. Performance varies considerably in different regions and between plans, but in the last four years no California health plan other than Kaiser Permanente has ranked among the top ten plans in the nation or above the 90th percentile for diabetes performance measures.[4]

Examination of costs and benefits for patients and payers is an important part of diabetes program comparative effectiveness and outcomes improvement evaluation. Currently, the level of reimbursement for diabetes programs varies but is virtually nonexistent for the uninsured or underinsured.[5,6] Most payers do not specifically cover diabetes disease management programs. Health plans that do invest in programs may not be the ultimate beneficiary of the potential cost reductions, including fewer ER visits and hospitalizations. Therefore, it is often difficult to justify the high initial costs to implement these programs even if they are shown to be clinically effective as evidenced by tighter blood glucose control and/or lower blood pressure.

Medication Therapy Management (MTM) services are interventions that involve pharmacist-physician team-based care. These programs are designed to improve the quality of medication therapy management services for the complex medication regimen required of patients with chronic diseases.[7,8,9,10,11,12,13] MTM is a range of services provided to patients to optimize therapeutic outcomes and to detect and prevent costly medication problems. MTM services do not operate under a common protocol. For example, some programs stipulate a face-to-face visit with the pharmacist and providers while others suffice with a phone consultation. Most MTM programs generally include: a) review of all medications used whether prescribed or over-the-counter and any herbal products to identify and address medication problems, e.g., incorrect use, duplication or unnecessary medications, need for medication for untreated condition; b) medication-related education provided to patient, family or caregivers to ensure proposed use of medications; and c) collaboration with physicians and other health care providers to develop a plan to achieve optimal goals of medication therapy for the patient.[14]

Interest in MTM by insurers, payers, providers, and policymakers is based on a growing number of studies that suggest MTM services can be effective in improving outcomes and lowering costs.[9,15,16,17,18,19,20] For example in California, the Center for Self Care in the University of California San Francisco Department of Clinical Pharmacy has been a leader in working with union trusts, self-insured employers, community clinics, and larger payers to explore new ways to increase access to MTM services through tele-pharmacy and community pharmacy and to achieve greater efficiencies in its operations to further improve return on investment.[21,22] A pooled assessment of the Center's experience across these MTM practice settings shows success in reducing mean hemoglobin-A1c (Hb-A1c) from 8.5 to 7.3 ($p<0.001$ pre/post), amounting to a 34% reduction in microvascular risk, as well as significant improvements in blood pressure and low-density lipoprotein (LDL) reductions, with net savings in disease-related medical claims costs of about 38%.[23]

The purpose of the first section of this report is to critically evaluate the support for claims that pharmacist-physician intervention models result in a significant return on investment compared to the usual standard of care in the managed care population. Some published studies report the return on investment ranges from $3[24] to $12[9] for every $1 invested. However, we intend to show these savings may be overstated as a result of potential inaccuracies in the cost-estimation methodology and weak study designs. This report does not address specifically the limitations in current work on safety or clinical effectiveness of MTM services for diabetes and cardiovascular disease care. Evidence exists for implemented programs that are successful in reducing HbA1c,

LDL-cholesterol levels, incidence of adverse events, and achieving improved blood glucose control.[25]

The second part of this report offers a hypothetical cost model of MTM programs applied in a smaller (1,000 member) or larger (50,000 member) managed healthcare plan. This model could be cost-effective for adults age 18 and older who have been diagnosed with diabetes or other chronic disease in the managed care population. The model is constructed such that a low-cost/low-intensity intervention is implemented with a larger population of diabetic patients and a higher-cost/higher-intensity intervention be delivered only to a select group. This cost analysis takes a payer perspective and the model estimates and assumptions are specified. A sensitivity analysis is performed using a low and high range of MTM services intensity and cost. The resulting estimated per member per month increase in premiums is placed in context with a comparison to the increase estimated by implementation of other proposed health insurance benefits programs analyzed by the California Health Benefits Review Program (CHBRP).

BACKGROUND

The largest MTM services program was established under Medicare Part D and administered by the Centers for Medicare and Medicaid Services (CMS) under the 2003 Medicare Prescription Drug Improvement and Modernization Act.[14] Providers and pharmacists can receive reimbursement for MTM services using three Current Procedural Terminology (CPT) codes that were established in January 1, 2008: a) 99605: Medication therapy management service(s) provided by a pharmacist face-to-face with the patient, with assessment and intervention if provided for initial 15 minutes with a new patient; b) 99606: initial 15 minute visit with an established patient; and c)

99607: each additional 15 minutes of the visit.[26] These three codes are listed in the 2011 CMS Medicare Fee Schedule, but accompanying non-facility relative values are not listed to convert into MTM payments.[27]

For 2012, CMS has approved MTM to be provided to Medicare Part D (and certain Medicare Advantage plans) for patients who have multiple chronic conditions, are taking multiple drugs covered by part D, and are identified as likely to incur annual costs that exceed $3,000. The 2012 threshold ($3,000) was lowered from the previous $4,000.[14,28] All targeted Medicare beneficiaries are now enrolled in these MTM programs unless they specifically opt-out.[29,30] Commercial and prescription drug plans who choose to offer MTM services to their enrollees can decide upon their own eligibility requirements. For instance, Humana offers MTM services to patients who have at least two chronic conditions, take five or more chronic, systemic part D medications, and will incur part D medication expenses exceeding $4,000 (2008 figure).[31]

Since commercial plans can determine their own eligibility requirements, services provided as MTM vary widely which makes comparability of programs difficult. CMS has mandated that MTM services must be paid out of administrative services which could also include non-pharmacy expenses such as marketing and sales, crossover fees, uncollected beneficiary premiums, and direct and indirect administrative expenses. Plans must also report to CMS on the fees paid to MTM programs.[30,32] The current CMS memorandum on MTM program development and submission for approval provides a description of the real-time medication review protocol, but does not include mandates regarding in-person review (MTM services can be performed by telephone) nor for time required per consultation. The manual also indicates MTM services can be

provided by pharmacists or other qualified provider.[29,30] Several pharmacy associations have attempted to interpret the CMS guidance in order to develop specific requirements for MTM programs and payment rates, but to date, the services provided to Medicare beneficiaries and payment for these services varies widely.[7]

MTM Services and Healthcare Reform Today

Major stakeholders in the pharmacy industry wrote a letter to the U.S. Congress in February 2010 requesting provisions for MTM services and "sufficient product reimbursement" for pharmaceuticals in the House and Senate health reform bills.[33] As evidence of the cost effectiveness and return on investment for MTM this letter cited the one study that reported a $12 return on investment for every $1 invested in MTM.[9] This study by Isetts and colleagues was mentioned in the industry letter to Congress and in several other articles[33,34,35] as a prime example of how investing in MTM services can result in overall savings. In addition, the most recent economic review of MTM services published in 2010 cites substantial cost savings to health plans and a significant return of $8 on average for every $1 invested in MTM for patients with chronic diseases.[36] Another study reports benefits including reductions in medical resource utilization of 39% fewer emergency room visits and 24% fewer hospital admissions for patients with diabetes.[35] Because of the importance of these studies and recent economic reviews, we examine them critically. Specifically, this critique focuses on cost savings, cost avoidance, and reduction in medical resource utilization cited in past cost-effectivness reviews and analyses of return on investment in MTM services.

Part I - Critical Review of Past Studies

The complexity of the health care delivery system, the existence of disease comorbidities, and variations in quality of medical care for chronic diseases makes it challenging to use the ideal randomized controlled trial as the methodology for evaluation of return on investment for MTM services. Further, the National Committee for Quality Assurance and CMS have recognized the difficulty in conducting such trials within health plans. Given these difficulties in pursuing the most rigorous design, most studies of MTM services return on investment have employed a pre-post methodology. However, many of these studies contain flawed methodologies or assumptions that fail to protect against well know biases. A report by Fetterolf and colleagues discussses how a historical control methodology can be correctly applied using health plan data, especially in the case of evaluting population based programs where a randomized controlled design is not feasible. They discuss the most common errors of selection bias, outcome calculation issues, and incorrect use of claims and insurance data when perfoming pre-post cost analyses.[37] Many of these issues are highlighted in the discussion of specific studies of cost-effectiveness of MTM services in this report.

Criteria for Review

We employ common criteria to review individual studies (see Table 1) included in this report. These studies were chosen because they have been cited repeatedly as the greatest support or make specific claims for the return on investment to be expected from engagement in MTM services programs. In the evaluation of studies, we consider the strength of the study design and the associated potential threats to internal and external validity[38,39] and seek to determine: a) Is the study design pre-experimental,

quasi-experimental, or experimental? b) Was any comparison group included? Could it be considered an equivalent control group? c) Was loss to follow-up an issue in the trial? How did the researchers choose to handle attrition? d) What is the basis of the study cost estimates? What figure was used as the denominator? The final section of this critique evalautes meta-analyses and multi-paper reviews on the cost effectiveness of these types of MTM interventions and highlights the ways these could be improved by reporting more specfically on the flaws the authors recognize are present in their reviews.

Basis for Study Inclusion

This review begins with "The Asheville Study" which has been described in several publications [18,40,41] and has been particularly persuasive to some. The Asheville Project has helped gain support and was the model for a number of related projects including The Diabetes Ten City Challenge, described as "Beyond Asheville: A Successful Replication of a Health Management Model that Benefits All Stakeholders."[42] The Asheville Model is a community-based pharmacy-physician collaborative services intervention and the published reports describe clinical and economic outcomes of a pre-post assessment conducted in twelve community pharmacies serving two pooled employee groups. Patients met with community pharmacists and diabetes educators and fees were waived for all diabetes drugs and related supplies. This critique focuses on the economic results of the five-year (1996-2001) longitudinal outcome assessment on a diabetic population. The Asheville studies represent an important step towards development of MTM programs, as they have become the basis of support for other interventions and expanded implementation of

MTM services models in multiple cities and settings.[42] However, there are several notable issues in the Asheville study design and execution.

This critque also includes a 2001-2002 study reporting clinical and economic outcomes of MTM services for Blue Cross Blue Shield (BCBS) patients with chronic diseases who participated in a 12-month trial in Minnesota. The authors calculated an impressive $12 return per $1 invested from the BCBS perspective, without inclusion of co-payments or deductibles paid by the patient.[9] This $12 return on investment result was cited in the 2010 letter to Congress[33] from major pharmacy industry leaders and was amongst the studies showing improvement in economic outcomes in the most recent economic review by Chisholm-Burns et al. [25] Unfortunately, the letter and the review did not include any specific critique of the study design, nor how the $12 return on investment figure was derived.

We also include a 2010 article on an innovative business model in which pharmacists at a community hospital based health system provided MTM services for employees of local companies. The model included contract agreements with company benefits departments to provide MTM services for participating employees. Johannigman and colleagues reported direct cost savings of $253 per patient per year and a return on investment of $2.21 per $1 spent. These findings are based on the first year of results from employees of three companies who participated in the wellness programs.[43]

Next we examine the paper authored by employees of the largest private MTM services provider, Outcomes Pharmaceutical Health Care, which has emerged as a leader in the design, delivery, and administration of MTM programs. To date, over 30

health plans have adopted their unified MTM platform which links plans to 39,000 chain, independent, consultant, and health system pharmacy providers. Outcomes even offers a product guarantee where its MTM pharmacists will achieve specific performance levels or refund shortfalls back to the client. They will offer clients a dollar-for-dollar guarantee for drug product cost savings alone as a proof of concept in year one. In other words, for every dollar spent on the Outcomes MTM Program, they will demonstrate at least equal to that amount in drug product savings, or they will offer the client the difference. The typical Outcomes client, according to their website, experiences an annual overall return on investment of $4.73 for every $1 spent on their program. Or, for every $1 spent, the client realizes $1.87 in drug product cost savings alone.[44] To explore these results more closely, we look to a recent article authored by Outcomes employees. This paper provides an analysis of Outcomes MTM services from seven years (2000-2006) and includes the results of their estimated cost avoidance and return on investment model.[7]

Finally, a recent article in *Health Affairs* reports on the findings of a Centers for Medicare and Medcaid demonstration project in Connecticut in which nine pharmacists worked with 88 Medicaid patients on drug therapy problems between July 2009 and May 2010. Their main economic finding was an estimated annual savings of $1,123 per patient on medication claims and $472 per patient on medical, hospital, and emergency department expenses. The authors state this was enough to pay for the contracted pharmacist services.[45]

Study Design Issues

The associated strengths and weaknesses of basic study designs are related to ease of execution and transferability of the intervention to real-world applications. *Pre-experimental designs*, such as a one-group pre-and post-test intervention, are often easier to perform and can be a more economical choice for researchers wishing to generate hypotheses regarding the effectiveness of an intervention. However, because participants are not randomized and the design often does not have a control or comparison group, there is an inability to adjust for baseline differences in groups. Pre-experimental designs are considered the weakest design choice because most importantly, the cause and effect relationship betewen the intervention and the outcome cannot be conclusively established. *Quasi-experimental designs* offer more flexibility and may be feasible where randomization is not possible. Two group pre- and post-test designs are common quasi-experimental designs. Where there are repeated measures and comparison groups, one can assess the equivalence of the groups at baseline. However, quasi-experimental designs lack the benefit of random assignment or baseline group equivalence and may be subject to multiple-group threats to internal validity. *Experimental designs* are generally considered the strongest study designs since they include randomization and have the benefit of reduced heterogeneity resulting from selection bias. Randomized designs with repeated measures allows for assessment of baseline equivalence of groups and those without repeated measures are subject to less bias or measurement error. However, experimental design studies are often expensive and difficult to execute. Some randomized studies may also have limited external validity if they are performed in highly controlled conditions.[38,39]

Researchers must choose their study designs keeping mindful of the feasiblilty to randomize groups and cost and ease of execution of the trial.

Most of the studies included in this critique employed designs considered to be weak in terms of internal and external validity. None of the studies employed experimental designs; four would be considered pre-experimental designs with a one group pre-post design[9] or one group post-test only design[7,43,45] and one used a quasi-experimental two group pre- post-test design.[18] As examples, the Asheville study was a pre-post assessment and the most recent demonstration project in Connecticut was post-test only. [18,45] The economic review of clinical pharmacy services by Perez et al. also recognizes that the studies used to derive their benefit to cost ratio are of quasi-experimental or pre-experimental designs.[48]

Comparison/Control Group Issues

The articles examined in this critique did not include equivalent comparison groups or control groups consisting of patients who did not receive the pharmacist intervention. Historical controls were used in two of the studies. [18,45] For example, in the Asheville study, the rates of cardiovascular events were compared during the trial to these rates in the same people before entering the study.[18] The use of the patients as their own historical comparison is problematic because we know that patients who volunteer for a program often do so because they feel ready to make lifestyle changes. These patients could have already felt incentivized to make health changes prior to participating in the study. This same issue can be applied to the method of cost estimation in the Connecticut study using claims made by the study group in the previous year.[45] Even with these flaws, the inclusion of a historical comparison group

is an improvement over no comparison group, which was the case with the remainder of the studies in this critique.

Two of the studies missed opportunities to strengthen their study designs with comparison groups or controls. From a convenience sample of 50 plan sponsors, the Outcomes paper reports on a total of 76,148 claims for 23,798 patients. The article represents the first results from a nationwide sample of MTM services claims submitted over seven years.[44] There is potential for this longitudinal data to show important cost benefits of MTM services and demonstrate the increasingly important role of the community pharmacist with creation of equivalent comparison groups. Also, the study by Johannigman and colleagues seemed to have missed an opportunity to include a control group, since all employees participated in a "baseline wellness visit"[43] where non-participants could have been easily separated and described. In both of these cases, the current study design did not take advantage of the opportunities to create comparison groups and complete a more rigorous cost analysis with the available data.

Sampling and Attrition Issues

Several selection issues and problems due to attrition of patients and loss to follow-up are present in the Asheville study. The economic study portion included 164 patients at baseline but only 28 patients (17%) were still participating by the fifth year. Total mean direct costs reportedly decreased by $1,200 to $1,872 per patient from baseline. Substantial improvements in lipid levels and and signficant cost savings with maintenance for up to five years are also reported.[18]

Not only was attrition an important factor, with only 17% of the original patients included in the final mean direct cost calculations, but also it is likely these participants

were highly self-selected.[18] No separation of incident versus prevalent cases, selective loss to follow up, and selection bias may have affected the study results.

At each follow-up period, a mean cost was reported for the group with different numbers of patients participating in each period according to the results tables.[18] This suggests that some patients participated in some follow up assessments and not in others which introduces an important bias.

Sampling issues were likely present in the study reporting $12 return on investment. The authors examined claims for 186 of 285 total patients who were continuously enrolled during the whole study period and one year before. Those that were not continuously enrolled were not included and were described as having "experienced some type of change in their health benefit converage."[9] The authors report the costs incurred by the MTM services group before and after the intervention, but no evaluation was made in relation to a control or comparison group. Regretfully, there was no disucssion or description of those who were included in the economic claims group versus those that were not. It is possible that those who were continuously enrolled and included in the economic analysis were more motivated to control their disease and file fewer claims than those who were not continuously enrolled or those who dropped out.

In the study by Johannigman and colleagues, the number of participating employees in each company was very small in two companies (n=21 and 23) and larger in the third company (n=168). The average cost savings and clinical measures were unweighted between the three companies.[43] Patient self-selection into the study group and potential effect of regression to the mean are other possible biases in this study. A

description of participant characteristics was missing from the report even though the following information is reported to the employer prior to their agreement to participate: demographic data, number eligible for MTM program, and number of high risk patients.[43]

The recent study in Connecticut does not describe the method for how the 88 patients included in the sample were selected. Information is also not provided on attrition or loss-to-follow up over the course of the trial.[45] These details are important especially in the determination of those who might be included or excluded from the economic analysis. If only patients who complete the trial are included in the estimation of cost, an important selection bias is introduced.

Cost Estimation Methodological Issues

We described the effects of attrition and selection on the cost estimation figures in the Asheville study described above. In addition, annual direct patient costs ranged from zero to several thousand dollars.[18] This is an unusual lower limit if all were required to have at least one pharmaceutical care visit, one baseline visit, and one follow-up visit to be included in the analyses. Also, patient costs were annualized for a third of the total patients (9 of 28 total) who had at least six months but less than 12-months of data. Finally, the results indicate patients with higher baseline costs experienced the most cost savings, a finding which could be a result of regression to the mean.

The cost avoidance figures described in the Outcomes paper were derived using self-rankings by the participating pharmacists. Specifically, the cost avoidance level in the Outcomes paper is estimated by the pharmacist using a self-reported test for

"reasonable and foreseeable" avoidance of an outcome for each claim. There are eight estimated cost avoidance levels ranging in severity from "Level 1 – Improved quality of care" to "Level 7 – Avoided life-threatening event." In addition, a final level indicates "prescriber or patient refusal of recommendation." Over the course of the seven year period, results for these eight cost avoidance levels are only reported every two years (2000, 2002, 2004, and 2006). The strong majority in all reported years (85.1%, 76.0%, 86.2%, and 66.1%) are Level 1 claims – meaning that the pharmacist completed patient education or monitoring whether classified as a therapeutic success or failure, all comprehensive medication reviews, and all other interventions that *do not* result in any reasonable and foreseeable cost avoidance. The Level 2 claims which "reduced drug product costs" are the next highest category of the seven estimated cost avoidance levels. These do not increase gradually (9.6%, 2.9%, 2.1% and 15%), but do show a spike in 2006. Of note, the "prescriber or patient refusal" category is a sizeable proportion of the claims for each year (2.4%, 19.5%, 7.1%, and 8.4%). An increasing proportion of MTM pharmacists self-rated their claims as involving higher cost-avoidance items between 2000 and 2006.[7] The authors were not sure of the reason for these sharp increases in 2006.

Unfortunately, cost estimation methods are not well-described in many of the cost effectiveness studies written on MTM services. For example, in one study the incremental cost to provide MTM services was $240 per patient per year, but the source for this figure was not provided.[9] Also, in the most recent study in Connecticut, the annual drug claims costs and total health care costs for the Medicaid participant in the previous year are listed as an aggregate number and there is little explanation about

how the figure was derived. Estimates of the costs for the study year were extrapolated and subtracted from the previous years' costs and then divided by the total number of participants (n=88) to arrive at the $1,123 in savings per patient on medication claims. This estimation method is subject to selection bias due to using the same group that completed the study to calculate these savings.[45]

On the whole, these studies represent some important beginnings of work on cost savings which could be realized from MTM services. However, from an evidence-based perspective, the Asheville Model and other related service interventions based on this model require more rigrous, careful evaluation because of the weaker experimental design and flaws in the economic analysis. The cost portions of the studies included in this critque tend to be weak and subject to limitations in study design due to a lack of control or equivalent comparison group which weakens the ability to attribute causality of the results to the intervention and introduces selection bias.

Some of the reports seem to have missed opportunities to report on multiple years of data or to create comparison groups. One article reports only on the first year outcomes even though this model was implemeted in 2004 and has been ongoing.[43] By 2012, there should have been an opportunity for the researchers to publish results on the program effectiveness addressing some of the limitations in this previous report.

While the Outcomes money-back guarantee poses an interesting proposition, we were unable to fully determine from the article results how the typical Outcomes sponsor receives a $4.73 for every $1 spent return on total investment or $1.87 per $1 spent in drug product savings. The percentage of claims related to reducing drug product costs do not seem to support this figure, but perhaps the savings could reflect

out-of-pocket cost savings to the patient from switching to generic medications or ceasing unnecessary medications.

While the cost and feasibilty of study execution may influence the choice of study design, the careful and objective inclusion of appropriate cost comparisons, sensitivity analyses, appropriate handling of attrition, and accounting for costs or benefits from multiple perspectives should be maintained. Furthermore, investigations of economic effects should adhere to the guidelines and recommendations of the Panel on Cost-Effectiveness in Health and Medicine to produce stronger evidence regarding the cost-effectivness of interventions involving MTM services.[46,47]

Pooled Analyses/Reviews

A systematic review of the effects of pharmacist provided direct patient care on health outcomes was published in 2010. The economic effects were reported separately from a larger review of clinical effects.[25] The selection criteria for the studies in the economic review included the reporting of "objective patient-related economic outcomes" and the presence of a "comparison group." Despite these requirements, for most studies included in the systematic review the authors acknowledge partial cost analyses, methodological limitations, and problematic economic assessments.

The article provides a listing of 20 studies that demonstrated improved cost and clinical outcomes and includes their main economic findings.[36] However, some of these studies with favorable economic outcomes may have included a "comparison group," but the authors neglect to mention they are historical[18] or non-economic[9] (clinical analysis) comparators. Further, these specific issues are not identified in any particular study nor explored in more detail for those with "favorable" results. They are

simply described as economically beneficial “thus demonstrating the favorable effects of these services on reducing drug expenditures, hospital admissions, lengths of hospital stay, and emergency department visits.”[36] The review would have benefited from a more balanced presentation of the positive findings and a specific critical review of some of the potential problems from the 20 studies.

In another recently updated pooled analysis of published economic assessments of pharmacist-provided MTM services from 2001-2005, Perez et al. report a return on investment of $7.98 for every dollar spent on MTM.[48] However, this figure is the mean of benefit to cost ratios derived from only 15 studies from 1998 to 2004 and was an average calculated by the reviewers in 11 of 15 of the cases. Also, the calculation was made regardless of currency which was Australian Dollars (22.99:1) and Euros (34.61:1) in the two cases with the clearly highest cost benefit ratios. (The current exchange rate for the Australian dollar to the U.S. dollar is $0.94 to $1 and the rate for the Euro is 0.70 to $1 U.S.).[49] The authors report the simple average despite potential confounding associated with comparing different health care systems on economic outcomes. According to the reviewers’ scan, of over 3,500 potentially relevant papers, only 93 were included in this systematic analysis. Also, with respect to appropriate study designs and rigor, of the 93, 27% (25 of 93 papers) were deemed to be of good quality, 16% (15 of 93 papers) were of fair quality, and 57% (53 of 93 papers) were determined to be of poor quality.[48] The authors reported this proportion of studies with stronger designs was an increase over previous reviews. However, the studies that contributed to the benefit to cost ratio calculation were not necessarily those that were considered of good quality. A chart in the appendix included all 93 studies in the review

that listed the study design, economic analysis method, input cost methodology, economic outcomes, sample, results, and currency year.[48] Regretfully, despite developing a grading system and rating each study on the quality criteria used to examine the methodological rigor, the authors omitted this rating from the appendix listing.

A lengthy report on current pharmacy practice was very recently released to the U.S. Surgeon General, Dr. Regina Benjamin.[50] This report is described as a "comprehensive, evidence-based report" that was reviewed and discussed collaboratively between the U.S. Public Health Service (PHS) Pharmacy leadership, the Office of the Surgeon General, and Dr. Benjamin throughout 2011. After reviewing the report, Dr. Benjamin wrote a letter of support of the main findings in the report which can be viewed and downloaded from the PHS website along with the report.[51] Of the 95 pages of the report, only two are devoted to the evidence for "cost-effectiveness and cost-containment" of pharmacist services, despite these being part of the main four focus points of the report. The authors include a bulleted list of results form various studies showing cost savings, but do not comment on the strength of this evidence based on the methodological rigor or quality of the studies. Finally, the authors present a reprinted table of benefit to cost ratios over time (from 1988 to 2005) from the economic review by Perez et al.[48] with a final conclusion that overall average benefit gained over the period is $10.07 per $1 of allocated funds for clinical pharmacy services.[50] However, they omit important information originally included in the table on the number of studies included in these benefit-to-cost ratios. Also not included are any comments on the quality of the studies used to develop these ratios, which are

discussed in the limitations in the Perez et al. article. This report at the very least should have included language that acknowledged the need for additional studies of the cost effectiveness of MTM services to further support and substantiate the findings as they do in the manuscript.

Conclusions

The intent of the first part of this review was to critically examine past cost effectiveness analyses of MTM services. We found that significant design and execution issues may undermine the conclusions for many of the studies. Pharmacists often conduct the research and the work is often supported by companies that have an interest in the industry and study outcomes. Compelling results minus any qualifications regarding study design validity often appear in pharmacy industry publications such as *Pharmacy Today* – a non-peer reviewed publication of the American Pharmacists Association or the *Journal of the American Pharmacists Association*. For example, a $3 in cost savings generated per $1 invested in the first 18 months of a Unity Health Insurance study appears in a quote from *Pharmacy Today* citing an article from the *Journal of the American Pharmacists Association*.[52] However, examination of the actual study does not mention this $3:$1 return on investment.[24] Several studies implied a causal link betwen the study interventions and the results even though they did not employ a control or equivalent comparison groups. Many analyses are potentially subject to selection issues, have incorrectly handled attrition, and employed unconventional cost estimation methods. The lack of standardized program costs and disease eligibility determination limits study comparability in reviews. While authors of pooled analyses and reviews acknowledge the majority of cost-effectiveness studies are

of poor methodological quality, they persist in reporting the returns on investment and conclude that the programs are economically favorable.

Part II - A Cost Model for MTM Services

The role of pharmacists on the care team has been studied as a potentially cost-effective method to improve disease outcomes and the quality of patient care. One unresolved issue is the development of cost-effective models for payers to compensate pharmacists for provision of MTM services. Using sophisticated object oriented simulation models, cost models have been developed; one such example is the "Archimedes" model developed by Kaiser Permanente.[53] Alternatively, costing schemes can be developed by applying results from the literature and combining them with simpler modeling techniques. We employ a basic model developed by the Lewin Group[32] combined with selected estimates for program costs found in the Archimedes model and recent MTM services trials.

The Archimedes diabetes model has been validated against 19 clinical trials and has been used to perform an extensive cost effectiveness analysis of the economic and humanistic effects of a Diabetes Prevention Program (DPP) which has been both modeled with simulation and clinically implemented. The DPP program is a preventive care lifestyle intervention that does not involve a pharmacist on the care team. However, the model includes calculations of the routine costs of providing health care to high-risk people before they develop diabetes, as well as to people with diabetes and its complications. The model also includes a mathematical representation of an entire health system. Further, the base-case analysis was formed by micro-costing detailed items from Kaiser Permanente practice.[53]

The Lewin Group model was developed to assist plans in developing cost and payment schemes specifically for MTM services. This model is based on a review of the literature and 32 key informant interviews with various representatives from community and chain pharmacies, state Medicaid programs, and ambulatory care clinics.[32] This model has not been as rigorously validated as the Kaiser Archimedes model, but it has been developed particularly for evaluating costs related to the provision of MTM services.

For this cost analysis, we limit the scope to pharmacist-physician intervention models for adults age 18 and older in the managed care population who have been diagnosed with diabetes. We evaluate adults with diabetes who may benefit from a pharmacist-physician intervention because currently there is uncertainty as to whether the optimal strategy is to 1) offer pharmacist-physician collaborative care during a single, short-term visit to all or a large proportion of patients; or 2) provide an initial comprehensive pharmacist-physician medication review visit for one long visit, plus several (3-5) shorter follow-up visits to a targeted small proportion of patients; or 3) provide usual care with separated physician and pharmaceutical services. Each of these three strategies are evaluated from the payer perspective using an incremental cost analysis including a reference base case.

Subjects in the *low complexity* pharmacist-physician intervention arm receive a 15 minute collaborative care visit when they initiate a routine visit to their physician for maintenance care of their diabetes.

Subjects who present to their physicians for routine care for their diabetes in the *high complexity* pharmacist-physician intervention arm receive a 40- minute initial

collaborative care visit and three follow-up visits with the pharmacist-physician team. The follow-up visits take place within 12 months of the initial visit.

Subjects in the hypothetical cohort receiving *usual care* visit their doctor and/or a pharmacy to receive their medications, but do not receive pharmacist-physician collaborative care. Subjects in this arm of the analysis are identified by identical criteria to the intervention arms in terms of demographics, specified disease, severity, and comorbid diseases.[8]

Eddy and colleagues compared the costs associated with managing people with diabetes and their complications according to the Archimedes model and compared them to the actual costs measured in an independently conducted study of patients with diabetes in Kaiser Permanente Northern California. According to the model, average annual diabetes related costs for patients with diabetes were $4241 in comparison to actual costs of $4683. Costs in the model are based on the cost-generating events that occur to them (e.g., tests, visits, treatments). These vary with the severity and progression of disease. Actual costs include the baseline costs (before treatment or complications) calculated from a population with a mean age of 66 years and a mean duration of diabetes of eight years and were assumed to apply to people with "early diabetes."[53] Bringing both of these figures from 2005 to 2010 U.S. dollars, we calculate the annual costs to be $4693 and $5183.[54] The Archimedes model was estimated with 10,000 people who met the entry criteria of the lifestyle trial and who were exposed to four different management strategies and followed for 30 years.[53] The Lewin Group estimated that 30% of Medicare beneficiaries would meet the $4,000 drug spending threshold in 2006.[32] Given the figures determined from the Archimedes

models, the use of a 30% eligibility rate for MTM programs in our model is conservative, especially since the drug spending threshold has been lowered to $3000 (See Table 2).

The original Lewin Group model with 2005 estimates results in a per member per month provider fee of $1.56 which they note is considerably higher than the $0.45 per member per month cost for MTM services in 2005 provided as an example in the bid pricing tool on the CMS website. Their model estimates are based on $2 to $3 per minute expected payment to pharmacists.[32] In cases where the medication problem severity is low and the visit lasts from 5 to 15 minutes, the expected Medicare fee payment is within the range of $2 to $3 per minute. However, in cases where the pharmacist may be required to spend 25 to 40 minutes with a patient, the level of payment is compressed to the low end.

A conversion factor (cf) takes the relative values into payments for the 2011 Medicare Fee Schedule. This total payment is reduced by the payment amount appropriate for payment to non-physicians.[27] The resulting MTM payments are in general a bit above or within the $2 to $3 per minute charge suggested as a “rule of thumb” by the industry respondents interviewed by the Lewin Group.[32] The $4 per minute charge is included in the Table 3 as a point of comparison. Most of the payments suggested by the Lewin group interviewees and by other industry sources fall within the $4 per minute expected payment. As examples, a major institution in Northern California suggested a $150 per visit rate and Minnesota Medicaid results indicate a $155 rate per visit.[14] Finally, Outcomes Pharmaceuticals offers a “consumer plan” to the public at $120 per year.[44] Assuming the initial MTM visit is about 40 minutes the result is a payment rate of about $3 to $3.85 per minute.

Payment amounts applied in the sensitivity analysis can be found in Table 3. This analysis revealed that the total cost of the MTM program varies depending on the MTM payment rate, the MTM program intensity, and the number of patients to which the MTM program was applied. A study by Kuo and colleagues indicated that 75% of their claims that were successfully reimbursed used the 25 minute CPT code.[55] Therefore, it seems that rather than use the 15 minute CPT code to represent the low-intensity intervention and follow-up visits, that the 25 minute code and accompanying cost might be more realistic. We explore both scenarios in the sensitivity analysis illustration (see Tables 4 and 5).

When the costs of an MTM program are spread over the entire enrollee membership of the health plan, the per member per month charge is within about $2 to $3. These calculations assume the health plan engages in an MTM program that is a combination of a low intensity intervention with about 30% of the membership and a higher intensity intervention with one longer visit and three follow-up visits for about 3% of the total membership. The higher intensity group members each have a medical condition such as diabetes and are taking several medications each month. When the costs of the MTM program are divided just amongst those who received any kind of MTM service, the cost ranges from about $77.85 to $109.86. Presumably this would be above and beyond, albeit a small proportion, of the approximately $4693 total annual costs to care for the average patient with diabetes.[53]

To put these estimated per member per month charges in context, we compare to other types of programs to be potentially mandated as part of health insurance coverage programs. The California Health Benefits Review Program (CHBRP) has

developed several evidence-based analyses of potential effects of selected California Assembly Bills to be introduced through the California State Legislature. CHBRP's analysis of specific mandate bills typically address the marginal effects of the mandate bill - specifically, how the proposed mandate would impact benefit coverage, utilization, costs, and public health, holding all other factors constant. The cost impact estimates are based on the California Cost and Coverage Model, an actuarial model that has been designed and validated to develop the CHBRP estimates of marginal financial effects.[56] For example, Assembly Bill 310 covers prescription drugs and would prohibit coinsurance as a basis for cost sharing for outpatient prescription drugs; limit copayments to $150 per one-month supply; and require that a health plan's or policy's out-of-pocket maximum include the outpatient prescription drug benefit. According to the CHBRP analysis, the increase in per member per month premiums as a result of this prescription drug benefit is between $0.00 and $3.69 depending on the market segment to which it is applied. For example, the privately-funded Department of Managed Health Care regulated large-group segment is estimated to increase by $1.12 per member per month for this prescription drug benefit.[57]

Table 6 presents CHBRP estimated increases in per member per month premiums as a result of implementing a variety of other potential health insurance mandated programs. There is wide variability of premium increases depending on the market segment to which the program is applied, with the publicly funded programs naturally being much lower than the private health insurance programs. Our estimated MTM program cost increases of $2 to $3 per member per month are higher than most of the non-essential health insurance benefit additions such as coverage for acupuncture,

fertility preservation, and tobacco cessation. The addition of the AB 310 prescription drug benefit described as an example in the previous paragraph is amongst the most costly per member per month compared to the other programs.

DISCUSSION

Do MTM programs lead to a legitimate cost offset for health plans? Do costs avoided because of MTM exceed the costs of the program? It does appear possible that resulting medication changes, dosage reductions, and possibly tighter hemoglobin-A1c test control could result in a reduction of medication and patient visit costs in the range of $77.85 to $109.76 per year. However, we are also reminded that nearly 80% of the claims were categorized as “improving the quality of care without reasonable or foreseeable cost savings” in the recent 7-year analysis of cost avoidance allocations from MTM services published by Outcomes Pharmaceutical Health Care. Only 4.7% of MTM encounters were classified as “reducing product costs.”[7]

To our knowledge, a critical review of the cost outcomes of MTM services studies has not been published. Further, this analysis adheres to the basic standards recommended by the Department of Health And Human Services Panel On Cost Effectiveness In Health and Medicine.[46,47] None of the previous studies applied these well-recognized standards.

There is a comprehensive review of a broad range of “diabetes education programs”[34] that includes some of the pharmacist interventions focused upon in this critique. The review concluded that more research is needed to validate the cost-effectiveness of these programs. Further, the paper presents a compilation of the article findings, but neglected to include a critical review of each article’s quality. This type of

non-specific critique leads to proliferation of intriguing study results without recognizing the potential shortcomings or issues in the study design and execution.

Limitations

This cost analysis has taken a payer perspective evaluating the costs of in-physician-office pharmacist MTM services using “incident to” billing for a medical plan of 1,000 members and 50,000 members. In future analyses, it will be important to evaluate whether MTM services programs can be tied to cost-savings and patient health related quality of life. The estimation of quality adjusted life years added as a result of MTM programs has yet to be explored.

One major limitation of the cost model in this paper is that estimates are derived largely from studies with weak experimental designs. There are no randomized controlled trials to support the estimates used for the calculations. The estimates from previous cost analyses were drawn from validated trials whenever possible. Several pilot projects and a randomized controlled trial of MTM services are currently underway as part of California Comparative Effectiveness and Outcomes Improvement Center efforts. It is expected that the cost outcomes from these trials will be instructive in development of suggested payment schemes for MTM programs that will adequately address the efforts of pharmacists and their changing role on the teams of professionals that care for patients with chronic diseases.

CONCLUSIONS

No common methodology exists for estimating return on investment for health plan disease management programs, yet it is one of the most common inquires by plan management and consultants in the course of valuation. Several groups are working to

find common nomenclature, definitions, and methods to compare disease management programs across plans and entities.[37] Future comparative effectiveness studies would greatly benefit from standardization of the components of the MTM programs.

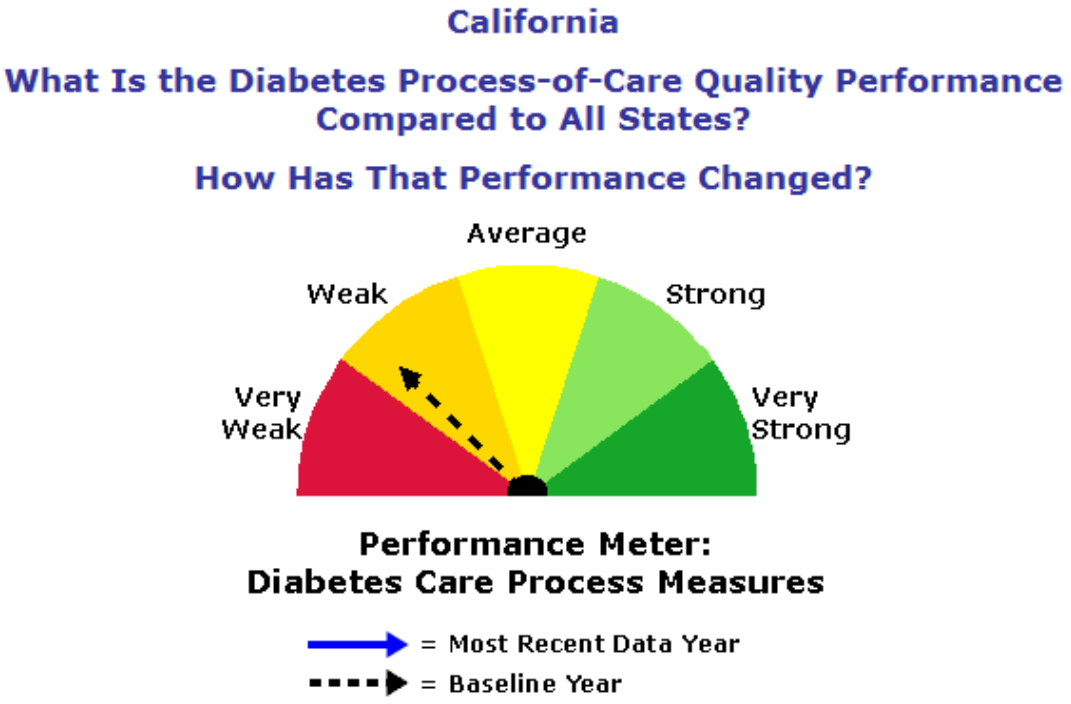
More rigorous research needs to be conducted with special attention to controlling threats to internal and external validity in order to validate the cost-effectiveness of MTMS. Fetterolf and colleagues recognize the difficulty of performing the gold standard randomized controlled study of complex population based problems. They suggest methods for using historical controls in the absence of a true randomized comparison group, especially when employing health plan data.[37]

This analysis and the hypothetical payment model contributes to our understanding of how prescription drug plans and pharmacy benefit managers might structure their MTM programs in a way that will reduce costs and improve patient health in the long run. This study critically examined the designs and cost estimation methods that have been used to determine the previously published estimates of savings for the programs, employers, and patients. We reviewed some of the most recent and widely cited studies and indicated why these costs may not be accurate and the savings overstated.

Based on the literature currently available, we find very little evidence to justify reimbursement for MTM services. Although a significant number of studies argue that these programs are effective and that they produce a return on investment, few of the studies meet minimum methodological standards. We are not arguing that MTM services are not effective or that they fail to offer economic returns. Instead, we are

suggesting that the current evidence is insufficient to justify policy changes. We encourage continuing investigations that employ stronger methodological standards.

FIGURE 1 Diabetes Process of Care Quality Performance Compared to All States



Source: AHRQ State snapshots 2010.[3]

TABLE 1 Individual Studies Review Criteria

First Author, Year, Reference	Study Design	Comparison/ Control Group	Loss-to-F/U or Attrition	Cost-estimates/ denominator
Cranor, 2003[18]	Weak 2-group pre-post design – Quasi-experimental	Historical comparison group, no controls	Yes, not handled properly	Unconventional methods, cost of selected patients annualized
Isetts, 2008[9]	Weak Pre-post 1-group design – Pre-experimental	No comparison group for economic analysis	Yes, potential selection issues	Selected patients used in MTM program cost calculations
Johannigman, 2010[43]	Weak 1-group post-test only – Pre-experimental	No comparison group	Selection issues, regression to the mean possible	Unweighted average reported. Selected patients used in cost calculations
Barnett, 2009[7,44]	Weak 1-group post-test only; multiple years reported – Pre-experimental	No comparison group	Convenience sample	Cost avoidance scale not associated with actual costs
Trapskin, 2009[24]	Collaborative provider group	No comparison group	Not discussed	Not discussed
Smith, 2011[45]	Weak 1 group post-test only – Pre-experimental	Historical comparison group, no controls	Not discussed	Total Medicaid drug claims for participants in previous year used as comparison to extrapolated costs had the MTM program lasted an entire year

TABLE 2 Model Assumptions and Estimates

MEASURE	ESTIMATE	SOURCE
Low intensity MTM model (one low intensity visit)	15 min to 25 mins	Lewin,[32] Kuo[55]
Higher intensity MTM model (one longer medication review visit plus 3 lower intensity follow-up visits)	40 min + 3 x 15 min visits to 40 min + 3 x 25 min visits	Lewin,[32] Kuo[55]
Cost of MTM per minute	$2-$3	Lewin[32]
2011 MFS conversion factor of relative values to payments	$33.98	CMS[27]
2011 non-facility relative value	99211 code (5 min) = $0.56 to 99215 code (40 min) = $4.15	CMS[27]
Reduction factor for non-physician payments	0.8	Lewin[32]
Percentage of patients eligible for basic (low intensity) medication review	29.3%	Lewin actuarial[32]
Percentage of patients eligible for comprehensive (high intensity) medication review	3.0%	Lewin actuarial[32]
Total number of plan members	1000 used in Lewin study to 50,000 people in an average size managed care organization	Lewin[32] Eddy[53]
Total Annual Diabetes Related Costs (Base case, usual care – no MTM)	$4693 from Kaiser study and $5183 from Archimedes model	Eddy[53]

TABLE 3 Calculation of MTM Services Payment Amounts from CPT Codes and Medicare Fee Schedule (MFS) for 2011

CPT Code	2011 cf, $	2011 rv	Total Payment, $	Non-physician share	2011 MFS MTM Payment, $	$2 per min	$3 per min	$4 per min
99211 (5 min)	$33.98	0.56	$19.03	0.8	**$15.22**	$10	$15	$20
99212 (10 min)	$33.98	1.24	$42.14	0.8	**$33.71**	$20	$30	$40
99213 (15 min)	$33.98	2.09	$71.02	0.8	**$56.81**	$30	$45	$60
99214 (25 min)	$33.98	3.08	$104.66	0.8	**$83.73**	$50	$75	$100
99215 (40 min)	$33.98	4.15	$141.02	0.8	**$112.81**	$80	$120	$160

TABLE 4 Illustrative Sensitivity Analysis Cost Calculation for a Sample MTM Services Package – 1,000 Member Plan

	Description	Estimated Cost	Persons Eligible	Total Costs
Low Intensity – pharmacist provided medication review	One **15-minute** visit @ $56.81	56.81	293	$16,648.67
Higher Intensity – Medication Therapy Review and Follow up	One 40-minute comprehensive medication therapy review @ $112.81 Three **15-minute** targeted follow-up visits @ $56.81	283.24	30	$8,497.20
Total Annual Cost				$25,145.87
Number of Enrollees				1000
Cost per month				$2,095.49
Cost per enrollee - spread across all 1,000 members of plan				$2.10
Annual cost per enrollee – across 323 members who received any MTM				$77.85

TABLE 5 Illustrative Sensitivity Analysis Cost Calculation for a Sample MTM Services Package – 50,000 Member Plan*

	Description	Estimated Cost	Persons Eligible	Total Costs
Low Intensity – pharmacist provided medication review	One **25-minute** visit @ $83.73	83.73	14,650	$1,226,644.50
Higher Intensity – Medication Therapy Review and Follow up	One 40-minute comprehensive medication therapy review @ $112.81 Three **25-minute** targeted follow-up visits @ $83.73	364.00	1,500	$546,000.00
Total Annual Cost				$1,772,644.50
Number of Enrollees				50,000
Cost per month				$147,720.38
Cost per enrollee - spread across all 50,000 members of plan				$2.95
Annual cost per enrollee – across 16,150 members who received any MTM				$109.76

*Eddy and colleagues report the average managed care plan has 50,000 members [53]

TABLE 6 California Health Benefit Review Program Estimates of Per Member Per Month Increases as a Result of Program Implementation

Assembly Bill	Topic (Year of analysis)	Per Member Per Month Increase in Premium
AB 72[58]	Health Care Coverage: Acupuncture (2011)	$0.0034 to $0.2924
AB 137[59]	Mammography Services (2011)	The average per unit cost of mammograms (including additional services due to false positive results) is $190. Part of essential health benefits, no measurable change in cost is expected.
AB 154[60]	Mental Health Services (2011)	$0.05 to $1.64
AB 171[61]	Autism (2011)	The premium impact would range by category from 0.14% to 0.24% for privately funded health insurance.
AB 185[62]	Maternity Services (2011)	All of the costs of the mandate would be concentrated in the CDI*-regulated individual market, where total expenditures are estimated to increase by 0.52% and premiums by 3.48%. Per member per month premiums are estimated to increase by an *average* of $6.92 in this market.
AB 310[57]	Prescription Drugs (2011)	$0.00 to $3.69
AB 428[63]	Fertility Preservation (2011)	$0.00 to $0.0373
AB 1000[64]	Cancer Treatment (2011)	$0.0120 (DMHC**-regulated large-group plans) to $0.0383 (CDI-regulated small-group policies)
SB 136[65]	Tobacco Cessation (2011)	$0.00 to $0.33
SB 1104[66]	Diabetes-Related Complications (2010)	Enrollee contributions toward premiums for group insurance regulated by DMHC or CDI are estimated to increase by $13,888,000, or 0.1083%.

*California Department of Insurance
**Department of Managed Health Care

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Examining Disparities in Health Insurance Sector,

Age, Gender, and Income on Long Term Medication Monitoring

INTRODUCTION

Proper monitoring of medication adherence is an essential component of avoiding drug-induced injury for adults on long-term pharmacotherapy. Failure to monitor high-risk medications is one of the leading factors contributing to adverse drug events.[1] The Center for Disease Control and Prevention estimates that adverse drug events trigger 700,000 emergency department visits a year, with a quarter of those visits coming from elderly adults 65 years and older.[2] Adverse drug events (ADE) are responsible for $4 billion in extra medical costs per year. Drugs that are commonly monitored in outpatient settings account for over half of all unintentional drug overdoses that resulted in an emergency room visit.[3] With monitoring, clinicians can adjust the patient's dosage and evaluate possible allergies or interactions to prevent avoidable adverse events.

Major public health organizations including the National Committee for Quality Assurance (NCQA) recognize ADEs as a public health concern as more over-the-counter drugs become available and drugs are prescribed and obtained in outpatient settings.[4] Annual monitoring for patients on persistent medications has been part of the NCQA/ Healthcare Effectiveness Data and Information Set (HEDIS) quality measures for commercial, Medicare, and Medicaid health plans since 2006.[5] The medications and associated conditions included in the HEDIS measures include: angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) used to treat hypertension and diabetes,[6,7,8] digoxin used for cardiovascular conditions,[9,10,11] diuretics for heart disease and congestive heart failure patients,[6,7,8] and anticonvulsants used to treat neurological disorders.[12,13,14]

This study focuses on the annual monitoring of these long-term medications for an adult population who are insured with a commercial health plan, Medicare, or Medicaid. These patients with chronic conditions and taking long-term medications are of special interest for health plans and other entities wishing to introduce or modify programs incorporating a pharmacist on the primary care team to assist with medication monitoring. The effectiveness and optimal design of these Medication Therapy Management Services (MTM) programs are currently under study by agencies such as the Agency for Healthcare Research and Quality. One current randomized controlled multicenter trial evaluates an MTM program in Medicare beneficiaries at high risk of ADEs measuring ADEs, hospital admissions, and emergency room visits.[15] It is unknown whether outcomes of patient safety, morbidity, and mortality can be influenced by MTM program participation. Questions remain regarding optimal MTM program design (e.g., visit frequency, modes of patient-pharmacist and pharmacist-physician communication, program content). In order to perform these additional studies, it is necessary to identify the patient populations that might benefit most greatly from MTM programs.

The 2003 Medicare Prescription Drug, Improvement, and Modernization Act included a requirement of MTM programs for beneficiaries who meet certain risk criteria (e.g., possession of chronic conditions such as diabetes and taking more than four medications). Since this time there has been successful demonstrations of safety and efficacy of MTM programs in various settings.[16] However, the inclusion of MTM programs as a requirement for all patients with chronic conditions who take long-term medications has not yet come to fruition in the most recent health care reform laws.

NEW CONTRIBUTION

This study will examine the relationship between health insurance status and monitoring of selected long-term medications for an adult population, while controlling for other factors including gender, median household income, and age. To our knowledge, this is a novel study examining long-term medication monitoring of beneficiaries across different health insurance products. Many of the existing studies on health insurance and medication monitoring look at patient cost-sharing models in one group, such as in the elderly (i.e., Medicare beneficiaries)[17,18,19] or those at socioeconomic disadvantage who are more likely to be Medicaid beneficiaries.[20,21] Most existing studies also do not examine more than one drug class.

This patient dataset has not been described elsewhere in the literature and includes 283,129 unique patients insured in the state of California during 2010. The dataset includes people with a wide range of household incomes, ages, and geographic locations (see description in methods section).

Measurement of annual monitoring for patients on persistent medications has been part of the HEDIS measures since 2006. Our review of the literature reveals few other reports written to date that have included these specific metrics. This quality measure has been included as part of those that may or may not be calculated differently depending on the use of administrative data only versus a hybrid of administrative and medical record data. The implication is that health plans that can incorporate electronic health record data may be at an advantage by being able to report higher numbers for performance compared to those using only administrative claims.[22] This study does not compare data for different plans or across years, so this

is not an issue here. This measure has also been included as an example of a quality metric calculated using laboratory or office procedure data. On particular measures, if the difference between the administrative data and medical record review rates vary more than 5%, they may be eligible for examination using a random 411 member sample.[23] This study uses the full complement of the data provided not a random sample; hence this is not an issue. Finally, one review examining measurement of the quality of medication use in older adults includes these metrics because they move beyond the traditional focus on select high-risk medications, addressing also the importance of monitoring and drug-disease interactions. This 2009 review includes only the NCQA aggregate HEDIS results from their "State of Health Care Quality" in 2007.[24] Our study appears to be the first that examines these quality measures using the entire recent dataset for a single large health plan.

In this report we seek to answer the following research questions: *What is the association of having a particular health insurance product on long-term medication monitoring in the adult population? What other associations exist between long-term medication monitoring and gender, age, and household income?* These questions will be addressed for each of these drug classes: ACE inhibitors/ARBs, digoxin, diuretics, and anticonvulsants.

METHODS

Data Source

This analysis utilized administrative data from Wellpoint/Anthem for the period of 1/1/2010 through 12/31/2010. These data included health insurance claims across the continuum of care (e.g., inpatient, outpatient) for enrollees who all have insurance in

California, but may be living in other states and abroad. This database includes a variety of fee-for-service, preferred provider organization, and capitated health plans. The database includes 242,014 = commercial health insurance enrollees, 27,237 = Medicare beneficiaries, and 13,893 = Medicaid beneficiaries. There is some overlap between the commercially insured and Medicare population – these dually eligible patients remain in both groups in this analysis.

Study Population

The dataset provided by Wellpoint/Anthem includes adults with an extreme range of household incomes ($6,964 annually to $200,001 annually, maximum cut-off; Mean: $52,635.45, SD: $20,545.01), from all geographic areas of California, and a wide range of ages (19.25 years to113.06 years; Mean: 63.64, SD: 13.34).

Patients (employees and dependents) were included in this study if they met 2010 NCQA's HEDIS Technical Specifications, for the annual monitoring for adults on persistent medications measure. All patients were required to be aged 18 years or older. Patients must have at least 120 days of continuous enrollment prior to measurement and at least one claim during the measurement period.

Medication Monitoring Measure

The primary outcome measure assesses whether or not adults received at least 180 treatment days of ambulatory medication therapy for each therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year.[4] The four therapeutic agents include: angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB), digoxin, diuretics, and anticonvulsants (e.g., carbamazepine, phenobarbital, phenytoin, valproic

acid).[22] Tjia and colleagues describe the annual medication monitoring laboratory test HEDIS recommendations for ACE inhibitors/ARBs as serum potassium and either serum creatinine or blood urea nitrogen and for the anticonvulsants as anticonvulsant drug serum concentration.[22] In the dataset, each record included a "1=inclusion" or "0=exclusion" for each therapeutic agent class denominator. For those included in the denominator, each record also included a "1=monitored" or "0=not monitored" for each numerator. A singular dichotomous "1=monitored" or "0=not monitored" dependent variable was created for each record for each therapeutic agent class. Essentially, we created four different datasets, one for each therapeutic agent class, which may include crossover records for people eligible for more than one therapeutic agent class. A separate dataset was created to capture an aggregate measure of overall adherence to monitoring for the three therapeutic agent classes used to treat heart conditions and diabetes (i.e., ACE/ARB, diuretics, and digoxin). Anticonvulsants were excluded from this aggregate measure because they are used to treat different types of conditions from the other three therapeutic classes.

Primary Independent Variable – Health Insurance Status

The primary regressor in each LOGIT model for each therapeutic drug class was the health insurance product group. Several sub-categories of each type were collapsed into three major categories: commercial insurance, Medicare, and Medicaid. Commercial insurance includes Health Maintenance Organization (HMO)/Point of Service (POS) plans, Preferred Provider Organization (PPO) plans, and all CalPERS (California Public Employees Retirement System) plans (Care, Choice, Select, and Msupp for each of these). Wellpoint/Anthem has specified that the CalPERS enrollees

are a subset of the CA Commercial PPO population (HMO patients are not included). Medicare insurance includes California Medicare HMO, Private Fee-for-Service (PFFS), and Regional Preferred Provider Organization (RPPO) plans. Medicaid insurance includes Los Angeles (LA) Care, Exclusive Provider Organization (EPO) and HMO Healthy Families, and HMO Medicaid programs for nine different California counties.

Patient Characteristics - Covariates

Patient characteristics include age, gender, and median household income. Age was calculated from the patient's date of birth using the date of analysis (in April 2012) as the reference. Patient gender was coded as "1=female" and "0=male."

In order to account for a non-linear effect of age on medication monitoring, the age variable was squared. Both age and age-squared were included initially in the regression models to allow for the effect of a one-year increase in age to change as one gets older. In all models except the one for anticonvulsant monitoring, both age and age squared were significant. Further examination of the collinearity of age and age squared and the associated variance inflation factor (VIF) and tolerance values led us to drop age squared in all models and use only age for ease of interpretation.

We tested for a significant interaction between age and gender in the regression models. These models must include both the age and gender main effects and their interaction, and if significant indicate there is a gender difference for different ages on long-term medication monitoring. The situation for interpreting a categorical predictor (female in this case) and continuous variable (age) interaction (female*age) in logistic regression is more complicated because the value of the interaction effect changes depending upon the value of the continuous predictor variable. In order to visualize and

interpret this interaction effect, we evaluated predicted probabilities when age is set at various values. We begin by setting age at 63.6 years (mean age for those on diuretics) and evaluate for when female = 1 and female = 0. We produced a graph showing the male-female probability difference over age by stepping through a succession of 40 different values for age (every two years) between 20 and 100 while computing differences in probability between female=0 and female=1. The graph (Figure 1) was able to show the values for which the age difference is considered statistically significant i.e., the ages above the "0" probability line. It was deemed unnecessary to include this interaction term in the regression models for the other therapeutic agents.

Median income data is used as a proxy for patient socioeconomic status and was determined by matching the median household income for the patient's US mail zip-code using census 2000 data.[25] There were 12,287 records of 283,129 total (4.3%) that could not be matched with the median household income data including 130 foreign or unreachable addresses, 213 addresses in areas with not enough data to calculate median income (i.e., too sparse population in the area or limited information on people in the area), and 11,944 records with not enough information on the zip code itself and not enough information to determine the median income. The income variable was examined in order to determine whether or not it is missing at random and the best method to impute the missing data.* We focused on the 11,944 records with limited information on the zip code and determined by using nearby zip codes that these are areas in a wide variety of locations around the state of California and hence, missing at

* Income data is a classic example of information not missing at random (if the value of the unobserved variable itself predicts missingness) because individuals with very high incomes tend to decline to answer questions about their income compared to those with more modest incomes. This may have been the case originally when the Census data was collected, but this issue has been addressed when the Census Bureau determines the median household income for an entire zip-code area.

random. Therefore, we chose a form of hotdeck multiple imputation in STATA 10 using chained equations (ICE) that is appropriate for data missing at random.[26] We conducted the logistic regressions with and without the imputed data and found no statistically significant differences in the results. Similar to age, after reviewing the skewed distribution of the income variable, we used the natural log of income in the logistic regression models in order to normalize the data and account for the non-linear effect of income so that the impact of each additional dollar decreases as income increases.

Statistical Analysis

Univariate analyses, including t-tests for continuous variables and chi-squared tests for categorical variables were used to analyze patient characteristics by therapeutic agent class. Logistic regression models were used to assess the impact of different health insurance products across the outcome of interest: medication monitoring for the long-term therapeutic agent. Covariates were included as part of the models if they were significant at the $p<0.001$ level with significant 95% confidence interval. Regression models were assessed for overall goodness of fit using the log-likelihood of the full model, several fit-statistics such as the McFadden's Rho^2 (analogous to the adjusted R^2 in ordinary least squares models), a nested models likelihood ratio test, and the Hosmer-Lemeshow chi-squared test. All statistical analyses were conducted using STATA 10.0 (College Station, TX) software.

RESULTS

Descriptive Statistics

Baseline descriptive statistics for the overall study population stratified by the therapeutic agent class are found in Table 1. The mean age in the overall study population was 62.36 years (SD=13.18) and 49.0% of the subjects were female. The largest majority of individuals were part of the ACE/ARB group (225,689), followed by diuretics (132,879), anticonvulsants (9,074) and then digoxin (6,837). Table 1 also shows the results of the chi-square test for categorical variables and t-test for continuous variables. Bivariate analyses showed age (t-test) and health insurance type (chi-square) are significant at the $p<0.0001$ level compared to monitored/not-monitored (dependent variable) for all therapeutic drug classes (except for health insurance type for anticonvulsants which was significant at the $p<0.001$ level). Income was significant according to t-tests for ACE/ARB and diuretics. Across all therapeutic drug classes, about 80% to 85% have commercial insurance, about 10%-17% have Medicare, and less than 5% have Medicaid insurance, except for the population taking anticonvulsant medications (about 13.5% with Medicaid). We conclude there is a significant difference in mean age (for all therapeutic drugs studied) and income (for ACE/ARB and diuretics) between those that are monitored versus those that are not monitored, allowing for differences in variances across groups.

Health Insurance Group and Gender on Medication Monitoring

Our null hypothesis is that there is no difference between health insurance groups and gender on medication monitoring. The chi-square test results in Table 2 show the observed distribution in our sample of males and females in each product type who did and did not receive medication monitoring. We compare these observed results with the calculated expected results in the target population if there were no difference

between health insurance groups or males and females. For example, if our observed values indicated 40% of everyone in the sample was not monitored, we would calculate expected values so that 40% of females were not monitored and 40% of males were not monitored. We then use the chi-square test to evaluate whether the difference we see in the observed values and the expected values are significant. The results of the chi-square test indicate males and females and the different health insurance groups are significantly different from the expected values for ACE/ARB ($p<0.0001$), digoxin ($p<0.0001$), diuretics ($p<0.0001$), all three drug classes (ACE/ARB, digoxin, and diuretics) ($p<0.0001$), and anticonvulsants ($p<0.001$). Therefore, we can infer that we have sufficient evidence to conclude that males and females are different in being monitored or not monitored in our target population. Likewise, those in different health insurance groups are also different in being monitored or not monitored in the target population. We have enough evidence to reject the null hypothesis that there is no difference between these groups and monitoring.

Regression Model Results

Table 3 reports the results of the logistic regression models for each therapeutic agent class, controlling for the potential patient characteristic confounding factors specified in Table 1 (age, gender, income). The primary regressor of interest, health insurance group was consistently significantly associated with monitoring and a significant contributor in all models. Across the therapeutic drug classes (except anticonvulsants), Medicare patients were most likely to have received medication monitoring, then Medicaid patients, and commercial patients had the lowest odds of medication monitoring.

ACE/ARB Monitoring - Model Results

The population taking ACE inhibitors and angiotensin receptor blockers (ARB) was the largest of the therapeutic agent subgroups with 214,944 individuals. Values of income were successfully imputed for 9,745 records using ICE. The overall fit of the regression determined by log likelihood of the entire model was significant at the $p<0.001$ level. We also performed likelihood ratio tests of the individual parameter estimates based on the differences in deviancies. These also showed that each parameter estimate added to the model and then tested against the nested model were significant at the $p<0.0001$ level. The McFadden Rho^2, which is analogous to the R^2 in ordinary least squares regression, was 0.041. The Hosmer-Lemeshow goodness-of-fit chi-square statistic was also significant at the $p<0.0001$ level.

In the ACE/ARB group, Medicare patients had significantly higher odds of being monitored on these long-term medications compared to the commercial insurance patients and Medicaid patients, after controlling for the other factors (age, income, gender) in the model. Using the commercial patient group as the reference, the odds of Medicare enrollees being monitored on their ACE/ARB medications were 2.918 times that of the Commercial insurance enrollees (OR = 2.918; 95% CI, 2.871-2.977). Likewise, the odds of Medicaid enrollees being monitored on their ACE/ARB long term medications were 1.045 times that of the Commercial insurance enrollees – the odds increase by 4.6% (OR = 1.045; 95% CI, 1.023-1.068) (all $p<0.001$).

The other significant variables found in this logistic regression model include the natural log of income, age, and gender. As discussed previously, income was (natural) log transformed in order to normalize the data and bring in any upper end outliers in

towards the rest of the data. The effect of income on medication monitoring is not extreme, but it is statistically significant. An odds ratio of 1.2 for natural log of income is the difference between a 50% and 55% probability (OR=1.232; 95% CI, 1.218-1.246). In other words, for a standard deviation increase in the natural log of income (SD=0.38), the odds of being monitored are 1.08 times greater, holding all other variables constant ($p<0.001$).[27] The odds ratio for age indicates that every unit increase in age is associated with a 4% decrease in the odds of being monitored on ACE/ARB long term medications (OR=0.961; 95% CI, 0.960-0.961). Alternatively, being 10 years older decreases the odds of monitoring by a factor of 0.68 ($=e^{[-0.039*10]}$), holding all other variables constant ($p<0.001$).[27] Since this model has several predictors and no interaction terms, the odds of monitoring for females is .99 times that of males. Compared to males, females have about 1.1% less odds of being monitored on ACE/ARB medications, holding the other variables constant ($p<0.01$).

The interaction term between gender and age was also significant in the model, but when added, the dummy variable for Medicaid patients became not significant. The graph of the male-female difference in probabilities can be found in Figure 1, but the variable was removed from the final model to allow for the significant health insurance product variable (the primary regressor of interest) to remain.

Digoxin Monitoring - Model Results

The digoxin group was the smallest of the single therapeutic agent groups studied with 6,837 individuals with 280 values for income imputed. The fit statistics for the overall regression of health insurance group on digoxin monitoring indicated the log likelihood of the entire model was significant at the $p<0.001$ level. The likelihood ratio

tests also showed that each parameter estimate added to the model and then tested against the nested model were significant at the $p<0.0001$ level. The McFadden Rho^2 was 0.075 and the Hosmer-Lemeshow goodness-of-fit test was significant at the $p<0.0001$ level.

Medicare patients on digoxin have the greatest odds of being monitored and commercial insurance beneficiaries have the lowest odds, after controlling for the other factors in the model. Medicaid enrollees appear to be in the middle. Using the commercial patient group as the reference, the odds of Medicare beneficiaries being monitored on digoxin were 3.705 times that of the commercial insurance enrollees (OR = 3.705; 95% CI, 3.455-3.972). The odds of Medicaid enrollees being monitored on digoxin were 1.727 times that of the commercial insurance enrollees or about 73% greater odds (OR = 1.727; 95% CI, 1.440-2.071) (all $p<0.001$). Again, Medicare enrollees have the highest odds of being compliant on this long-term medication.

Age, natural log of income, and gender were also considered to be significant variables in the logistic regression model of digoxin monitoring. As with ACE/ARB, a standard deviation increase in the natural log of income (0.36), increases the odds of monitoring 1.05 times, holding all other variables constant (OR=1.156; 95% CI, 1.084-1.233).[27] For each year increase in age, the odds of being monitored on digoxin decrease by .96 times or decrease by about 4% (OR=0.960; 95% CI, 0.958-0.962). In other words, being ten years older decreases the odds of monitoring by a factor of 0.66 ($=e^{[-0.041*10]}$), holding all other variables constant.[27] The regression model of digoxin monitoring also has several predictors and no interaction terms, so the odds of monitoring for females is .84 times that of males, so females have about 15 percent less

odds of being monitored on digoxin, holding the other variables constant (OR=0.841; 95% CI, 0.803-0.882).

Diuretics Monitoring - Model Results

There were 132,879 people who take diuretic medications in the sample and income was successfully imputed for 2,656 of them. The logistic regression model of diuretics monitoring included significant contributions by health insurance group, natural log of income, age, female, and the interaction of female*age (all significant at the $p<0.001$ level). Again, as with the other therapeutic agents, the Medicare enrollees have the greatest odds of medication monitoring on diuretics and commercial insurance beneficiaries have the lowest odds, with Medicaid enrollees in the middle. The likelihood ratio tests also showed that each parameter estimate added to the model and then tested against the nested model were significant at the $p<0.0001$ level. The McFadden Rho^2 was 0.042 and the Hosmer-Lemeshow goodness-of-fit test was significant at the $p<0.0001$ level.

Using commercial insurance enrollees as the reference group, the odds of Medicare enrollees being monitored on diuretics were 3.024 times that of the commercial insurance beneficiaries (OR=3.024; 95% CI, 2.965-3.084). The odds of Medicaid enrollees being monitored on diuretics were 1.07 times that of commercial insurance beneficiaries, or about 6.7% greater odds (OR=1.067; 95% CI, 1.037-1.097).

Similar to the previously reported regression results on monitoring for digoxin and ACE/ARB, the natural log of income can be interpreted for diuretic monitoring as follows. For a standard deviation increase in the natural log of income (0.37), the odds

of being monitored are 1.20 times greater, holding all other variables constant (OR=1.200; 95% CI, 1.182-1.217).[27]

Both the main effects for age, female, and the interaction term female*age were significant in this regression. Even though these variables have high collinearity and VIF values, in order to include the interaction term in the regression, the main effects should also be included. As described in the methods, we calculated predicted probabilities when age is set at various values. We begin by setting age at 63.6 years (the mean) and evaluate for when female = 1 and female = 0 (males). We produced a graph (Figure 2) showing the male-female probability difference over age by stepping through a succession of every two years (40 different values) between 20 and 100 while computing at differences in probability between female=0 and female=1. The resulting graph shows that the difference in probabilities for male and females is statistically significant between values of age of approximately 20 to 50 years and is not significant above that age (the line dips below 0).

All Three Therapeutic Drug Classes Monitoring - Model Results

We performed a logistic regression model of monitoring for those taking ACE/ARB, digoxin, and diuretics. This was the smallest group studied with 1,993 patients and 97 requiring multiple imputation values for income. We decided not to include those taking anticonvulsant drugs in this group, as these types of medication and the conditions for which they are taken are markedly different from the other studied therapeutic agents. We fit a series of regressions, with the final and most parsimonious model including health insurance group (commercial, $p<0.001$, Medicare, $p<0.001$, and Medicaid, $p<0.1$), age ($p<0.001$), and gender ($p<0.001$). The full model log-likelihood

was p<0.0001 and likelihood ratio tests showed that each parameter estimate added to the model and then tested against the nested model were significant at the p<0.0001 level. The McFadden Rho^2 was 0.076 and the Hosmer-Lemeshow goodness-of-fit test was significant at the p<0.0001 level.

As with the other groups, the Medicare enrollees have the greatest odds of medication monitoring if taking all three medications and commercial insurance beneficiaries have the lowest odds, with Medicaid enrollees in the middle. Using commercial insurance enrollees as the reference group, the odds of Medicare enrollees being monitored on all three medications were 3.81 times that of the commercial insurance beneficiaries (OR=3.814; 95% CI, 3.331-4.366). The odds of being monitored on all three medications for Medicaid enrollees were 1.28 times that of commercial insurance beneficiaries, but the confidence interval crosses one and was not considered statistically significant (OR=1.278; 95% CI, 0.965-1.691). An increase in age is associated with lower odds of being monitored on all three medications of approximately 4.3%. Compared to males, females were about 15.4% less likely to be monitored on all three medications, holding the other variables constant. We tested the effect of income in several models, but there does not appear to be a significant effect in this regression.

Anticonvulsant Monitoring – Model Results

There were 9,074 members in the sample taking anticonvulsant medications and of these, 362 included imputed values for income. Overall, the mean age (52.6 years) for those on anticonvulsants is ten years younger than for the other drug classes examined. Also, on the whole, those on anticonvulsants were less likely to be monitored than any of the other therapeutic agent classes. Over half of those on anticonvulsants

with commercial health insurance and Medicare insurance were not monitored and almost half (46.7%) of the Medicaid group were not monitored. Model selection was not as straightforward with this group. The final model does not include gender but includes age-squared ($p<0.001$), natural log of income ($p<0.001$), and the health insurance group variables (commercial, $p<0.001$, Medicare, $p<0.001$, Medicaid, $p<0.05$). The full-model log likelihood test was significant at $p<0.001$. Two of the nested likelihood ratio tests were not significant, but the other three were significant at the $p<0.0001$ level. The McFadden Rho^2 was 0.075 and the Hosmer-Lemeshow goodness-of-fit test was significant at the $p<0.0001$ level.

The odds of Medicare enrollees being monitored on anticonvulsants were 1.59 times that of the commercial insurance beneficiaries (OR=1.593; 95% CI, 1.480-1.714), with commercial insurance beneficiaries as the reference group. The odds of Medicaid enrollees being monitored on diuretics were 0.94 times that of commercial insurance beneficiaries, or about 6.0% decreased odds (OR=0.940; 95% CI, 0.886-0.996, $p<0.05$). Unlike the other therapeutic agents, the Medicaid enrollees on anticonvulsants have the lowest odds of being monitored, not the commercial insurance enrollees.

For a standard deviation increase in the natural log of income (0.38), the odds of being monitored were 0.89 times less, holding all other variables constant (OR=0.886; 95% CI, 0.841-0.933).[27] There seems to be an opposite effect of income on monitoring of anticonvulsants. There also appears to be a weak opposite effect of age on monitoring of anticonvulsants. For an age squared increase, the odds of being monitored were very close to 1, which means the odds decrease, but by very little (OR=0.99; 95% CI 0.999-0.999).

DISCUSSION

Consistent with the last five years of HEDIS reports,[4,5,28,29] we found Medicare enrollees have the highest odds of annual medication monitoring for adults on various long-term medications. Further, in all therapeutic drug classes except anticonvulsants, those that have commercial health insurance have the lowest odds of monitoring, with Medicaid beneficiaries in the middle. Our results indicate the odds of medication monitoring for commercial insurance enrollees can be up to about 3 times less likely as monitoring for Medicare beneficiaries, holding other factors constant. The chi-square analysis of health insurance group and gender on medication monitoring also supported the significant differences amongst insurance groups and also showed a significant difference between males and females in being monitored vs. not monitored. In logistic regression models with a significant gender effect, it was modest and showed that females were less likely to be monitored on medications. In most of the logistic regression models, an increase in age was associated with a decrease in odds of being monitored on medications. Several regressions also showed a positive weaker effect of income on medication monitoring. This study describes an important significant difference in medication monitoring for several therapeutic agents across different types of health insurance that supports HEDIS reports on this measure. In addition, our findings show a significant difference in medication monitoring for males and females, and significant effects of income and age for several different therapeutic agents not described elsewhere.

Despite the commercial insurance population having the lowest rates of medication monitoring, the bulk of the published studies focus on medication adherence

in Medicare beneficiaries, older, and vulnerable patients.[24,30,31] We encourage additional studies on monitoring of medications in the commercial insurance population to determine if there is a potential market for medication therapy monitoring programs. Also, it appears that there are opportunities for better long term medication monitoring programs in all the health insurance groups and across the therapeutic agent classes, so perhaps these monitoring programs would not need to restrict their offerings to any one particular insurance product beneficiaries or those on any particular types of medications.

Limitations

Several limitations should be considered when interpreting these findings. Some of the study sub-groups were large which may allow us to detect statistically significant findings for relatively small absolute differences between groups in some comparisons. On the other hand, the size of the groups allows us to be more confident that the samples are good representations of the larger populations. To evaluate the magnitude of this issue, we determined effect sizes for the groups with large sample sizes (e.g., diuretics, ACE/ARBs) and found that the effect is similar to what was described in the results narrative. That is, the effects of income, gender, and having Medicaid insurance on medication monitoring may be modest. The effects of age (40% difference) and having Medicare insurance (80% difference in reference to commercial insurance) were larger. The larger effect sizes and the calculated odds ratios substantially larger than one support that the differences in our findings do indeed indicate significant absolute differences.

We relied on administrative (insurance) data and no information was available on comorbid conditions, health status, or other medications the patient populations may have been taking. We were unable to identify patients who did not complete tests or were not monitored because they were no longer using the medication. Also, generalizability of these results is limited to the time frame assessed by this data.

Omitted variable bias is a possibility in this study, as the original data includes only a few patient characteristic variables, so there could be unobserved confounders that were not adequately controlled for in the multivariate analysis. The data on medication monitoring was compiled using administrative data only without additional medical record information and without the exclusion for hospitalized patients. Although HEDIS has taken the precaution of preventing potential undermeasurement of monitoring due to hospitalization, it appears that going to the effort to exclude hospitalized patients from outcome measurement does not make a significant difference.[22] Even without this concern, the findings of this study are subject to the usual limitations of administrative datasets.[32,33] For instance, the health insurance product or therapeutic agent data may be misclassified. Future analyses would be enhanced by using a combination of sources and methods to measure medication monitoring and adherence (e.g., self-report, pill counts, pharmacy refill rates, and electronic adherence monitoring).

Patients may receive medication monitoring or treatment that may not be reported or submitted to their health plan for reimbursement, and hence may not be included in the administrative claims data. Examples might include advice or treatment provided over the telephone or Internet. This is a possible consideration for future

studies that evaluate implementation of MTM programs because some of them, and some which may already be currently offered for Medicare patients, allow for sessions to be conducted over the telephone.

We used median household income matched to the patient's zip code as a proxy variable for socioeconomic status. We also used multiple imputation techniques to complete missing income data. We do not know how good of an approximation this proxy may be for socioeconomic status or the exact effect of imputing the missing data.

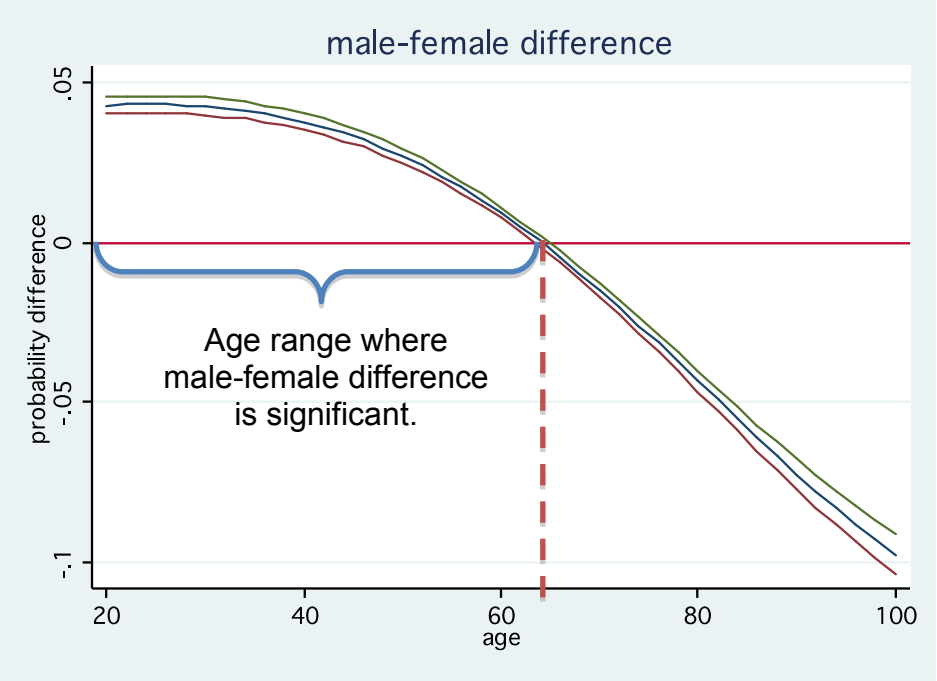
Future Studies

We hope to be able to perform additional studies on this dataset to help determine which patients will benefit from more intensive or more complete medication monitoring. The original dataset includes patient addresses, which can be geocoded and should allow us to perform advanced geographic information systems analyses and determine if there are particular geographic "hot-spots" or "cold-spots" and geographic patterns associated with medication monitoring. This geocoded data can also be used to match several other patient characteristics (e.g., indirect race estimation) and census measures. It would be most ideal if additional information could be obtained from the insurers on each patient's health conditions, concurrent medications, and comorbid conditions.

As a result of this analysis, this health plan can better identify and target patients who will benefit from more intensive long term medication monitoring. From this analysis of patient characteristics, we may now have more information to determine whether MTM or similar medication monitoring intensification programs should be targeted to the elderly (Medicare), women, or community clinics serving beneficiaries of Medicaid or

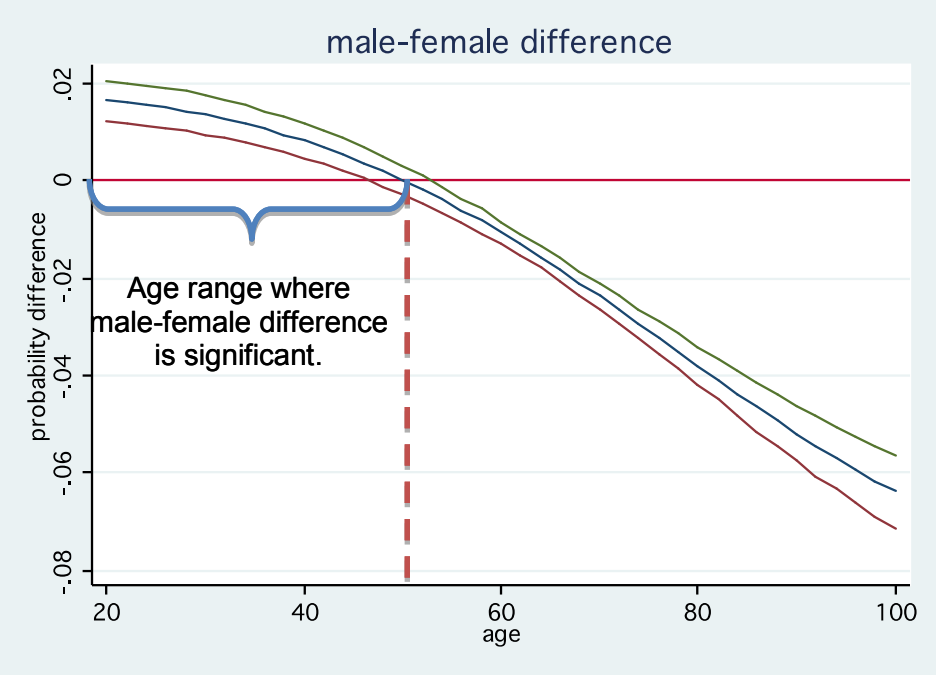
Medicare insurance. In addition, better monitoring of all patients on long-term medications would reduce the likelihood of hospitalization and emergency department visits and increase adherence rates. The results from this study can also be used in concert with geographic analysis of retail and community pharmacies to reveal potential strategic partners and/or market competitors with the ultimate goal of improving the quality of pharmacologic care for all adults.

FIGURE 1 **Male-Female Probability Difference Over Age for ACE/ARB Medications**



The graph above is generated for the sample of patients who are taking ACE/ARB medications. The graph indicates that there is a significant difference between males and females for the ages from approximately 20 to 65. Age 65 is where the line crosses the 0 probability difference line.

FIGURE 2 **Male-Female Probability Difference Over Age for Diuretic Medications**



The graph above is generated for the sample of patients who are taking diuretics. The graph indicates that there is a significant difference between males and females for the ages from approximately 20 to 50.

TABLE 1 Demographic Characteristics, by Therapeutic Agent Class

	Total Sample (N=283,129)	**ACE/ARB** (N=225,689)	**Digoxin** (N=6,837)	**Diuretics** (N=132,879)	**All Three**[†] (N=1,993)	**Anticonvulsants** (N=9,074)
Female, n	138,778	101,713	3,171	74,271	881	4,606
%	49.0	45.1	46.4	55.9	44.2	50.8
Age, mean	62.36	62.51[‡]	73.97[‡]	63.64[‡]	73.71[‡]	52.60[‡]
[SD]	13.18	12.51	13.37	13.34	12.98	16.90
Insurance group						
Commercial, n	242,000	194,593[§]	5,435[§]	112,705[§]	1,590[§]	7,129[**]
%	85.47	86.22	79.49	84.82	79.78	78.57
Medicare, n	27,237	20,817[§]	1,217[§]	14,232[§]	329[§]	717[**]
%	9.62	9.22	17.80	10.71	16.51	7.90
Medicaid, n	13,892	10,279[§]	185[§]	5,942[§]	74[§]	1,228[**]
%	4.91	4.55	2.71	4.47	3.71	13.53
Income, mean	53,282.32	53,437.37[‡]	51,599.41	52,635.45[‡]	50,174.28	52,530.44
[SD]	20,850.92	20,897.03	20,353.31	20,545.01	19,054.28	20,912.16
Monitored, n		157,564	4,341	90,080	1,269	4,394
%		69.81	63.49	67.79	63.67	48.52
Not monitored, n		68,125	2,496	42,799	724	4,680
%		30.19	36.51	32.21	36.33	51.58

[†] All three = Patients taking ACE/ARB, digoxin, and diuretics
[‡] p<0.0001 in two tailed t-test of continuous variable by "monitored/not monitored" assuming unequal variances
[§] p<0.0001 using chi-square test with "monitored/not monitored"
[**] p<0.001 using chi-square test with "monitored/not monitored"

TABLE 2 Effect of Gender and Health Insurance Type on Medication Monitoring

ACEARB	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	33,336	27,817	2,058	2,397	979	1,538	36,373	31,752		
Yes	77,170	56,270	7,556	8,806	2,877	4,885	87,603	69,961		
	110,506	84,087	9,614	11,203	3,856	6,423	123,976	101,713		
No%	30.2%	33.1%	21.4%	21.4%	25.4%	23.9%				
Yes%	69.8%	66.9%	78.6%	78.6%	74.6%	76.1%				
Expected	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	32,421.07	26,249.65	2,820.63	3,497.27	1,131.30	2,005.08	36,373.00	31,752.00	p<	0.0001
Yes	78,084.93	57,837.35	6,793.37	7,705.73	2,724.70	4,417.92	87,603.00	69,961.00		
	110,506.00	84,087.00	9,614.00	11,203.00	3,856.00	6,423.00	123,976.00	101,713.00		
Digoxin	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	1,105	1,121	106	133	15	16	1,226	1,270		
Yes	1,861	1,348	511	467	68	86	2,440	1,901		
	2,966	2,469	617	600	83	102	3,666	3,171		
No%	37.3%	45.4%	17.2%	22.2%	18.1%	15.7%				
Yes%	62.7%	54.6%	82.8%	77.8%	81.9%	84.3%				
Expected	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	991.90	979.45	206.34	230.09	27.76	40.46	1,226.00	1,250.00	p<	0.0001
Yes	1,974.10	1,489.55	410.66	349.91	55.24	61.54	2,440.00	1,901.00		
	2,966.00	2,469.00	617.00	580.00	83.00	102.00	3,666.00	3,151.00		
Diuretics	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	16,552	21,638	1,182	1,904	423	1,100	18,157	24,642		
Yes	34,720	39,795	4,459	6,687	1,272	3,147	40,451	49,629		
	51,272	61,433	5,641	8,591	1,695	4,247	58,608	74,271		
No%	32.3%	35.2%	21.0%	22.2%	25.0%	25.9%				
Yes%	67.7%	64.8%	79.0%	77.8%	75.0%	74.1%				
Expected	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	15,884.28	20,382.54	1,747.61	2,850.36	525.12	1,409.09	18,157.00	24,642.00	p<	0.0001
Yes	35,387.72	41,050.46	3,893.39	5,740.64	1,169.88	2,837.91	40,451.00	49,629.00		
	51,272.00	61,433.00	5,641.00	8,591.00	1,695.00	4,247.00	58,608.00	74,271.00		

TABLE 2 cont. Effect of Gender and Health Insurance Type on Medication Monitoring

All Three*	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	328	320	30	32	7	7	365	359		
Yes	576	366	141	126	30	30	747	522		
	904	686	171	158	37	37	1,112	881		
No%	36.3%	46.6%	17.5%	20.3%	18.9%	18.9%				
Yes%	63.7%	53.4%	82.5%	79.7%	81.1%	81.1%				
Expected	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	296.73	279.54	56.13	64.38	12.14	15.08	365.00	359.00	p<	0.0001
Yes	607.27	406.46	114.87	93.62	24.86	21.92	747.00	522.00		
	904.00	686.00	171.00	158.00	37.00	37.00	1,112.00	881.00		

Anticonvulsants	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	1,842	1,893	163	209	215	358	2,220	2,460		
Yes	1,838	1,556	170	175	240	415	2,248	2,146		
	3,680	3,449	333	384	455	773	4,468	4,606		
No%	50.1%	54.9%	48.9%	54.4%	47.3%	46.3%				
Yes%	49.9%	45.1%	51.1%	45.6%	52.7%	53.7%				
Expected	Commercial		Medicare		Medicaid		All Insurance Types			
Monitored	Male	Female	Male	Female	Male	Female	Male	Female		
No	1,828.47	1,842.06	165.46	205.09	226.07	412.85	2,220.00	2,460.00	p<	0.001
Yes	1,851.53	1,606.94	167.54	178.91	228.93	360.15	2,248.00	2,146.00		
	3,680.00	3,449.00	333.00	384.00	455.00	773.00	4,468.00	4,606.00		

* All three = Patients taking all three medications: ACE/ARB, digoxin, and diuretics

TABLE 3 Factors Associated with Medication Monitoring HEDIS Measure: Results of Logistic Regression Analysis

	ACE/ARB (N=225,689)			Digoxin (N=6,837)			Diuretics (N=132,879)			All Three* (N=1,993)			Anticonvulsants (N=9,074)		
	Odds Ratio	LL 95% CI	UL 95% CI	Odds Ratio	LL 95% CI	UL 95% CI	Odds Ratio	LL 95% CI	UL 95% CI	Odds Ratio	LL 95% CI	UL 95% CI	Odds Ratio	LL 95% CI	UL 95% CI
Insurance group															
Commercial†	0.343‡	0.336	0.348	0.270‡	0.252	0.289	0.331‡	0.324	0.337	0.262‡	0.229	0.300	0.628‡	0.583	0.676
Medicare§	2.918‡	2.871	2.977	3.705‡	3.455	3.972	3.024‡	2.965	3.084	3.814‡	3.331	4.366	1.593‡	1.480	1.714
Medicaid§	1.045‡	1.023	1.068	1.727‡	1.440	2.071	1.067‡	1.037	1.097	1.278††	0.965**	1.691**	0.940††	0.886	0.996
Age	0.961‡	0.960	0.961	0.960‡	0.958	0.962	0.968‡	0.967	0.969	0.957‡	0.953	0.961			
Female	0.989‡‡	0.980	0.997	0.841‡	0.803	0.882	1.357‡	1.284	1.435	0.846‡	0.775	0.924			
Income§§	1.232‡	1.218	1.246	1.156‡	1.084	1.233	1.200‡	1.182	1.217				0.886‡	0.841	0.933
In selected models															
Female*Age							0.994‡	0.993	0.995						

Note: All models with "monitored=1/not-monitored=0" as dichotomous dependent variable
* Patients taking all three medications – ACE/ARB, digoxin, and diuretics
† Relative to Medicare group
‡ p<0.001
§ Relative to commercial insurance group
** Confidence interval not significant – crosses 1
†† p<0.05
‡‡ p<0.01
§§ Natural log of income

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Community Pharmacists As Primary Care Team Members:

A Community Health Collaborative

INTRODUCTION

Collaborative partnerships have grown in prominence as a promising vehicle for addressing the "gap" between health services research and community practice.[1,2] This difficulty in translation of evidence-based interventions into applied settings and implementation into varied contexts has been well recognized.[3,4] Research on collaborative partnerships has produced substantial support that the effectiveness of these entities as agents of change in health services is strongly influenced by the organizational characteristics of the partnership.[5,6] In particular, successful strategies include the active partnership of community and academic research centers to create methodologically sound investigations and evidence-based recommendations that resonate and are embraced and promoted by the communities served.[7] Longer-term evaluation of these collaborations reveals that their establishment is not enough to ensure success and that the deliberate management of contextual factors, resources, and internal demands is necessary to achieve the outcomes and goals of the partnership's initiatives.[1,8]

Several models have been developed to investigate various dimensions of collaborative community health partnerships. These frameworks describe a range of concepts such as the elements that motivate and contribute to successful partnership formation[9] (e.g. partnership synergy[6] and shared vision[10]), creating effective leadership and management of the partnership,[5,8] building a partnership to maximize intervention implementation,[11] and fostering the sustainability of collaborative capacity.[12]

In this study, we employ a framework describing essential elements for successful initiative implementation and dissemination in healthcare intervention research. The model, described later in detail, is drawn from the combination of a conceptual framework developed by Bazzoli and colleagues in their evaluation of partnerships in the Community Care Network (CCN) and their ability to implement goals and initiatives[11,13] and a model of dissemination in healthcare intervention research developed by researchers at UCLA, RAND and the National Institutes on Mental Health.[1]

This article examines the efforts of a multi-sector collaborative partnership consisting of public and private partners to implement a medication therapy management (MTM) initiative for people with diabetes in the San Diego, California area. Specifically, we ask: *What contextual, resource, and internal conflict factors affect this unique community collaboration's potential to implement initiatives?* To address this question, we use data on the partnership characteristics (e.g., number of partners, organization types), survey data on the partnership experience by the collaborative leadership, an inventory of milestones and action steps taken towards implementation thus far, and information on organizational relationships gathered from the key informant interviews conducted with the partnership directors from the participating health plan, community health association, research organizations, and commercial pharmacy group. This data forms the basis of our comparison of this collaborative partnership to a conceptual framework of effective collaboration implementation. This paper highlights the unique nature of this particular collaboration and comments on the potential for this partnership to implement research pilots and other further initiatives.

We analyze this collaboration using a combination of methods to gather multiple stakeholder perspectives and relate these views with a set of hypotheses based on the significant dimensions of an implementation conceptual framework. A discussion follows on how these hypotheses could be further tested by using additional quantitative methodologies to analyze other partnerships aimed at addressing translation of health services research to the community. We conclude with future implications for collaborative partnerships and tips for effective operation as popular vehicles in development of real-world models for improving health care coordination, quality, and population health outcomes.

RELEVANCE

Accountable Care Organizations (ACOs) have gained recent interest as a means to slow the growth of health care spending while improving quality of care. Proponents of the concept envision ACOs as having potential advantages for patients, providers, hospitals and payers – particularly in providing more cost-effective care to those with chronic conditions such as diabetes.[14] Currently, people with chronic illnesses often see multiple physicians for co-morbid conditions and in different locations. This can lead to uncoordinated care, which results in avoidable hospital admissions and readmissions, poor medication adherence, and incomplete follow-up care. ACOs can help respond to these issues by creating a financial incentive and payment methodology that will reward providers for keeping patients well. The main features of ACOs include a team-based approach to take responsibility for patient care on a episodic basis using bundled payments, public reporting of performance measures, and use of electronic

records and visits to create better integration and less fragmentation amongst care providers.[15,16]

A key policy issue for the Centers for Medicare and Medicaid Services are details on how the ideal ACO will be organized and implemented including what financial incentive structures will reduce spending. Demonstration projects are examining how ACOs might specifically improve care and reduce costs, but what has yet to be researched and where there is additional interest, is in the effects of ACOs on the costs and quality of care in the private sector and non-Medicare population and what organizational and contextual factors contribute to success.[17]

Ideally, the ACO includes a continuum of care via a provider network, but what remains to be determined are: organizational structure, leadership, care processes, and influences from the external environment such as market structure and state health policies. Several approaches for how ACOs might organize have been suggested including: Patient-Centered Medical Homes (PCMHs), integrated delivery systems with a common ownership (e.g., Kaiser Permanente, Group Health Cooperative of Puget Sound, and Geisinger Health System), multi-specialty group practices with a strong hospital affiliation and contracts with multiple health plans (e.g., Mayo Clinic, Cleveland Clinic), physician-hospital organizations that are a subset of the hospital's medical staff (e.g., Advocate Health in Chicago), independent practice associations that contract with health plans and might organize to engage in quality improvement initiatives or practice redesign project such as implementation of electronic health records (e.g., Hill Physicians Group in Northern California), and virtual physician organizations which may be small, independent physicians located in rural areas (e.g., Community Care of North

Carolina).[16] Some of the most structurally integrated systems might be natural candidates for capitation or bundled payment systems, in which providers assume a higher degree of risk. In contrast, the less integrated groups might be better suited for a limited, partial capitation for certain illnesses with a lower degree of risk. In order to accommodate these different organizational arrangements, a tiered qualification system has been suggested so that practices can begin at a lower level with fewer capabilities and rewards, but advance to higher levels and greater rewards over time.[16]

ACO capabilities and structure requires testing in actual real-world scenarios like the one presented in this study to determine which models work best under local market circumstances. Further, challenges faced by this collaborative partnership such as shared responsibility for electronic data systems, coordination of care, measurement and accountability, clinical and managerial leadership, and engagement of the patient population are likely to be important considerations for ACOs as well. While ACOs and PCMHs might take several forms, there is agreement that they should include structures such as electronic health records, reporting systems, e-prescribing, and care coordination that lead to the desired outcomes. For care of chronic diseases such as diabetes, stakeholders in the U.S. health care reform movement agree that positive transformation requires “improving population health, engaging patients in making decisions and managing their care, and improving safety and care coordination.”[18] The collaboration described here provides important potential learning regarding how these systems might be implemented in an applied setting employing a structure that is open to the community and encourages member involvement in the prevention as well as the treatment of diabetes.

NEW CONTRIBUTION

This study uses qualitative investigation to provide insight into how physician medical groups, health plans, community organizations, and commercial health services providers might work more effectively together to improve quality and produce cost-savings. The detailed nature of qualitative study has allowed us special insight into specific organizational and management challenges over the course of the development of the pilot. As each step in the project is implemented, new hurdles were exposed such as deciding whether on-site glucose testing is possible, and how to and who will pay for it. The qualitative inquiry allows us to gather detailed information on how each partner might deal with these issues and what other potential problems may arise as a result. Details on negotiation and insight into the working and management style of partners are not easily observed with quantitative study.

This collaboration involving several public and private partners is the first of its kind to be described in the scientific literature, to our knowledge. The partners involved include a private health plan (UnitedHealthcare), research organizations/universities (RAND, UCLA, UCSD)[*], a group of commercial community pharmacies/pharmacists (Ralphs Pharmacies/Kroger Co.), a community health benefits association contracted with San Diego public school districts (California Schools Voluntary Employee Benefits Association), a health law professor/representative (Warren Barnes, JD), with partial funding through a federal grant from the National Heart, Lung, and Blood Institute (part of the National Institutes of Health), and affiliation with the Right Care Initiative (a public health initiative founded by the California Department of Managed Health Care). We can

[*] These organizations are part of the California Comparative Effectiveness and Outcomes Improvement Center – a collaborative comparative effectiveness research entity. RAND = The Rand Corporation, UCSD = University of California, San Diego, and UCLA = University of California, Los Angeles

use the lessons learned from these research and practice collaborations as health services organizations develop practical models for implementation of PCMH and ACOs. This collaboration is a fine example of how we might build multi-sector partnerships to create shared responsibility for population health, outcomes, and equity.[19]

CONCEPTUAL FRAMEWORK, HYPOTHESES, & PARTNERSHIP SURVEY

No single theory or school of thought can capture adequately the dynamics of intervention dissemination within complex community settings. Therefore, our framework draws from multiple research perspectives from psychology, social and organizational change, resource dependency, strategic management, economics, political science, and diffusion of innovations theory. These theoretical bases give rise to hypotheses regarding initiative implementation that are practically tested with question items on a survey of the partnership leaders. The five major domains of the conceptual framework are: external context, resource demands, partnership conflict, leadership style, and goal achievement in initiative implementation (see Figure 1). We present the theory that motivates each domain, associated hypotheses, and related survey questions below.

External Context

We look to psychology to understand certain external contextual factors such as determinants of individual and group behavioral change from Bandura,[20,21] and Ajzen and Fishbein.[22] Sociological theory provides characteristics of successful collective movements toward social and organizational change.[23,24] Resource dependency theory posits that external forces may create barriers for the partnership that limit its

ability to achieve its potential. Bazzoli et al. interpret this as meaning that external forces that dominate collaborative processes can create distrust and disharmony in a partnership where members expect consensus in decision-making and collaborative action and ultimately impede progress.[11] In the partnership studied here, external forces may have led to delays in progress, but it is not clear if they affected partnership leaders' perceptions of control over processes or created feelings of distrust or disharmony amongst the partners. Therefore, we frame our hypothesis on the effect of external control as follows:

Hypothesis 1: The less partnership leaders perceive external control over partnership decision-making ability or resources, the more likely the partnership will implement its initiatives.

Resource dependency theory also suggests that munificent environments produce more success in implementing partnership initiatives compared to those that have less resources (e.g., urban versus rural environments, areas with higher versus lower per capita income, areas with a variety of advanced versus only basic health service delivery options) to draw upon to implement their initiatives.[25,26]

Hypothesis 2: The more partnership leaders perceive a greater availability and generosity of local resources, the more likely the partnership will implement its initiatives.

Economic theory provides insight on the effects of incentives on individual and group behavior.[27,28,29] In this community-partnered context, we take this to mean the principle of mutual benefit, i.e., finding "win-win" situations for all participants in the partnership. The diffusion of innovation theory derived from several disciplines allows us to examine the process of implementation and understand factors that might promote the uptake and sustainability of effective inter-organizational collaborations for

community health.[30,31] While all these theories contribute to the items contained in the contextual environment dimension, we place special focus on the level of external control on the partnership and philanthropy of local resources as particularly influential in achieving the implementation of partnership initiatives.[111]

The two above hypotheses, modified slightly from Bazzoli et al. give rise to the following two items in our survey of partnership leaders:

> *To what degree do you agree or disagree with the following statements in regards to this collaborative partnership:*[†]
>
> A low level of external control over the partnership's decision-making abilities has helped the partnership to implement its initiatives.
>
> A high level of generosity of local resources has helped the partnership to implement its initiatives.

Resource Demands

The resource demands dimension draws from strategic management theory that focuses upon internal organizational competencies and appropriate matching of these with the scope of partnership activities. Accordingly, large scope activities are best associated with organizations and partnerships that can accommodate complexity.[32] Smaller more limited partnerships might be most effective at implementing more targeted interventions. In the context of this partnership, we take resource demands to include those typical of clinical and community health interventions – such as funding for dedicated tasks (e.g., care or data management), specialized personnel (e.g., pharmacists, laboratory specialists), and infrastructure (e.g., consultation areas, meeting space, office staff). In addition, we recognize community-partnered projects

[†] *We used a 5-point Likert-style answer choice range including "strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree." An answer choice of "not applicable" is also included.*

also often rely on mostly voluntary and non-reimbursed efforts for referrals, organizing, and awareness-raising. In this context, we form the following hypothesis:

Hypothesis 3: A narrow partnership scope, which here means leaders perceive fewer resource demands on them, including unreimbursed and voluntary activities, the more likely the partnership will implement its initiatives.

This is the corresponding survey item:

To what degree do you agree or disagree with the following statements in regards to this collaborative partnership:

The limited scope of the partnership's planned activity has helped the partnership to implement its initiatives.

Partnership Conflict

From political science theory, we incorporate the dimensions of collaboration politics and conflict negotiation amongst members. It is essential to effectively deal with interpersonal and inter-organizational conflict to ensure the benefits of collaboration are equally distributed, especially given the varying agendas and needs of organizational partners.[33,34] In the context of this partnership, this is defined as conflict that might arise when interests of different partners are not aligned, creating a “principal-agent” problem.[27] For example, the health plan wishes to increase quality of care and reduce costs by implementing programs that include a pharmacist on the care team. However, providers must bear the near-term costs of accommodating these programs by educating their staff, coordinating their laboratories, and sharing data and will see modest, if any, immediate savings. Therefore, in this case, the “principal” the health plan, may need to negotiate with and incentivize the “agent”, the primary care physicians. These theoretical principles have helped form the basis for this hypothesis:

Hypothesis 4: The more partnership leaders perceive they have a greater ability to resolve conflict and negotiate across partnering organizations, the more likely the partnership will implement its initiatives.

Accordingly, we developed a survey item related to this hypothesis:

To what degree do you agree or disagree with the following statements in regards to this collaborative partnership:

A high emphasis on resolving conflict and building bridges across organizations has helped the partnership to implement its initiatives.

In our framework, we also emphasize the abilities and qualities of partnership leadership to effectively build relationships across organizations and deal with partnership conflicts. We surveyed the partnership leaders' perceptions regarding this concept in the following survey items adapted and modified from Bazzoli et al.:

How well do the following phrases describe how this collaborative partnership deals with conflict and problem solving?[‡]

Conflict Management Factor 1: Collaborative

- All partnership organizations will work hard to arrive at the best possible solution.
- Everyone contributes from his or her experience and expertise to produce a high-quality solution.
- All points of view will be carefully considered in arriving at the best solution to the problem.
- Each partnership organization involved will give in a bit and settle on compromise.

Conflict Management Factor 2: Refer

- When two partnership organizations disagree, they will seek a third partnership organization to help resolve this issue.
- A problem between two partnership organizations will be referred to another partnership organization for resolution.

Conflict Management Factor 3: Avoidance

- When partnership organizations disagree, they will ignore the issue, pretending it will "go away."
- Partnership organizations tend to withdraw from conflict.

[‡] *Respondents were asked to rate the phrases on a 5-point Likert-style answer choice range including "strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree."*

- Disagreements between partnership organizations will be ignored.
- Partnership organizations yield their position on an issue to others to maintain harmony and stability.

The above items were presented in a different random order for each respondent and were not identified as belonging to a particular "conflict management factor" so that we could analyze which factor played the biggest role in this partnership.

Leadership Style

The leadership element of the framework focuses upon the abilities of the partnership leaders to both build relationships and get things done. Bazzoli and colleagues chose to incorporate strategic management and leadership more generally across all domains of their framework. We feel the roles of effective leadership and management style to be of great importance in terms of task coordination, conflict resolution, and delegation amongst partners. In fact, other conceptual frameworks of collaboration such as those developed by Zakocs and Edwards,[35] Ansell & Gash,[36] and Bryson, Crosby & Stone[37] emphasize leadership as the central factor in effective collaborative endeavors. Therefore, our framework includes a specific domain to address these items.

In the context of this partnership, representatives from the primary working partners form the collaborative leadership team. We wanted to see if there were varying partnership leaders' perspectives on the abilities of the team to resolve conflict and delegate tasks (i.e., having an action orientation) specific to implementing partnership initiatives:

Hypothesis 5: The more partnership leaders perceive they have abilities to resolve conflict and delegate tasks effectively the more likely the partnership will implement its initiatives.

Other favorable leadership qualities such as abilities to utilize many people's talents, build relationships and consensus, and having a clear vision for the partnership are also important to the effectiveness of the collaboration. While this hypothesis posits that having an "action orientation" will increase the likelihood of implementation of partnership activities, leadership factors related to "relationship building" could also be equally important in "getting things done." Therefore, partnership leaders were asked about both "action-orientation" and "relationship-building" leadership factors, modified slightly from Bazzoli et al.:

> *Which of the following phrases best describes this collaborative partnership's LEADERSHIP TEAM? Please choose up to 4 phrases.*
>
> Leadership Factor 1: Action oriented
> Partnership leadership:
> - Is able to secure resources
> - Gets things done
> - Has a clear vision for the partnership
> - Advocates strongly for their own opinions and agenda
>
> Leadership Factor 2: Relationship builder
> Partnership leadership:
> - Is ethical
> - Utilizes the skills and talents of many, not just a few
> - Builds consensus on key decisions
> - Is effective at keeping the partnership focused on tasks or objectives

The above eight leadership characteristics were presented in a different random order for each respondent and were not identified as belonging to a particular "leadership factor" so that we could analyze which items played the most salient roles in this partnership.

Finally, to specifically address the importance of task coordination[25] in implementing partnership initiatives, the following survey item was included:

To what degree do you agree or disagree with the following statements in regards to this collaborative partnership:

A high level of task coordination within this partnership has helped to implement its initiatives.

Goal Achievement

The number of actions completed and ability to accomplish tasks are major goals in this collaborative partnership framework of initiative implementation. Bogue and colleagues[38] developed a categorization scheme for partnership actions including: strategic actions, instrumental actions, and evaluative actions (each category is further defined in the survey item below). In the context of this partnership, if the partnership leaders perceive the collaboration to be completing actions in one particular area, perhaps the other two areas might be neglected. Or, alternatively, if there's no clear consensus on the types of actions the collaboration can achieve, this may be an indication why the collaboration may not be operating at its highest efficiency. In order to categorize the types of actions in which the partners perceived the partnership was most engaged, we asked respondents to answer the following:

Which of the following categories best describes the types of actions this collaboration is able to achieve?

- *Strategic Actions*: lead to decisions or decision-making capacity (e.g., establishing board structures or bylaws for the partnership, holding public hearings)
- *Instrumental Actions*: bring about a particular outcome (e.g., acquisition of office space or van to provide health services, hiring and training staff, marketing services to community)
- *Evaluative Actions*: assess local needs or the effectiveness of partnership activities (e.g., studying the community health needs, tracking clients served, assessing benefits and costs of collaborative efforts)
- None of the above

Finally, to gather the partnership leader's perspectives on the collaboration's ability to complete action steps in a timely fashion and according to plan, the following survey item was also included:

> *With regards to the ability for this collaboration to achieve its initiatives and associated actions, would you say action steps were most often:*
>
> - Completed as originally planned
> - Completed with modifications to time frame and/or scope
> - Ongoing, but not yet completed
> - Postponed
> - Abandoned
> - Have unknown status

DATA & ANALYTICAL METHODS

We explored these hypotheses of collaborative initiative implementation using the partnership survey and qualitative interviews. We use the empirical factor analysis results from Bazzoli et al.[11] in their analysis of the initiatives implemented as part of the CCN compared to our descriptive survey results. A case study approach and key informant interviews help to further elucidate the effects of the conceptual framework domains on collaborative partnership initiative implementation.

The survey and interview data is gathered from the leadership representatives from each of the major working partners: UnitedHealthcare, Ralphs/Kroger Co., the California Schools Voluntary Employee Benefits Association, and RAND/UCLA/UCSD. The surveys (n=8) were collected in February 2012, about a month before the pilot study was initiated, using a confidential and anonymous Internet survey instrument. Table 2 shows the mean descriptive statistics on key variables examined in the multivariate analyses presented by Bazzoli et al. compared to our survey results. Certain variables that were not applicable to our partnership or situation have been

omitted.

The majority of the items used in the collaborative partnership survey are described above with the discussion of the theoretical bases of the conceptual framework and associated hypotheses. In addition, respondents were asked to provide additional comments regarding the amount of time they spent on this collaboration per month, their level of satisfaction with the partnership, whether they would continue working with the partnership after the pilot has been completed, and what particular strengths, weaknesses, opportunities, and threats they feel characterize this collaboration.

In order to compare our collaborative partnership and the results of our survey to the variables described in the Bazzoli framework, we gathered data on partnership characteristics such as the number and type of partners and the sectors to which they belong. Also, we looked to the HealthLeaders-InterStudy research Market Overview (2009)[39] for San Diego County, California to create an area profile and compare area statistics to the state of California on certain variables such as location type (i.e., rural, suburban, or urban), per capita income, and health maintenance organization and preferred provider organization market share.

The quantitative analysis conducted in the Bazzoli et al. article includes multivariate LOGIT analysis to assess the relationship between partnership measures and action step accomplishment. They constructed a logistic dependent variable that equaled “1” if the CCN partnership reported completing the action as planned or with modifications and “0” otherwise. They examined this dependent variable as a simple linear function of the partnership measures. They applied this LOGIT analysis to 524

unique action steps related to 144 initiatives in 25 different CCN partnerships.[11] In our analysis, we compare the variables they found to be statistically significant in a positive (more likely to help the partnership complete its initiatives) or negative (less likely to help the partnership complete its initiatives) direction to the collaborative partnership leader's perceptions collected in the survey.

Key informant interviews were conducted with the leadership team members in the earlier project planning stages in August 2011. This qualitative information provides additional insight on the hypotheses described in the previous section and also fills in gaps in the survey analysis especially related to highly generalized explanatory variables and contextual variances between the CCN partnerships and our collaboration. The content of these interviews included questions regarding partner goals and interests in the implementation of this pilot, clarifications of the procedure and protocol for the pilot, and the partner's views on the future viability of medication therapy management (MTM) programs as well as how they might be structured and funded. The study principal investigator at RAND and the primary project manager at UCLA conducted the interviews and took notes that served as the written chronologies of the sessions.

Interviews with the key partners were conducted fairly early in the process in order to clarify roles and responsibilities and begin to work through the expectations and procedures throughout the pilot project. There were several unknowns and uncertainties in how the partners might have to negotiate with each other at this point. For this reason, it was useful to talk through expectations and gather information on each partner's perspectives and interests. The intent in reviewing these interviews for this

analysis is to discuss the most important roles and interests that arose which impacted the partnership's abilities to implement initiatives.

RESULTS & ANALYSIS

Collaborative Project Description

As part of their efforts to identify cost-effective ways to improve care quality and outcomes for their members with diabetes, a large employer group - California Schools Voluntary Employee Benefits Association (VEBA) and health plan (UnitedHealthcare) in San Diego are conducting this pilot program in which up to 300 participating patients will see a community pharmacist in concert with their usual physician care. The aims for this initial pilot project are to enroll patients who have diabetes in this six-month MTM intervention to determine if the use of a community pharmacist to assist with medication review, compliance, and adherence would be feasible, useful, and improve their health outcomes. The primary health outcome measures are the HbA1c and systolic/diastolic blood pressure. In addition, participants have a complete metabolic blood panel and a fasting lipid panel conducted at baseline and six months.

Including pharmacists as part of the medical care team along with physicians to help patients manage and optimize the medications they are taking (i.e. medication therapy management or MTM) has been shown in studies in selected settings and populations, to lower costs, reduce hospital visits and adverse events, and improve diabetic outcomes. Though persuaded that if MTM is effectively implemented, it can potentially benefit their patients' health (and reduce costs), decision makers in employer groups and health plans are less certain about the feasibility and desirability of deploying MTM in the settings and populations they serve. Hence, these collaborative

partners have decided to conduct an initial pilot program to clarify these issues.

Pharmacists based in thirteen Ralphs/Kroger Co. grocery stores throughout San Diego serve as community pharmacists during the pilot. Based on the pilot results and feedback from an accompanying formative evaluation led by RAND, the employer and health plan will decide whether and how best to scale-up use of community pharmacists on the care team. A larger and more rigorous intervention trial involving other employer groups and health plans will be considered if the initial pilot results are promising.

Potential patient participants in the pilot include school district employees (and/or their dependents) with diabetes associated with VEBA insured through UnitedHealthcare. Participants received announcements about the pilot program and if interested were asked to attend an informational meeting conducted by VEBA health specialists. Ralphs pharmacists and research team members also attend these informational meetings. During the meeting, potential participants learn full details about what their participation in the pilot entails, benefits, and risks before they are given an opportunity to go through the formal consent process and sign patient health information release (HIPAA) authorizations. Participation in the pilot for eligible patients is completely voluntary, without any direct costs to patients, and they are not randomized. This project and its evaluation were approved by the IRB at UCLA.

Area Description

Table 1 displays selected population, area, and health care market characteristics for the geographically mixed area of San Diego County, CA. This collaborative initiative was implemented in a county where a relatively few number of health plans dominate the majority of the market. The biggest players (Sharp, Scripps,

and Kaiser Permanente) are highly integrated, technologically advanced, and known for being innovative. The San Diego area is at the center of several recent demonstrations of pay-for-performance for physicians and other cost-saving efforts for employers. This collaborative study is a part of the Right Care Initiative, a multi-stakeholder, multi-sector effort in California aiming to improve health outcomes for people with high cholesterol levels, heart disease, high blood pressure, and diabetes. The initiative leaders have chosen San Diego as its demonstration project center with several research initiatives and a patient activation public awareness campaign underway called "Be There San Diego" with former San Diego Chargers football kicker, Rolf Benirschke, as the campaign spokesperson. The goal is to make San Diego a "heart attack and stroke free zone."[40] These characteristics make this environment a good fit for this type of innovative and potentially cost-saving community pharmacist project.

Collaborative Partnership Composition

This collaborative partnership included nine members at the start and to date, that number has decreased to eight members. These members included half from private health organizations (RAND, UnitedHealthcare, Healthy Adventures Foundation/California Schools Voluntary Employee Benefits Association, and one no longer participating health plan), private non-health organizations (Ralphs/The Kroger Co. and Warren Barnes, JD), government entities (Right Care Initiative – Department of Managed Health Care), and education partners (UCLA and UCSD). The eight partners currently working on the initiative would be considered "Full Working Partners" with dedicated specific staff and/or financial resources to assist the partnership in implementing its initiatives.

In response to the survey question, “In a typical month, about how many hours do you devote to this collaborative effort?” answers ranged from three hours to 80 hours. Half (4/8) of the partnership leaders indicated they spend about four to eight hours per month on this collaboration. Six of eight respondents said they were “extremely satisfied” or “moderately satisfied” with this collaborative partnership. One respondent indicated they were only “slightly satisfied” and one felt “moderately dissatisfied” with this partnership. Further, almost all partnership leaders (7/8) indicated they would be “extremely likely” or “very likely” to continue working with this collaborative partnership once the initial pilot was completed. One partnership leader indicated they were only “moderately likely” to continue.

In the Bazzoli et al. analysis, their LOGIT specification revealed a significant result related to the number of collaborative partners and the change in number of partners. In support of Hypotheses 3 and 4, larger initial numbers of CCN partnering organizations and greater growth in the number of partners, both of which may be related to partnership complexity and conflict, were significantly related to lower likelihood of implementing action steps as planned.[11]

This partnership included nine members and was reduced to eight after about six months of establishment, which is a lower number of partners than the 11.54 mean number of partners in the Bazzoli et al. analysis.[11] Interestingly, the member that left the partnership is a health plan that is highly integrated, technologically advanced, and a closed system, but considered one of the top-performers in the area and state. Ironically, the more fragmented and less streamlined health plan participant ended up being more flexible and capable of integrating this type of community pharmacist model.

Perhaps the insular and closed nature of the health plan that dropped out contributed to its inability to find a way to participate in a community health model that employed many "outside" elements.

In addition to partnership member number, the composition and type of partner significantly affected the likelihood of completing planned actions according to the Bazzoli analysis. Partnerships with higher proportions of private sector, non-health organizations were more likely to implement action steps as planned. Bazzoli and colleagues hypothesize that a more action-oriented partnership culture may result from the partners that come from the private business sector.[11]

This partnership included two of eight non-health organization members. One effect of having these non-health members in the collaboration was a healthy diversity of thought and an air of basic inquiry in comparison to the "research" oriented university-based members. One non-health member, who also served as the primary bi-weekly meeting moderator, brought up questions related to the research design or process that might seem naïve or basic to the researchers, but helped the team work through the project's core feasibility effectively. Both the survey responses and qualitative interviews support a genuine feeling amongst the group that minds are equally coming together from different sectors and ways of thinking to arrive at the best common solutions. In fact, when asked to describe the partnership's greatest strengths, the characteristics the leaders cited were the "*variety of abilities*," "*very high skill sets*," "*talents*," "*backgrounds*," "*scope of practices*," "*collective expertise from many stakeholders*," and statements related to "*bridging healthcare delivery, research, and*

government." Further, in terms of opportunities, some mentioned that this project is a good "*practical application of known best practices*" that "*merges diverse solutions*."

Dual Effect of Contextual Forces on Functioning

The partnership leaders cited certain external entities as a hindrance in the functions and processes of the collaboration. In support of this notion and in regards to Hypothesis 1, three partnership leaders indicated they "disagreed" that "a low level of external control over the partnership's decision-making abilities helped the partnership to implement its initiatives." Qualitative answers provided by leaders in regards to partnership weaknesses help further explain why external forces may have impeded progress in implementing the initiatives. Three people mentioned "*bureaucracy in the process with the IRB*," "*IRB and other legal hurdles*," and "*stuck awaiting external (IRB) approval.*" Also cited as possible threats to the partnership were references to rule or IRB delays, "*killed by rules," "further delays," and "IRB-caused delays."* However, regarding the munificence of local resources and Hypothesis 2, all respondents either said they "agreed" or "strongly agreed" that "A high level of generosity of local resources has helped the partnership to implement its initiatives." If we look to the external market forces (e.g., high availability of health services, rich urban local environment, and comparatively high per capita income) and the general enthusiasm and support from the local schools and physicians to complete this pilot - these conditions support this finding. These results indicate certain "external forces" (e.g., IRB review and corporate legal departments) were viewed as barriers to implementation and functioning, while the munificence of "local resources" (e.g., favorable environmental characteristics, enthusiasm and devotion to effort from school districts and physicians) served to

encourage initiative implementation.

Contextual Community Partner Involvement

In the interview with the California Schools VEBA leaders, it was immediately clear they would be this collaboration's most important connection to the community and population of interest. Since the pilot effort would not include conducting separate focus groups with the potential participants regarding their thoughts on the benefits and barriers of this pharmacist intervention and their willingness to participate in this type of project, it became paramount that this collaboration draw upon the experience and wisdom of the VEBA leaders to provide this background. In this regard, discussions with VEBA health coaches has largely centered on the best ways to market to, recruit, and engage this diabetes patient population. For example, VEBA has been able to provide statistics about the percentage of participants expected to be reached through email and direct mail marketing versus flyers to District Benefit Managers. Also, VEBA has imparted knowledge about the best times, methods, and language to reach potential participants. Even with this assistance, there is concern from the partnership leaders about participant inducements and recruitment related issues, *"making the study appealing to patients/marketing"* and *"recruiting sufficient numbers of participants."*

Throughout this process, the collaboration continues to rely on the relationships that the VEBA health coaches have developed with this patient population to assist in connecting these initiatives with the interests of the community. VEBA's role as an important community connection has improved the abilities to implement this pilot initiative and to reach this target population in a meaningful way. In terms of partnership

opportunities, leaders indicated this partnership initiative could, "*complete useful research and help members of the community*" by "*helping those with diabetes and building new relationships with partner organizations*" and "*do something unique*."

The involvement of another community partner, the community-based pharmacy group part of Ralphs/Kroger Co. has added an interesting dimension to the partnership functioning. In certain ways, some complexity is added because this partner is not affiliated with a particular medical group or health organization. For example, UCSD and Sharp Reese-Stealy have "in-house" pharmacists that provide MTM services to patients. At UCSD, these pharmacists might be associated and employed with a particular department such as Family Medicine or General Internal Medicine. Therefore, it is an interesting question whether it is feasible to introduce a member of the patient care team that is both geographically and in practice not associated with the primary care physician or medical group. Further, it is unknown whether community pharmacists may play an important role in connecting the patient to a health professional they can conveniently interact with while performing day-to-day duties like grocery shopping. On the other hand, because Ralphs pharmacists are not associated with a particular medical group or health organization, there is more flexibility for the patient in being able to choose a time, location, and provider that works for them. There is general agreement that added convenience and coordination in patient care is a major goal for all stakeholders involved.

Resource Demands on Partners

This collaborative partnership demands time and resources from each partner and at times it is unclear where responsibility or longer term funding lies. In support of

this finding, one partnership leader indicated that "*no clear ongoing funding source*" was a weakness of the partnership and another mentioned "*limited time people can devote to the project given all of their other responsibilities - and conflict of funded vs. non-funded work that has to be done by many.*" Several respondents also mentioned funding or resource related issues as threats to the partnership in the longer term, "*very slim funding," "losing staff due to lack of long-term funding stream," and "lack of funding to carry project to next levels."*

Despite this uncertainty, the partners have responded and adjusted in the near term when flexibility or extra effort is required. For instance, the UnitedHealthcare (UHC) leaders discussed in their interview important strategic considerations as they develop practical solutions for how to feasibly implement these types of MTM models. The UHC partners have been open in their discussions in terms of their struggles with how to pay for and set-up contracts for pharmacists to provide MTM services, especially if they decide to expand these services to all of their enrollees. This partner has also introduced important considerations such as how to work with and integrate the Pharmacy Benefit Management companies in these models. UHC is also the closest partner to the primary care physicians for the participants. This means UHC has had to negotiate the relationship between the physician medical group offices for participants and their associated laboratories in order to obtain lab tests and results for this pilot. In this regard, UHC has both contributed to the longer range vision on how these MTM programs might be contracted, financed, and structured and has also assisted in the practical near term implementation of this initial pilot.

Similarly, the Ralphs/Kroger Co. pharmacists responded to a need for greater flexibility and expansion of service offerings. Recently, they decided to expand the pharmacist services offerings for this project without additional charge to include additional lifestyle, quality of life assessment, and coaching elements as well as more comprehensive prescription and over-the-counter medication reviews for each patient. Also, the Ralphs pharmacists increased the selection of locations, modes, and times to meet with patients. One partnership leader expressed hope that this increase in services and flexibility will help to improve the appeal of the program to recruit more participants and facilitate progress toward completing this pilot initiative.

Partnership Functioning and Completing Actions

We received mixed responses from partnership leaders regarding their perspectives on the type of actions this collaborative is capable of completing. Three of eight respondents felt most of the actions of this collaborative partnership can be described as either "instrumental" i.e., bring about a particular outcome. Another three of eight felt the partnership was most concerned with "evaluative" actions, which assess local needs or the effectiveness of partnership activities. One leader perceived the actions of the collaborative to be more "strategic" i.e., leading to decisions or decision-making capacity. Finally, one respondent felt the activities achieved by this collaboration could be described as none of these types of actions. This mix of responses may indicate leaders perceive the collaborative to be completing many types of actions or may also indicate no clear prominent type of action.

There was also some difference in opinion about whether the "limited scope of the partnership's planned activities has helped the partnership to implement its

initiatives." as described in Hypothesis 3. Part of this mixed feeling may come from a difference in opinion about whether the partnership's activities are actually limited. One partnership leader commented, *"what the organization is trying to do is neither easy nor simple but the project itself is both easy and simple."*

In regards to the ability to complete action steps on time and as planned, respondents felt that most of the collaborative activities were either "completed with modifications to scope or time frame" (3/8) or "ongoing but not yet completed" (3/8). Two respondents felt most partnership activities were "postponed." Two others mentioned delays in partnership activities as a weakness, "*tied up by rules and regulations*" and "*inability to overcome barriers in a timely manner*." The 14 major collaborative partnership action steps completed are listed in a Gaant chart (see Table 3). One can observe that the action steps mapped on the calendar do indeed indicate that steps were completed, but with modifications to time frame and some that were postponed or are ongoing. Finally, regarding task coordination in Hypothesis 5, a good majority (6/8) said they "agreed" or "strongly agreed" that "A high level of task coordination within this partnership has helped to implement its initiatives." One partnership leader indicated this project allows for "*learning from not only the results of the project - but the processes of the project. How other stakeholders think and approach issues is enlightening.*"

Leadership Style and Partnership Conflict

Respondents chose statements to describe the leadership team that are associated with "relationship building" (25/37) rather than "action orientation" (12/37). Of the "relationship building" characteristics, "is ethical" was chosen most often, followed

equally by the following statements: “utilizes the skills and talents of many, not just a few,” “builds consensus on key decisions,” and “is effective at keeping the partnership focused on tasks or objectives.” Also, partnership leaders perceive partnership conflict is dealt with using a “collaborative style” rather than “referring” to a third party or using conflict “avoidance.” Bazzoli and colleagues found stronger action orientation helps the partnership to implement initiatives.[11] According to the stakeholder perspectives we gathered, this partnership’s leadership style is focused on “relationship building” which may be a contributing factor to delays in implementing action steps.

The survey question related to Hypothesis 4 asked respondents to rate the degree to which they agree with the statement, “A high emphasis on resolving conflict and building bridges across organizations has helped the partnership to implement its initiatives. Most respondents (6/8) either “agreed” or “strongly agreed” with this statement, although one partnership leader said that they “strongly disagreed” with this statement and wrote in their comments, *“I don’t feel like there has been much conflict.”*

DISCUSSION OF KEY FINDINGS AND IMPLICATIONS

In this work, we employ a framework that attempts to bridge the research-to-practice gap by providing a theoretically grounded understanding of the multi-layered nature of community and healthcare contexts and the mechanisms by which new programs and practices diffuse within applied settings. We combine the studies of the CCN demonstration programs and partnerships with the survey and interview results of a multi-sector partnership to gain insight into how these partnerships can best implement initiatives, the barriers and opportunities they encounter, and how they can achieve their potential. We summarize the key findings from our qualitative and

descriptive survey analyses and discuss the implications of these findings for future multi-sector collaborative partnerships.

We found an influence of contextual factors in both the positive and negative direction in studying the transportability of this health intervention into everyday community settings. In this collaboration, the items that affected the initiative in the positive direction (towards getting action steps completed) included support and time contributed by external community partners such as school district managers and participating physician medical groups. In the negative direction, the most notable influences that led to project delays were due to gaining appropriate IRB, investigator, and legal department approvals. However, the project leaders collectively agreed that adhering to the ethical standards and gaining the appropriate research reviews was an important value to the partnership, so it makes sense that effort and time would be spent ensuring full compliance.

The CCN initiative was designed to increase the ability of public-private partnerships to address community health improvement projects that require multi-sector collaboration. The four dimensions of their overall evaluative model included: 1) community health focus – focus on the health status of communities, not just individual patients; 2) seamless continuum of care – implementation of mechanisms that would facilitate and coordinate service delivery at the right time and in the most appropriate settings; 3) manage within limited resources – provide care delivery in the most efficient manner possible; and 4) community accountability – actively involve community groups to help identify, prioritize, and respond to local needs and provide ongoing reports to these parties.[10] On the whole, the collaborative partnership is achieving these goals,

especially with respect to the first three dimensions. On the fourth dimension, community accountability, the results indicate that additional focus will likely be required because mechanisms are not developed to gather information from community groups and report back to them on the partnership's efforts. Other work on community health collaborative partnerships[2,7] emphasize the importance of including a Community Advisory Board to assist with community accountability and formal establishment of the community as a partner, especially in collaborations that involve community-based organizations and academic institutions. Because the demonstrations and initiatives described here are framed as research projects – which can be a distancing factor, it would be useful for the collaborative leaders to maintain focus on the community at large and utilize the community connections already established through VEBA to continually incorporate the community as a significant partner. Some possible ways to address this might be to conduct focus groups with the school district employees and more formally include their opinions and thoughts in the design of community-based MTM projects in the future.

Study Limitations

This analysis of a unique partnership involving several community partners, academic institutions, commercial provider, and health insurance organization has limitations that should be mentioned. The partnership leader survey was conducted with a small number of respondents (n=8) who were part of one collaborative partnership. Though this number of responses is low, we did receive completed surveys from the total census of the leaders from the regular working partners involved. The sample chosen to receive the invitation to complete the survey was purposefully selected and

included those who are partner leaders or who work on the project regularly. Those who did not complete the survey were either ancillary to the project or are only involved on an occasional basis. However, we are unable to determine what the responses of those who did not complete the survey might entail, and what different perspectives they may have compared to those who did complete the survey. We do not know whether the partners who completed this survey or the partnership itself are representative of a larger population of partnership leaders or collectives. The intent of this analysis is to perform a descriptive comparison of this particular collaborative partnership to those described in the literature. There is no intention to determine causal inference. Confidentiality of the survey responses was well maintained and answers were candid and not subject to being overly optimistic. Self reported data was used to develop the list of action steps completed. Also, those directly related to the operation of the partnership provided commentary on it, and hence there may be a halo effect by respondents to report on it positively. For the formal formative evaluation, it would be useful for this collaborative partnership to obtain an outside evaluator's perspective on the functioning and sustainability of this partnership.

The method we used allows us to draw limited conclusions about the activities of this partnership alone. Additional analyses using a greater number and variety of partnerships and partners are needed to empirically test hypotheses derived from our qualitative inquiry. These studies might employ both surveys to gather a statistically significant number of responses and qualitative approaches using focus groups or interviews to add detail. Ideally, if many leaders from several partnerships were included in an analysis, their responses and statements could be classified and then tested and

validated to see if they statistically support each of the different hypotheses. Several researchers could independently code the statements to establish the reliability of their classification. We have focused on gathering stakeholder perspectives on the abilities of this one partnership to complete actions toward initiative implementation. However, a full evaluation of the collaborative partnership would include examination of additional areas such as factors that encourage sustainability and successful connections with the community. A fitting opportunity for this additional research might include the recent nationwide formation of Clinical and Translational Science Institutes by the National Institutes of Health focused on bridging the gap between biomedical research and community practice.

We relied upon the results of the LOGIT specification for the CCN partnerships described in Bazzoli et al. to guide our analysis of significant variables that impact implementation of initiatives. Their analytical model is cross-sectional and does not involve multiple measurement points or a control group. Their framework and analysis is based on a large number of partnerships, but examines the effects of a three-year demonstration project that took place about a decade ago. Longer-term effects such as those that may have occurred as a result of major leadership or staff changes were not captured. The partnership pilot we studied is still underway and at the time of writing will likely be running for another twelve months. The implementation of the pilot could still take additional turns or run into additional delays, especially since future funding and ongoing recruitment for the pilot is uncertain.

Study Implications

This analysis provides a qualitative and descriptive statistics approach to advance a theoretically grounded conceptual framework for multi-sector dissemination of community health collaborative partnership interventions. Through this framework, we examine contextual influences, resource demands, and internal conflict factors that affect this collaborative partnership's ability to implement initiatives. This analysis reveals several important implications for collaborative partnerships in dissemination of health interventions to communities.

Maintain ongoing focus on priorities and plans. Throughout the implementation process there are bound to be delays and action plans that get postponed. It is important that at least one leader keeps continuity in pushing the rest of the priorities forward even if one part is stalled. In this case, a several month postponement occurred due to difficulties in gaining the appropriate IRB and various legal departments' approvals for collaborative partners and the initiative pilot. During this time, it was important that the research team continue to move forward on recruitment strategies, patient questionnaires, and procedural work.

Recognize and respect limits on resources. Participants in these collaborative partnerships are largely doing so voluntarily and often may be using their own personal time and resources. It is important to recognize extra efforts and adhere to the rules and norms established by the group in order to maintain good relations amongst partners. This means starting and ending meetings on time and following through with tasks during the interim time periods. The collaboration we studied has done a good job on this point – not any one partner feels as if they have had the burden of duties – and this has consequently engendered a sense of camaraderie and mutual respect.

Be flexible and willing to adapt. The partners in this collaboration are good at responding to external changes by devising alternate solutions when barriers are presented. Each partner has been willing to learn how to adapt to another system's way of doing business. When it became clear that there might be difficulties in gaining legal approvals by the commercial partners in concert with the university-based research work, each responded by adapting their procedures to be able to work together. Also, for example, when vetting different flyers and approaches for recruiting patients for the pilot, there has been some negotiation on the tone of the materials. The "research study oriented" language and the more "commercially targeted" direct social marketing approaches have had to come together on one flyer.

This examination of the influences of context, resources, and conflict on implementation within health services research is an approach that attempts to move beyond addressing the gap between research and practice. The partnership leaders perceived this collaboration as an effective way to bring together expertise from a diverse group and practically apply best practices to bring about community health systems change.

FIGURE 1 **Conceptual Framework of Dissemination and Implementation of Collaborative Initiatives**

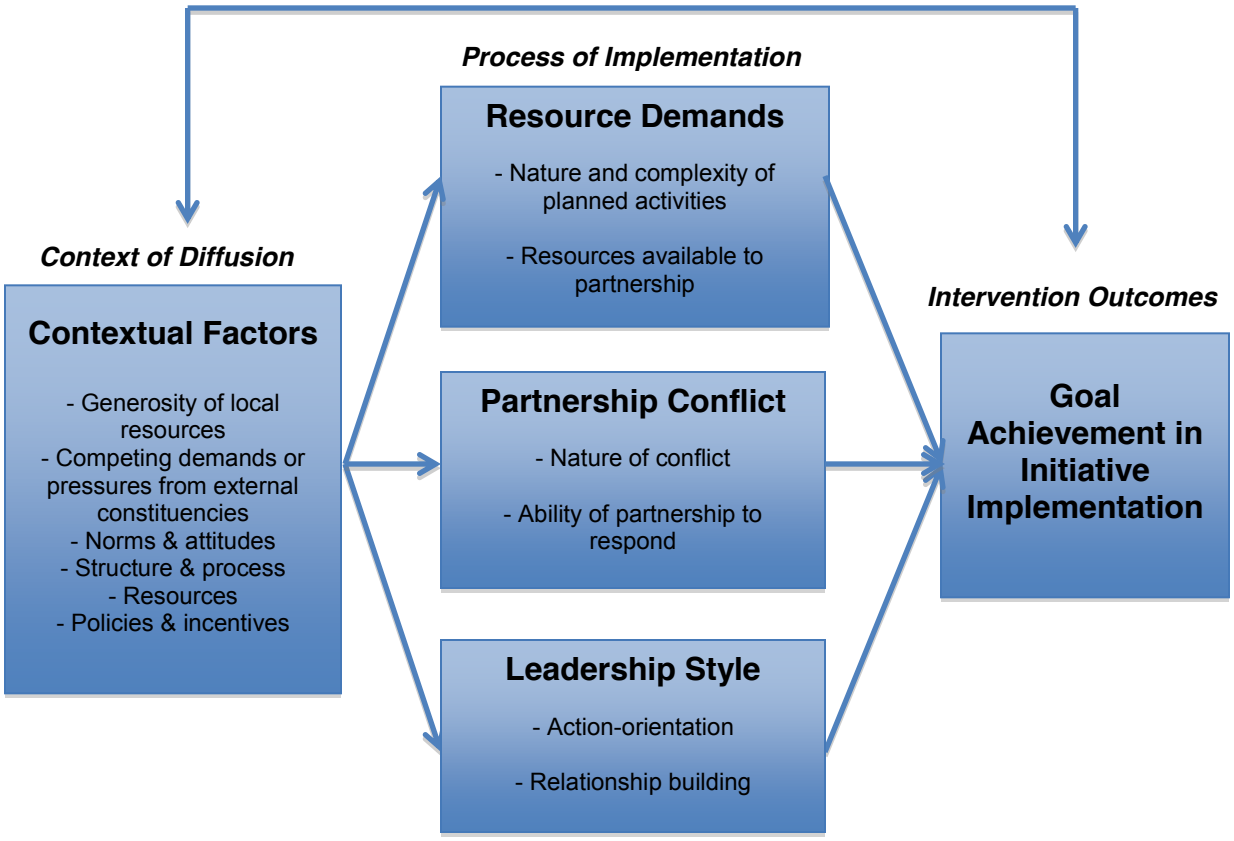


TABLE 1 Selected Environmental and Health Care Characteristics of San Diego County, California

Characteristic	Estimates
Total population*	3,066,820
Income per person in HH*	$18,841.88
Location of Partnership	San Diego County
Urban, Suburban, Rural	Combination
SD School District	5th largest employer in SD
Market share – major health plans**	
Sharp HealthCare	26%
Scripps Health	25%
Palomar Pomerado Health	11%
Kaiser Permanente	10%
University of California, San Diego Medical Center	8%
Tri-City Medical Center	7%
Others	13%
HMO market share**	43.2%
Leading HMOs	
Kaiser Foundation Health Plan	37%
UnitedHealth Group	17%
Health Net	12%
PPO market share**	26.0%
Leading PPOs	
WellPoint	41%
California Physicians' Service dba Blue Shield of CA	19%
UnitedHealth Group	17%
Market Stage**	Innovative
- High consolidation/integration of physician groups and health systems/hospitals	
- Extensive use of disease management, utilization management	
- Multiple price/quality controls used by managed care (P4P; tiering physician, hospital, pharmacy benefits; etc.)	
- Serious interest, enrollment in advanced benefit design (CDHPs, HSAs, etc.)	

Note: HMO = health maintenance organization, PPO = preferred provider organization, P4P = pay for performance, CDHP = consumer driven health plan, HSA = health savings account

* Source: County of San Diego, HHSA, Public Health Services, Community Health Statistics Unit (2006)[41]

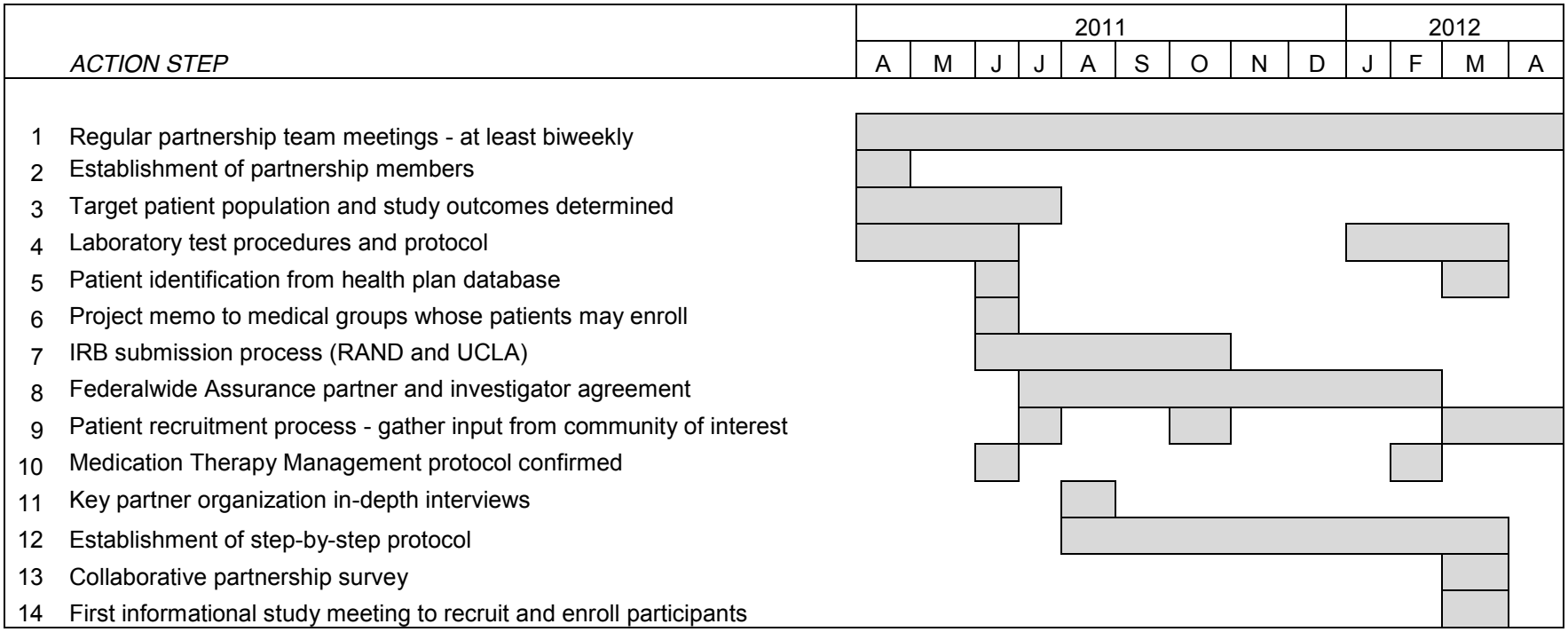
** Source: HealthLeaders-InterStudy Market Overview (2009)

TABLE 2 Descriptive Statistic Comparison on Variables Examined in Multivariate Analyses of the Collaborative Care Network (CCN) by Bazzoli et al. (2003) and the UnitedHealthcare CA Schools VEBA Ralphs/Kroger Co. Partnership

	CCN, Bazzoli et al. (N = 580)		*United VEBA Ralphs* (N = 8)	
Variable Type and Name	M	SD	%	Count
Action Characteristics				
Type of action				
Evaluative	0.40	0.49	12.5	1
Instrumental	0.34	0.47	37.5	3
Strategic	0.26	0.44	37.5	3
None of the above			12.5	1
Timeliness of completion				
Completed as planned (%)	49.5		0.0	0
Completed with modifications (%)	12.4		37.5	3
Ongoing but not yet completed (%)	21.6		37.5	3
Postponed action (%)	1.7		25.0	2
Abandoned action (%)	10.7		0.0	0
Uncertain status (%)	4.1		0.0	0
Number of action steps per initiative	7.42	5.00	100	14
Partnership Characteristics				
Number of original partners	11.54	0.49	100	9
Change in number of partners (%)	91.37	118.86	11.2	8
FWP private, nonhealth (%)	21.14	15.99	25	2
FWP government (%)	14.70	18.39	12.5	1
FWP education (%)	13.38	15.68	25	2
FWP private health organization (%)	50.78	49.99	37.5	3
Leadership				
Factor 1: Action oriented	8.60	0.44	37.63	12
Factor 2: Relationship builder	11.53	0.49	78.13	25
Conflict Management				
Factor 1: Collaborative style	12.73	0.73	1.85*	8
Factor 2: Avoidance	5.69	0.58	3.85*	8
Factor 3: Refer	4.11	0.41	2.88*	8

* Scored from 1-5 where 1 = Strongly Agree and 5 = Strongly Disagree
Note: FWP = full working partner; HMO = health maintenance organization

TABLE 3 Collaborative Partnership Action Steps Completed - Gaant Chart



Note: Study expected to continue for another 12 months at least (until March 2013)

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CONCLUSION

This dissertation concludes with a discussion of the important findings and lessons learned from the three research studies. Future studies to confirm and extend the major findings will also be suggested.

The analyses of costs and return on investment of MTM services are instructive for health plans and other health care entities that wish to develop MTM programs. The major finding from the critique of existing economic studies of MTM programs is that better research studies are required to support the significant return on investment reported. The existing cost analyses are subject to several threats to internal and external validity due to issues with study design, sampling bias, handling of attrition and loss to follow-up, lack of equivalent comparison or control groups, and unconventional cost-estimation methods. A hypothetical model of costs to deliver MTM services was constructed with a resulting $2.10 to $2.95 (USD) per member per month charge. To put this result in context, it was compared with several other non-essential programs that have been evaluated using a similar method by the California Health Benefits Review Program (CHBRP). The comparison programs include acupuncture, tobacco cessation, and fertility preservation. Compared to these other programs, which typically yield a per member per month charge between $0.00 to $0.30, the $2 to $3 (USD) charge for MTM services is high. This cost model is based on estimates that are drawn from non-experimental studies. Future models of costs would be stronger if they could employ costs from randomized controlled studies including actual costs of delivery (e.g., pharmacist time, equipment, materials/supplies, laboratory tests) from a specific type of

MTM services delivery (e.g., commercial community pharmacist, in-physician office, or medical department delivery).

A second component of the dissertation was an analysis of the association between different types of health insurance and other patient characteristics (e.g., age, gender, and income) on long term medication monitoring. The results of this study may help us to identify patient groups that can benefit from better medication monitoring programs such as MTM services interventions. Significant findings indicate substantially higher odds of medication monitoring for those who have Medicare insurance and significantly lower odds of monitoring for those who have commercial insurance. Those with Medicaid insurance appear to be between these groups on medication monitoring. These results were consistent amongst the largest groups studied, that is, those taking ACE inhibitors/ARBs and diuretics. Weaker, but still significant effects, were observed for the covariates in the logistic regression models. Older age was associated with lower odds of monitoring. Higher income was associated with higher odds of monitoring. Females had lower odds of monitoring, except in the groups taking anticonvulsants and diuretics. Some results varied depending on the therapeutic agent studied which indicates that monitoring programs may need to differ if targeting those that take ACE inhibitors/ARBs versus anticonvulsants, for example. Also, further stratified analysis of the health insurance groups would be informative to see if patients using different types of insurance products, such as those that have preferred provider versus health maintenance organization insurance also experience disparities in medication monitoring. Future studies might also include additional variables already present in the dataset or connection to census data through use of the geographic information

systems information matched to patient addresses. It appears those who have Medicare insurance receive medication monitoring at a higher rate than those on commercial or Medicaid insurance, so it could be useful to investigate if there are particular features or benefits offered to Medicare patients that allow them to access these monitoring services more readily.

The final study included a qualitative investigation of the factors that affect the abilities of a multi-sector collaboration to implement an MTM services pilot intervention. This unique community partnership included leaders from a private health plan, a community-based grocery store pharmacy group, a community health employee benefits association, and several research organizations/universities. The findings indicate that it is feasible to implement this community based MTM intervention, but significant delays occurred due to gaining internal review board approvals, legal department agreements, and Federal-wide assurance numbers. The stakeholders all support the pilot implementation of MTM services, but no one entity can carry the effort forward on its own. It is recommended that future studies employing use of community collaboratives to implement MTM services interventions be prepared for delays and maintain flexibility and endurance. Larger studies of implementation of MTM services would also benefit from inclusion of cost tracking mechanisms and an equivalent control group to compare those who receive the MTM intervention to those who do not.

This review of the evidence indicates the support for significant return on investment for MTM services is not strong enough at this point to recommend reimbursement be enforced for all adults with chronic diseases and taking medications. Additional study is also needed before groups of patients are identified that would

benefit most from more aggressive medication monitoring. The results of the pilot implemented in San Diego will be informative for other multi-sector partnerships who will face similar challenges as they develop models for the application of MTM services in the community.