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Reducing Health Care Costs and Improving Clinical Outcomes Using an Improved Asheville Project[®] Model

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Keywords: Healthcare cost, Chronic Care Model, Population health management, Disease management, Collaborative care, Asheville Project[®], Diabetes, Diabetes mellitus, Hypertension, Hyperlipidemia, Dyslipidemia.

Relevance and Contribution to Literature: This study was designed to add to the body of knowledge gained through the original Asheville Project studies, and to address some of the limitations of the earlier studies.

Scalability. Since the original Asheville Project publications there have been some successful replications, however, there is a need to broaden the geographic scope and increase the size of the study population.

Study Design. Previous studies were limited to pre-post, self-as-control design. We added a control group.

Model improvement. We were able to incorporate an electronic record of care. This allows incorporation of medical and prescription claims, ease of documentation, improved data capture, reporting, standardization of care, identification of deficiencies in care, and communication with other health care providers. This enhancement may be worthy of more comment than we devoted to it, however, we didn't want to detract from the main goal of the study, and we wanted to avoid any hint of commercialization on the part of the organization that provided the electronic record.

Relevance to profession. We sincerely hope the relevance goes beyond the profession of pharmacy and that it reinforces the message that the profession of pharmacy offers real solutions to rising health care costs in the U.S.

Abstract

Background: A large (12,374 financial cohort, 2,623 clinical cohort), multi-year (4 year), multi-site (7 states, 70 communities), multi-employer (10 employers) study to determine if a previously successful single-community chronic care model (Asheville Project[®]) could be replicated in multiple communities. **Objective:** Assess long-term clinical and financial outcomes of a chronic disease management model for diabetes, hypertension, and/or dyslipidemia. **Design:** Observational, longitudinal, retrospective, 4 year, quasi-experimental, multi-site, pre-post and control group study. **Setting:** Ten self-insured health plans, 70 community locations across the U.S. **Patients:** Members with eligible condition meet with a "health coach", pharmacist or health educator, on a regular basis between physician office visits. Participants received reduced co-payments on disease related medications as incentive.

Main Outcome Measures: Changes in health plan costs, changes in guideline clinical measures. **Results:** Financial analysis—Participant group's total health plan cost decreased by \$2,148.83 per person per year (PPPY) diabetes, \$414.37 PPPY dyslipidemia, \$139.56 PPPY hypertension, \$943.86 PPPY combining all programs. In contrast, control group's total health care costs increased \$752.63 PPPY diabetes group, \$520.42 PPPY dyslipidemia group, \$789.95 PPPY hypertension group, and \$690.26 PPPY combining all control group patients. Return-On-Investment (ROI) for participant groups: \$5.49:1 (diabetes), \$2.36:1 (dyslipidemia), \$1.86:1 (hypertension), and \$4.05:1 combined programs. Participant's costs decreased 25.5%, control patient's costs increased 15.1% (net difference of 40.6%) over 4 year study. Clinical analysis—(2,623 in clinical cohort): Group not at nationally recommended clinical goals at baseline had statistically significant changes (improvements) in clinical measures related to diabetes, hypertension, and dyslipidemia. Group at mean clinical goal at baseline continued to be at goal. **Conclusion:** A replication of the Asheville Project[®] chronic care model resulted in reduced net health plan costs and improved clinical measures for diabetes, hypertension, and dyslipidemia, using this model that provided frequent follow-up by pharmacists/health educators, emphasis on appropriate medication therapy, patient education, guideline goals.

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Introduction

A fundamental goal for improving health care delivery in the U.S. is to control health care costs while maintaining or improving quality of care. The need to do so has increased to almost crisis levels. In 2011 U.S. health care spending reached \$2.7 trillion according to the Centers for Medicare and Medicaid Services, costs continue to increase and by 2021 government spending is projected to be nearly 50 percent of national health expenditures.¹ One approach proposed to help improve clinical outcomes and control, or reduce, health care costs is the use of chronic care models. One of the chronic care models that has provided evidence of success in improving clinical outcomes and reducing health care costs is the Asheville Project[®] model. This model uses community based providers (pharmacists, health educators – nurses, dietitians) in a “health coach” role. These providers meet with patients with chronic medical conditions between the patient’s routine physician office visits. They focus on appropriate medication therapy, providing education on the benefits of improved nutrition/physical activity, and reaching guideline clinical goals. This model was initially developed and implemented by a workgroup of the North Carolina Association of Pharmacists.² Publications on this model have consistently shown clinical and financial improvement, however, the Asheville model has been limited geographically, technologically, and in study design.³⁻¹¹ Criticisms of the Asheville model studies have included questions regarding national scalability and the lack of a control group.

In 2005, American Health Care (AHC), a pharmacist-owned company that provides clinical pharmacy and Population Health Management services, began replicating this model in communities across the U.S. and this study summarizes the outcomes of 4 years of program participation for 10 employers in 70 communities across the U.S. The earliest employer program in this study started November 2006, the latest April 2011, and all of the programs are ongoing at this time

Objectives

The objectives of this study were: 1) determine if this model could be replicated in multiple locations across the country, 2) add a control group, 3) add advanced electronic patient record keeping/reporting technology and, 4) determine if the study outcomes would further validate previously published clinical and financial outcome improvements for individuals with diabetes, hypertension and/or dyslipidemia.

The reason for focusing on these chronic conditions, and in particular a focus on appropriate medication therapy, is that according to the Centers for Disease Control and Prevention

(CDC) diseases such as diabetes, heart disease and stroke are among the most common, costly, and preventable of all health problems in the U.S.¹² As such, a significant portion of U.S. health care costs are driven by a handful of chronic medical conditions such as the ones listed above. Since these chronic conditions are important drivers of health care costs, and since medication therapy is a major component of the treatment plan for these conditions, a focus on improving medication use in individuals with these conditions is a logical health care improvement strategy.

According to a review article in the *New England Journal of Medicine* patient medication compliance/adherence in individuals with chronic conditions (just one of several important medication related issues) is “complex, labor-intensive, and generally ineffective”.¹³ And as C. Everett Koop, M.D., former Surgeon General of the U.S., famously said, “Drugs don’t work in patients who don’t take them.” Therefore, health care models that target improvement in appropriate medication use are fertile ground for research.

The unique aspects of this study model were: 1) voluntary participation, 2) community-based, 3) appointment-based, 4) face-to-face counseling by pharmacists and health educators, 5) long-term, 6) reduced prescription co-payment incentives, 7) a focus on appropriate medication therapy, 8) patient education, 9) adherence to evidence-based guidelines, and 10) availability of telephonic counseling when face-to-face sessions were not practical.

The cutoff for publication data was February 2013. Participants for whom face-to-face health coaching was not possible due to a lack of providers in some communities received services via telephonic management. However, only 3.7% were managed telephonically. Training, tools and electronic patient records were developed by pharmacists at AHC, a pharmacist-owned company. National guideline-based protocols were also integrated into the electronic patient record. The chronic care coaches received training in best practices, patient counseling and documentation. The typical health coach visit averaged thirty minutes every three months. Recommendations were made to physicians when deficiencies were identified and patients were referred back to their physicians when deficiencies warranted further assessment or when therapy changes needed to be considered. In this model the physician continued to be the primary decision maker. However, the individual with the chronic condition received additional support between routine physician office visits to assist them in achieving their treatment goals. The cost of the program was borne by the employer’s self-insured health plans with the desired

outcome that costs for health coaching, incentives, and administration would be offset, or more than offset, by savings due to fewer adverse medical outcomes.

As in the original Asheville Project the program was provided to self-insured health plans. This was accomplished through sales/marketing calls directly to employers or through meetings arranged by insurance brokerage firms whose business it is to recommend innovative services to their clients. The services were provided under a three-way contract between the employer, AHC, and the health coaches. All of the program locations had access to a pharmacist for medication review even when a pharmacist was not the primary health coach. All of the health coaches followed the same protocols and health coach fees were the same regardless of health coach salary, experience, or professional training. The amount of the reduced prescription incentive varied somewhat from employer to employer but the typical recommended incentive was zero co-payment on generics and \$20 off on preferred brands. (See Figure 1 for a schematic of the Asheville model published as part of an AHRQ Innovations Profile in 2012.)¹⁴

AHC's role was to: 1) locate and contract with employers willing to pay for the services, 2) provide a web-based, secure, electronic record of care, 3) identify the eligible population, 4) inform eligible individuals of the option of having a health coach, 5) inform eligible individuals of the intended health benefits of the program, 6) administer financial incentives, 7) outline requirements for routine laboratory testing and follow-up with physician, 8) import medical and prescription claims data into the electronic record on a monthly basis, 9) provide standardization of care through incorporation of guidelines of care into the electronic record to direct the health coach-patient interaction, 10) identify deficiencies in care, and 11) generate outcomes reports of clinical and financial results for the employer/health plan on a regular basis. Six of the items above (1,2,8,9,10 and 11) were enhancements to the original Asheville model, as was the addition of a control group to the study. A weakness of the original Asheville model was the lack of a mechanism for sales/marketing of the service. It started simply as a pilot program with one employer. Its success led to the desire to create a business model which included the need for sales/marketing. Another need following the pilot programs was an electronic record of care for health coaches to use to document their visits consistently. The charts in the original pilot program were traditional paper charts. Another enhancement to the original program was to incorporate each patient's medical and prescription claims (historical and current) into an electronic record. This allowed identification of gaps in care

(e.g. patient not seeing physician, appropriate laboratory tests not being ordered, frequent emergency department visits). This claims data was provided by each employer's Pharmacy Benefits Management company and their Third Party Administrator on a monthly basis and this data was incorporated into each patient's individual electronic record. There was also a need to standardize care and incorporate national guideline standards into the process so that whether it was a pharmacist in North Carolina, or California, the same standards would apply. One of the biggest deficiencies in the Asheville Project program was the need to collect, collate, and analyze data manually. This is now incorporated into the electronic record of care.

Methods

Main outcome measures:

- Changes in health plan costs over time for program participants and for a control group of patients who did not participate.

Secondary outcome measures:

- Changes in clinical measures over time [Table 1]. This was paired data and the baseline and most recent data for the population were normally distributed; hence, paired T-test was conducted.
- Other secondary measures included several qualitative measures based on guideline recommendations for lifestyle changes [Figures 2a, 2b]. Mean baseline values were compared with the mean of the latest values (non-paired data).

Design: This study was an observational, longitudinal, retrospective, 4 year, quasi-experimental, multi-site, pre-post and control group cohort analysis. It examined clinical and financial outcomes for individuals who had the option under their health plan to enroll in a chronic disease program for diabetes, hypertension, and/or dyslipidemia. The financial control group was composed of individuals with an eligible condition who did not participate in the program. The original and ongoing aspects of the study were approved by the Investigational Review Board of Mission Hospitals.

Setting: Ten self-insured employers (7 states, 70 locations) agreed to cover the program under their health plan benefits and it was offered to health plan members with any of the eligible conditions. The program provided participants a personal health coach, a pharmacist or health educator (nurse, dietitian) who were to meet with them at least quarterly, but visits could be as often as once a month depending on the patient's needs. All program participants had access to a pharmacist for medication assessment. Eligibility for the program was determined through medical and prescription claims. Participation was voluntary,

however, participants received incentives (reduced prescription co-payments on disease related prescriptions/supplies).

Methodology: Health care professionals used an electronic record to document patient care visits; a proprietary, secure web-based communication portal that created an integrated medical profile. The record provided continuously updated medical and pharmacy claims data, clinical data, health coach visit documentation and also identified gaps in care. It was also the source of data for reports on clinical and financial outcomes.¹⁵

Health plan members with diabetes, hypertension, and/or dyslipidemia were offered the option of enrolling in a voluntary "health coach" program to assist them in the management of their condition. By enrolling they agreed to meet face-to-face with a health coach in their community on a regular basis. This could be as often as once-a-month if in the judgment of the health coach the individual needed that level of interaction. Participation qualified the individual for reduced prescription co-payments on medications for their chronic condition. The same standard protocols were followed by the health coach providers, regardless of their professional background, and the protocols mirrored the recommendations of the relevant national guidelines relative to appropriate medication therapy, monitoring, assessment, and goal setting. The guidelines used were from the American Diabetes Association, Joint National Committee, and National Cholesterol Education Program.^{16,17,18} The same national guideline standards were also the basis of the original Asheville Project provider training.

The diabetes group's data extended over 4 years and the hypertension and dyslipidemia group's data extended over 3 years. This study reports changes over time in total health plan costs (financial analysis) and clinical values (clinical analysis). Total health plan costs were defined as the sum of all medical claims and all prescription claims paid by the employer's self-funded health insurance plan for health plan members with an eligible condition. The study does not examine patient's out-of-pocket costs. It looks at health care costs strictly from the perspective of the costs to the self-funded health plans. Plan members with an eligible condition who did not enroll in the program were the financial control group.

Three basic financial comparisons are made: 1) changes in health plan costs for participants over time (self-as-control), 2) changes in health plan costs for non-participants (self-as-control), and 3) a comparison of participant costs and non-

participant costs over time (control group comparison). In addition, return-on-investment (ROI) analyses are provided.

Return-On-Investment (ROI) was calculated by dividing gross savings (relative to baseline costs) by total program costs. Program costs included all administrative fees, health coach fees, reduced prescription co-payment cost and additional laboratory testing.

This study reports on changes in clinical values over time for participants (self-as-control) using paired data. Clinical data on non-participants was not available so the report does not provide a control group for the clinical data.

Inclusion criteria: 1) covered plan member of a participating employer, 2) had diabetes, hypertension, and/or dyslipidemia, 3) enrolled and had at least one health coach encounter and, 4) were enrolled for a minimum of a year (and up to four years).

To be included in the participant group financial analysis, in addition to the above inclusion criteria, plan members also needed to have both a complete year of baseline (historical) medical and prescription claims data and at least one complete year of medical and prescription claims for a subsequent study year. In order to be included in the control group financial analysis, non-participant individuals needed to meet the same criteria as the participant financial group, but did not enroll in the program and had no health coach visits.

To be included in the clinical analysis participants needed to be a plan member, have an eligible condition, participant for at least a year, plus have at least a baseline clinical value and a subsequent value. Baseline was defined as the value closest to the first health coach visit within a ± 3 month window of their first visit. Most recent value was defined as the last follow-up value documented in the electronic record.

Exclusion criteria: Individuals (participants and non-participants) were excluded from the financial analysis if they did not have a complete baseline year of financial data and at least one complete subsequent year of financial data. Individuals were also excluded from the participant and non-participant (control) group financial analysis if they had high cost events (greater than \$12,000) that were unrelated to their program health condition (e.g. cancer, spine surgery, HIV). If this fell in their baseline year they were excluded from the financial analysis completely. If the unrelated high cost event fell in a subsequent year their financial data was excluded for only that year and these criteria were applied equally to participant and non-participant (control) groups. Individuals were excluded from the clinical group if they were

missing a baseline value, a follow-up value, or both (paired data was required).

Financial data was aggregated based on enrollment dates. Each individual's baseline year was determined by their individual enrollment date. For example, everyone's first year of participation was aggregated as the "first program year" regardless of when they enrolled. An adjustment for inflation was applied using an inflation factor published by Pricewaterhouse Coopers LLP (<http://www.pwc.com/us/en/health-industries/behind-the-numbers>).

Data Analysis

In this retrospective analysis baseline clinical outcomes were compared to the most recent outcomes using a paired T-test or Wilcoxon Rank sum test as appropriate for data distribution (parametric or non-parametric). The normality of the data distribution was tested to examine skewness and kurtosis. Statistical significance was set at $p < 0.05$. Analyses were performed using STATA 10.1 Statistics/Data Analysis software.

Disease state goals were established based on national guidelines [American Diabetes Association (ADA)¹⁶ and American Association of Clinical Endocrinologists (AACE) for diabetes program, JNC-7 and American Heart Association for Hypertension (AHA) program, and National Cholesterol Education Program (NCEP), ATP III, AACE and AHA for dyslipidemia program.¹⁷⁻²⁰

Patients: The average age of the participant group was 54.8 years and the average age for individuals in the non-participant group was 56.4 years. Sixty-five percent of the participant group were female and 54% of the non-participant group were female.

Results

Financial results: Over the time period of the study the participant group's total health plan cost decreased by an average of \$2,148.83 PPPY for the diabetes group, \$414.37 PPPY for the dyslipidemia group, \$139.56 PPPY for the hypertension group, and \$943.86 PPPY when combining all programs. In contrast, over the same time period the non-participant (control) group experienced an increase in costs by an average of \$752.63 PPPY, \$520.42 PPPY, \$789.95 PPPY, and \$690.26 PPPY respectively for diabetes, dyslipidemia, hypertension, and combined groups.

Participant's health plan costs decreased 25.5% and non-participant control patient's costs increased by 15.1% (a delta of 40.6%) over the 4 year time period of the study. [Table 2]

Total emergency department and hospital visits decreased by 32.8% in the participant group and increased by 8.7% in the non-participant group.

ROI for participant groups was \$5.49:1 for diabetes, \$2.36:1 for dyslipidemia, \$1.86:1 for hypertension, and \$4.05:1 for all programs combined (including all program costs). ROI was calculated by dividing the gross cost savings relative to baseline by the total of all program costs. Program costs included all administrative fees, health coach fees, reduced prescription co-payment cost, and any additional laboratory testing or physician office visits that resulted from the program interventions.

Clinical results: Clinical data was examined to address two questions: 1) Did the group who were not at goal at baseline improve? 2) Did the group who were at goal continue to be at goal?

The group who were not at goal (based on guidelines for their condition(s) at the time they entered the program were examined. The most recent clinical results were statistically different (improved) from baseline (p -value < 0.05) for all measures; A1C, SBP, DBP, LDL, HDL, TC, TG, and TC/HDL ratio. [Table 1]

Notable clinical findings [Table 1] include: Diabetes group: A1C decreased by an average of 0.58, SBP decreased by an average of 10.2 mm/Hg, DBP decreased by an average of 7.2, LDL decreased by an average of 17.9mg/dL, HDL increased by an average of 1.8mg/dL, TG decreased by an average of 45.3mg/dL, and TC/HDL ratio improved from an average of 6.20 to 5.23. Hypertension group: SBP decreased by an average of 17.0mmHg and DBP decreased by an average of 12.4. Dyslipidemia group: SBP decreased by an average of 16.0mmHg, DBP decreased by an average of 12.8, LDL decreased by an average of 16.0mg/dL, HDL increased by average of 2.1mg/dL, TG decreased by an average of 43.5mg/dL, TC decreased by an average of 17.0mg/dL, and TC/HDL ratio improved from an average of 6.43 to 5.73.

Lifestyle/behavior change improvements were observed in all participant groups. [Figure 2a, 2b]

The group who were at goal at the time they entered the program were examined to determine if they remained at goal. End of study averages for the group who were already at goal at baseline: Diabetes group: A1C 6.6% (goal $< 7\%$), blood pressure 120/73mmg/Hg (goal $< 130/80$), LDL 79mg/dL (goal < 100), HDL 52mg/dL (goal > 40), TG 112mg/dL (goal < 150), TC 156mg/dL (goal < 200), TC/HDL 3.55 (goal < 5). Dyslipidemia group: LDL 99mg/dL (goal < 130), HDL 58mg/dL

(>40), TG 103mg/dL (goal <150), TC 171mg/dL (goal <200), TC/HDL 3.55 (goal <5). Hypertension group: blood pressure 122/75mm/Hg (goal <140/90).

Discussion

This large, multi-site, multi-year, control group study looked at the financial and clinical impact of a community based chronic care model for individuals with diabetes, hypertension, and/or dyslipidemia. This model uses “health coaches” (pharmacists, health educators) who meet on a regular basis with patients between normal physician office visits. All participants had access to a pharmacist for medication review, clinical assessment, patient education, and recommendations to other health care providers.

A notable finding of the study was that the group not at clinical goal upon entering the program experienced statistically significant improvements on all clinical measures. And the group of patients who were already at clinical goal upon entering the program continued to be at goal on all clinical measures at the end of the 4 year study period.

Over the 4 year study period participant’s health care costs decreased by 25.5%, whereas non-participant (control group) health care costs increased by 15.1%. Therefore, the potential positive impact of the program was a savings of 40.6%. It is notable that both groups had very similar historical (baseline) health plan costs. Baseline costs for the participant group was \$4,648 PPPY vs. \$4,753 PPPY for the non-participant group. [Table 2]

Return-On-Investment (ROI) calculation, which takes into account all the costs of the program, for 1,314 participants with diabetes was \$5.49:1 (for every dollar spent on the program \$5.49 was saved). ROI for 730 dyslipidemia participants was \$2.36:1, and for 1,488 hypertension participants was \$1.86:1. [Table 2] This is the first study of the Asheville model using a financial control group and it is noteworthy that the savings experience was very similar to the earlier non-control group studies which provides further validation of the earlier studies. The Asheville Project published a PPPY savings average for the diabetes group of \$1,200 - 1,872 PPPY (vs. \$2,901 PPPY in this current study). And an Asheville Project savings of \$628 PPPY was reported in their hypertension/dyslipidemia group (vs. \$931 PPPY in this current study).^{3,5}

Total emergency department and hospital visits decreased by 32.8% in the current participant group, whereas there was an increase of 8.7% in the non-participant control group.

Successful control of health plan costs is often viewed as simply decreasing the rate of increase in health plan costs. However, this model has not simply decreased the rate of increase, it has consistently decreased costs in multiple studies for thousands of patients over a period of more than 15 years.

There are similarities between this program and Medication Therapy Management (MTM). Both are models that use face-to-face encounters between patients and pharmacists. Both focus on appropriate medication use, adjustments in medication therapy and improving care. A primary difference is that this current model has regular ongoing sessions with the patients, whereas MTM visits are typically once a year. The current model could be viewed as “frequent” MTM and, therefore, has the potential to be more impactful than the current “infrequent” MTM model. This model also differs in that it typically provides services for younger individuals who are currently in the workforce, as opposed to the typical retired Medicare recipient. The implications of the latter are that there is potentially more benefit the earlier in life someone receives better management of their chronic medical condition.

Although this study exclusively used self-insured plans the results are applicable to other health payment systems. Whether the payment system is managed care, commercial insurance, Accountable Care Organizations (ACO) or Medical Home models, someone is paying for the poor medical outcomes of these chronic conditions. Whoever is incurring these costs should be interested in models of care that effectively lower their costs. The authors believe this model could integrate well with ACO efforts and Medical Home models since it is:

- 1) Community-based
- 2) Paid for by health plans
- 3) Saves more than it costs
- 4) Addresses patient needs between routine physician office visits
- 5) Improves patient care without requiring physician offices to invest additional time and resources
- 6) Supplements, rather than replaces, health care services already being provided
- 7) Takes advantage of underutilized community health resources (pharmacists and health educators)
- 8) And for pharmacists, takes advantage of their broad geographic distribution, a potentially significant access point for public health improvement

This potential is largely untapped, however, this study indicates that when pharmacists and health educators are

paid to provide “health coach” services, objective clinical measures improve and there is a net health plan savings.

Limitations

Lack of a randomization process is a limitation of this study. Participation was voluntary and there may have been differences between those that enrolled vs. those that did not enroll. Enrollees may have been more motivated to pursue treatment success than non-enrollees. Selection bias, therefore, may be a study limitation.

There were two potential confounding variables related to enrollment. On the one hand the reduced prescription co-payment incentive may have motivated individuals with more medical issue (those taking more medications) to enroll and result in a *participant* group with a greater potential for cost savings than their non-participant peers. On the other hand the reduced prescription co-payment incentive would not be a strong incentive for individuals who were failing to take their medications and, because of this, would be at higher risk for increased medical costs. This could have resulted in a *non-participant* group with a greater potential for cost savings than their participant peers. These two factors, therefore, could have offsetting effects. However, this study was unable to assess the specific impact of each factor. The non-participants were slightly older on average than the participant group (56.4 years vs. 54.8 years) and the non-participant group had a 11% higher percentage of males than the participant group (46% vs. 35%). These differences could have influenced the results of the analysis. It was encouraging, therefore, that in spite of these differences both groups had virtually identical baseline historical health plan costs. The average annual historical health plan cost average was \$4,753 PPPY for non-participants and \$4,648 PPPY for participants. [Table 2] The participants were not the more costly group historically and, therefore, the reduction in costs they experienced does not appear to be attributable to a greater cost reduction potential at baseline in the participant group.

Of particular concern with a study of changes in health plan costs over time is the potential for regression-to-the-mean, the chance that decreases in costs were due to improvements that would have occurred without the program interventions because, on average, a bad year would be followed by a better year. A related factor being that individuals who had just experienced a bad year may have been more motivated to enroll than someone who had a good year, another potential source of selection bias. Having the control group’s costs be virtually identical at baseline, however, speaks against this “bad year” scenario since the actual observation was that participants did not have a worse

baseline year financially than the non-participants. Additionally, a possible factor speaking against regression-to-the-mean was the length of the study (4 years). Chronic conditions tend to get worse over time rather than better. Therefore, regression-to-the-mean is less of a factor as the length of a study increases and improvements continued to be sustained, which was the observation in this study.

Additional limitations were the lack of availability of clinical data on the non-participant group, missing and/or unreported clinical data, as well as the limitations (and errors) inherent in the claims processing world.

Having a control group, a study population of several thousand patients, application of the same inclusion and exclusion criteria to both groups, and a study period of 4 years mitigate some of the above limitations. However, this study was unable to account for all potential variables or to determine which of the basic program elements; health coaching, incentives, standardized protocols, or the use of an electronic record with integrated guideline care processes were responsible for all, or part, of the observed improvements. It can only be stated that the combination of these elements resulted in the successful outcomes observed.

Conclusion

This study demonstrates that the Asheville model is replicable in other communities. It also adds further evidence that this chronic care model which uses pharmacists and health educators to focus on improving medication therapy, patient knowledge and goal achievement, results in clinical improvement and lower overall health care costs for individuals with diabetes, dyslipidemia, and/or hypertension.

It is possible to improve care and reduce health care costs for individuals with diabetes, dyslipidemia, and/or hypertension using a chronic care model. What is lacking in the U.S. healthcare system are widespread, efficient, affordable chronic care approaches which assure that medications are being used effectively and that lifestyle changes are actually taking place. There is growing evidence that this particular chronic care model is one such approach.

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Table 1: Clinical Results: Baseline vs. Most Recent value for individuals who were not at goal at baseline

Clinical Metrics*,**	Number	Age (yr)	Male/Female (#)	Baseline Average**	Most Recent Average**	Change**	p-value***	Confidence Interval	
DIABETES MELLITUS									
A1C \geq 7	554	50.43	215/339	8.45	7.87	-0.58	<0.0001	.4472057	.7130831
SBP \geq 130	549	53.81	260/289	141.99	131.77	-10.22	<0.0001	8.806705	11.62317
DBP \geq 80	493	51.02	228/265	85.16	78.00	-7.16	<0.0001	6.285761	8.034726
LDL \geq 100	339	50.98	111/228	126.92	108.99	-17.93	<0.0001	14.64035	21.22868
HDL $<$ 40	297	51.90	168/129	33.22	35.00	+1.78	<0.0001	1.021244	2.540372
TG \geq 150	308	52.65	122/186	239.06	193.81	-45.25	<0.0001	32.37279	58.10773
TC \geq 200	166	50.96	39/127	227.25	200.64	-26.61	<0.0001	19.83242	33.38445
TC/HDL \geq 5	114	50.37	44/70	6.20	5.23	-0.97	<0.0001	.6598332	1.285168
DYSLIPIDEMIA									
SBP \geq 130	74	56.45	27/47	148.22	132.24	-15.98	<0.0001	12.67727	19.26868
DBP \geq 80	41	51.71	20/21	94.12	81.37	-12.75	<0.0001	9.921684	15.59051
LDL \geq 130	92	50.15	20/72	160.41	144.40	-16.01	<0.0001	8.509113	23.50828
HDL $<$ 40	76	52.00	45/31	33.40	35.48	+2.08	<0.0363	.1369637	4.031457
TG \geq 150	131	52.22	44/87	241.45	197.98	-43.47	0.0001	22.48157	64.46499
TC \geq 200	142	51.30	35/107	235.71	218.74	-16.97	<0.0001	10.65376	23.2899
TC/HDL \geq 5	43	50.09	16/27	6.43	5.73	-0.70	0.001	.2969621	1.093502
HYPERTENSION									
SBP \geq 140	133	54.86	42/91	150.57	133.53	-17.04	<0.005	14.24011	19.83508
DBP \geq 90	186	51.70	108/78	94.40	81.96	-12.44	<0.005	10.99624	13.88548

*Clinical Metrics column shows "not at goal" parameter (e.g. Guideline A1c goal is <7%, so "not at goal" parameter is \geq 7)

**Values: A1c (%), SBP/DBP (mm/Hg), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), TC/HDL (ratio)

***Statistically significant: p-value <0.05

Table 2: Financial Results

Program	# of Health Plans	Study Time Period	Number of Individuals	Baseline Avg. PPPY* Health Plan Costs	Total Net Plan Savings/(Loss) Relative to Baseline Over Study Period**	Change in Total Health Plan Spend Relative to Baseline	Savings (or Loss) PPPY avg.	Savings (Participant relative to Non-participant control group) PPPY avg.	Spread/Delta (Participant savings plus Non-participant control group loss)	ROI*** Participants relative to their baseline)
DIABETES MELLITUS										
Participants	10	48 months	1314	\$7,716.19	\$2,823,565.60	-31.7%	\$2,148.83	+\$2,901.46	43.4%	\$5.49:1
Non-Participant Controls	10	48 months	2451	\$7,287.43	(\$1,844,691.53)	+11.7%	(\$752.63)			N/A
DYSLIPIDEMIA										
Participants	10	36 months	730	\$4,192.89	\$302,489.63	-17.2%	\$414.37	+\$934.79	30.6%	\$2.36:1
Non-Participant Controls	10	36 months	2931	\$3,857.10	(\$1,525,359.10)	+13.4%	(\$520.42)			N/A
HYPERTENSION										
Participants	10	36 months	1488	\$2,161.74	\$207,668.77	-14.0%	\$139.56	+\$929.51	35.3%	\$1.86:1
Non-Participant Controls	10	36 months	3460	\$3,716.33	(\$2,733,218.01)	+21.3%	(\$789.95)			N/A
TOTALS										
All Programs/All Years (Participants Population)	10	36-48 months	3532	\$4,648.00	\$3,333,723.90	-25.5%	\$943.86	+\$1,634.12	40.6%	\$4.05:1
All Programs/All Years (Non-Participant Control Population)	10	36-48 months	8842	\$4,753.00	(\$6,103,268.64)	+15.1%	(\$690.26)			N/A

*PPPY = per person per year

**Net savings: Includes all program and incentive costs

***ROI = return-on-investment

N/A: Not applicable

Figure 1: Diagram of Improved Asheville Chronic Care Model

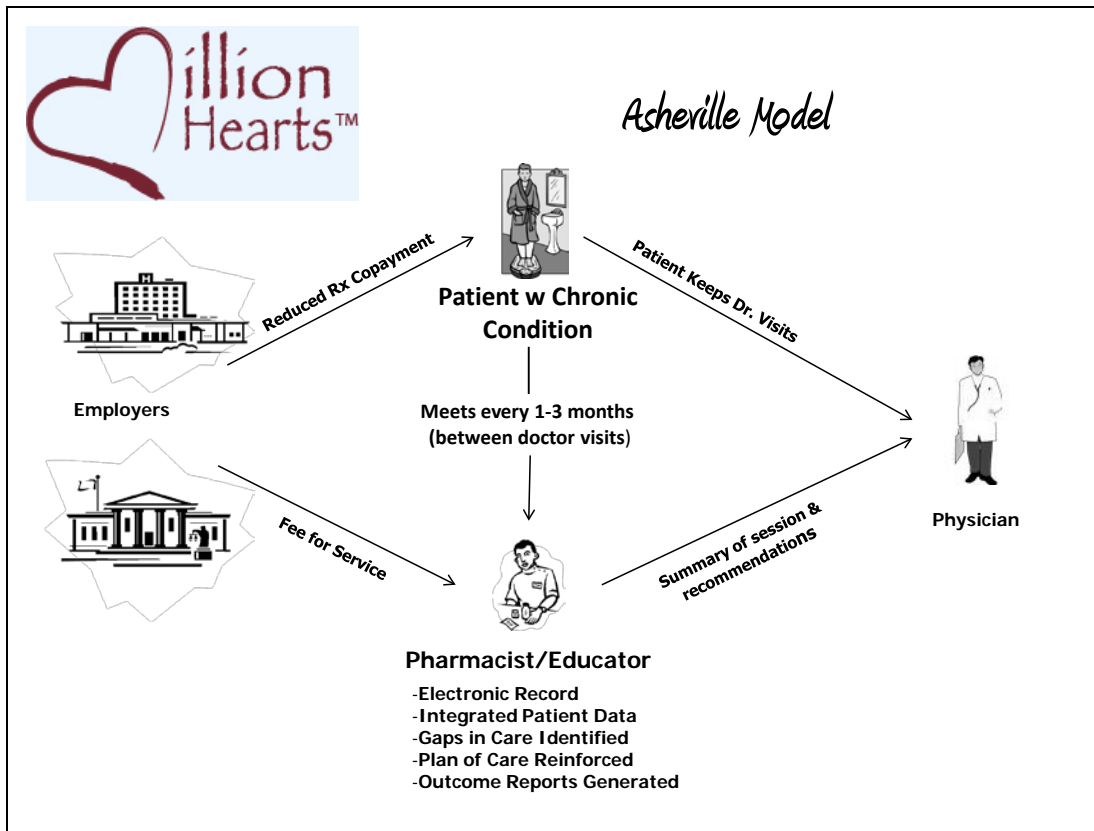


Figure 2a: Lifestyle/Behavior Changes

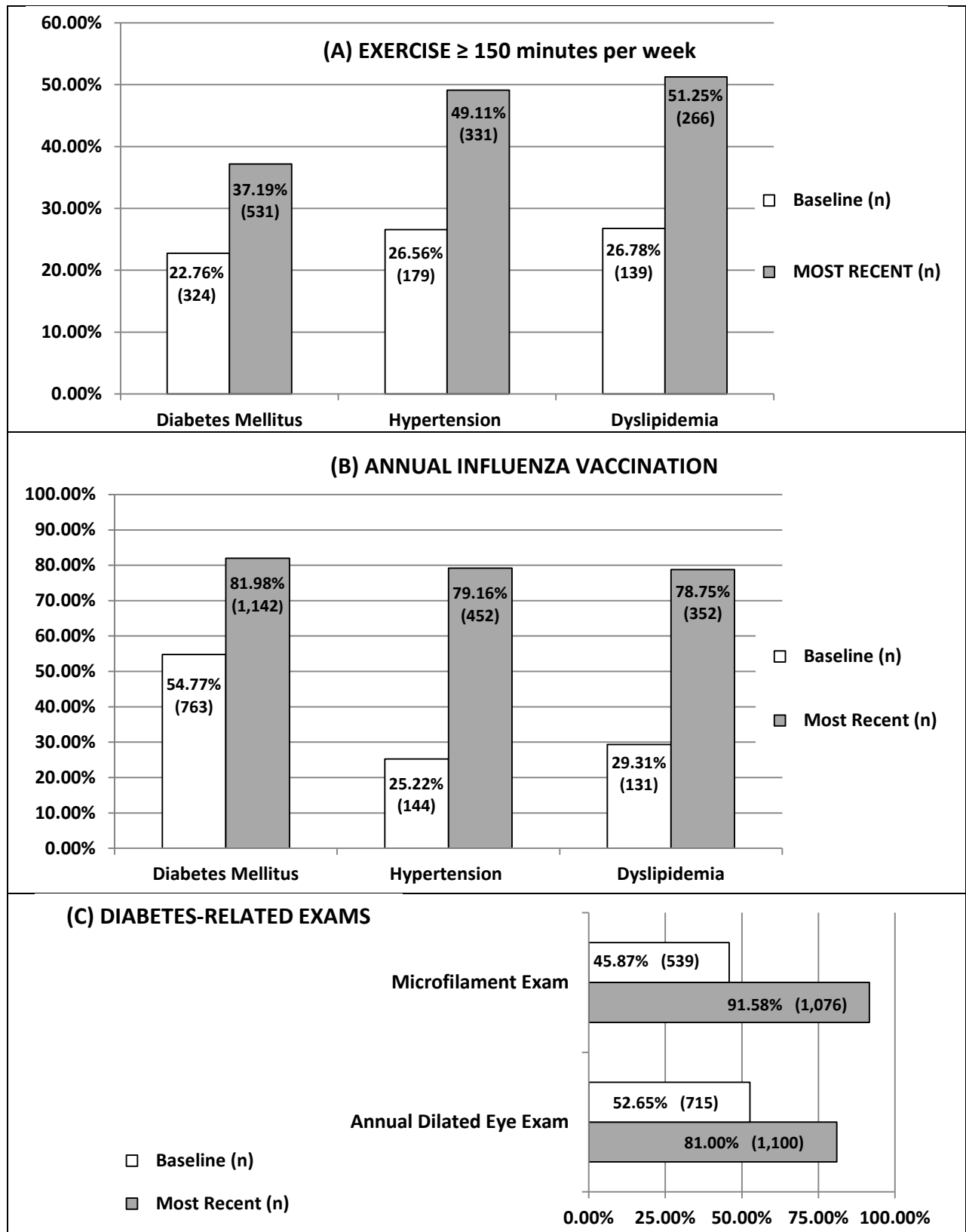


Figure 2b: Lifestyle/Behavior Changes (Continued)

