

ADVANCING
ADHERENCE
& THE SCIENCE OF
PHARMACY CARE

Volume 3

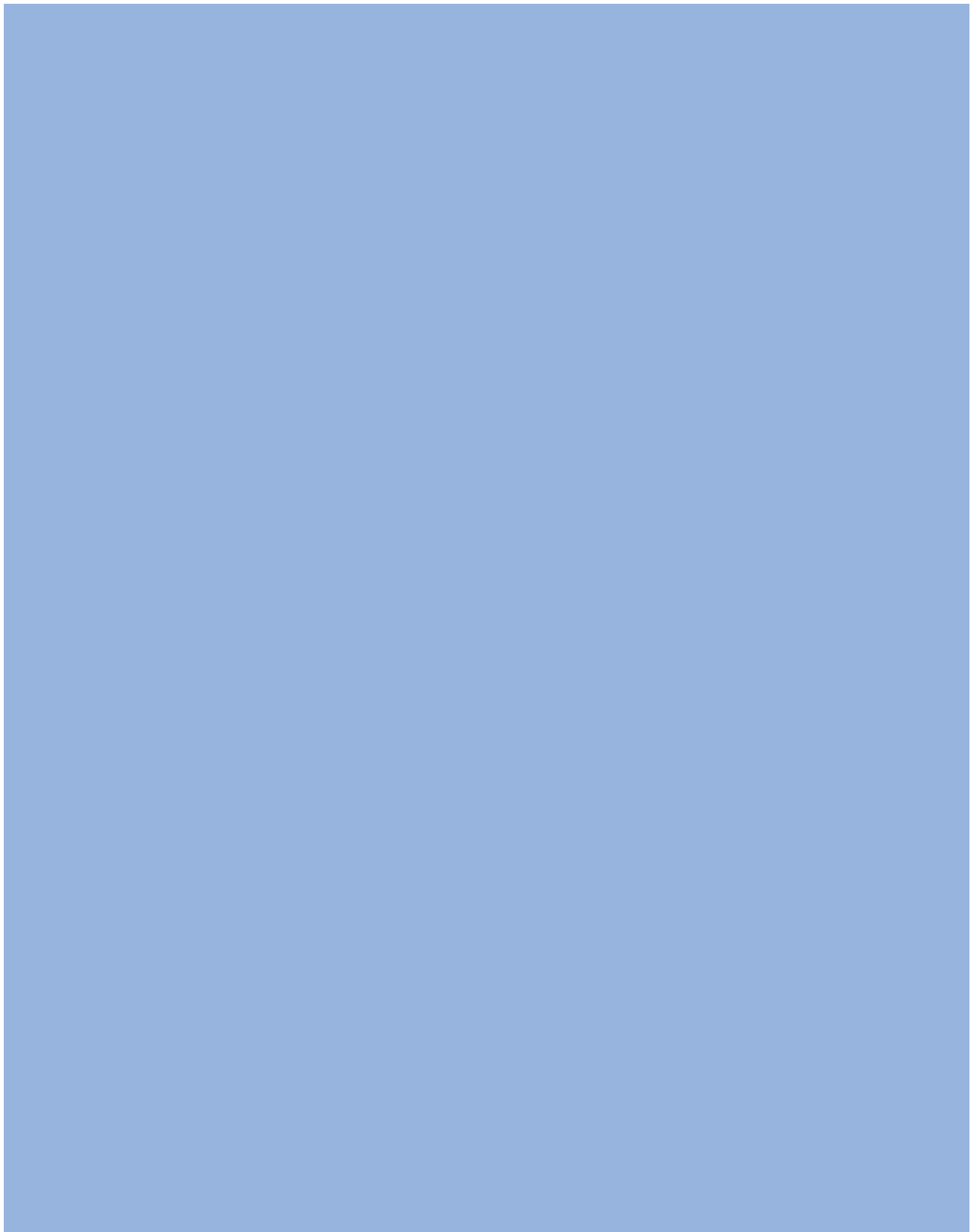


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Prescription medicine helps sick people get better.

Despite that, an alarming percentage of patients do not take their medications as directed by their doctors. Research shows that 25 percent of patients prescribed medications for a new illness fail to fill their initial prescription. Half of patients taking maintenance medications for a chronic disease stop taking their medications within a year of starting therapy.

The CVS Caremark Pharmacy Care Research Institute (PCRI) is pleased to present the third edition of our annual compendium of published academic research – Advancing Adherence and the Science of Pharmacy Care. This publication summarizes the important research conducted by CVS Caremark and our research partners over the last several years, beginning with a focus on developing a better understanding of medication adherence. This research is one example of how CVS Caremark pursues pharmacy innovation and strives to deliver the highest standard of pharmacy care for the patients we serve.

Medication adherence remains critically important in a rapidly evolving health care environment. While soaring health care costs and the persistent increase in chronic disease continue to impact American families, we do have the capability to make our health care system better. We can work together to improve the health care community's understanding of the underlying factors that impact adherence and translate this knowledge into programs that help patients take their medications as directed and stay healthy.

Our research begins with identifying issues and challenges that lead to poor adherence and employing scientifically rigorous methods to get to the heart of the issue. Over the years we have explored a number of topics including the financial impact of adherence, the role health care professionals can play in encouraging adherence and how technology can impact adherence. The studies included here align with these topics and expand upon them to include the impact of the Medicare Part D “donut hole,” the role of social networks and the role that gender and race play in adherence.

In addition, we have begun to broaden our research to look beyond medication adherence and consider other important factors that can improve and advance pharmacy care. In this edition, we include published studies resulting from our research collaborations which aim to provide good data on a variety of policy questions in the pharmacy care area. For example, these studies look at how direct-to-consumer drug advertising changes when a drug moves from prescription to over-the-counter status and how FDA warnings can affect patient behavior.

We're proud of the work presented here, which represents a collaboration between some of the most respected researchers in this field.

CVS Caremark works closely with Brigham and Women's Hospital Division of Pharmacoepidemiology and Pharmacoeconomics to conduct this research and publish the findings in respected journals. In this way, we have helped advance the knowledge base supporting medication adherence and we have the potential to improve adherence rates and ultimately the health of our communities.

As a pharmacy innovation company helping people on their path to better health, CVS Caremark has taken a leadership role in adherence research because we recognize the opportunity it presents to drive solutions for both patients and payors.



Troyen A. Brennan,
MD, MPH
Chief Medical Officer
CVS Caremark

SECTION I

FINANCIAL IMPACT OF MEDICATION ADHERENCE

The Impact
of Medication
Adherence on
Coronary Disease
Costs and
Outcomes:
A Systematic
Review

Published in *American
Journal of Medicine*,
April 2013¹

Heart disease is the leading cause of death in the United States for both men and women – approximately 600,000 people die of heart disease in the United States every year with coronary artery disease (CAD) being the most common type, killing more than 385,000 people annually. Heart disease also costs the United States \$108.9 billion each year,² but there are ways those costs can be controlled.

Researchers from CVS Caremark and Brigham and Women's Hospital published a paper in the *American Journal of Medicine* which found that patients with CAD who are adherent to their prescribed medications can save the health care system up to \$868 per patient per year. The findings showed a consistent trend toward improvement in coronary artery-related events, mortality, readmissions, and costs among those patients who were most adherent to their medication regimens.

The researchers reviewed more than 2,500 studies published between 1966 and 2011, analyzing in detail the 25 studies that met the inclusion criteria related to adherence and CAD outcomes.

¹ Bitton A, Choudhry NK, Matlin OS, Swanton K, Shrank WH. The Impact of Medication Adherence on Coronary Disease Costs and Outcomes: A Systematic Review. *Am J Med.* April 2013; 126(4).

² <http://www.cdc.gov/nchs/data/infodiv/infodiv.htm>

A subset of the studies measured the impact of medication adherence on primary prevention of CAD and the remainder focused on the relationship between medication adherence and costs and outcomes related to secondary prevention of the disease. All of the studies found that adherence significantly improves health outcomes, and those that analyzed costs found reduced total annual CAD costs (consistently between \$294 and \$868 per patient).

While the study found consistent outcomes in cost reductions and health improvements related to better medication adherence, the researchers also identified an opportunity for greater standardization and improved research methods across medication adherence studies. The authors pointed out that many of the studies they reviewed did not account for what they refer to as the “healthy adherer” effect; noting that few of the studies they analyzed controlled for predisposed healthy behaviors in the patients that were followed.

Overall, the study is an important driver in quantifying the cost-savings potential associated with better adherence.



Patients with CAD who are adherent to their prescribed medications can save the health care system up to \$868 per patient per year.

Impact of Medication Adherence on Absenteeism and Short-Term Disability for Five Chronic Diseases

Published in *Journal of Occupational and Environmental Medicine*, July 2012³

The cost of health care is a serious issue for American businesses as they work to balance rising costs with a desire to provide their employees with affordable and comprehensive health care coverage. To further complicate the issue, recent surveys show that chronic diseases may affect as many as 68 percent of working-age adults in the U.S.⁴ One study found that lost workplace productivity as a result of chronic disease was in excess of \$1 trillion for one year, with this figure expected to triple over the next 10 years.⁵ In recent years, research has shown that medication adherence can help contain health care costs. As people stay adherent to medication regimens, their health improves and hospitalizations, emergency department visits and hospital readmissions are reduced. While there is a growing body of published research describing the benefits of adherence in terms of improved health and overall cost-savings, the impact of adherence on employee productivity had not previously been well-documented.

A CVS Caremark sponsored study published in the *Journal of Occupational and Environmental Medicine*, found a positive link between medication adherence and employee productivity for employees with certain chronic conditions. In fact, those employees with chronic conditions who were adherent to their

prescribed medications had up to seven fewer days away from work annually (including absenteeism and short term disability days) than those who were not adherent, translating into estimated annual savings of nearly \$1,700 per adherent employee.

The study examined data on prescription drug usage, absenteeism and short-term disability for more than 100,000 employees at 16 medium to large-sized employers. Employees included in the study were diagnosed with diabetes, high blood pressure, congestive heart failure (CHF), high cholesterol or asthma/chronic obstructive pulmonary disease (COPD). The research found significant differences between adherent and nonadherent employees in the number of short-term disability days taken for all conditions studied, and between adherent and nonadherent employees in absenteeism days for those with diabetes, high blood pressure, high cholesterol, and asthma/COPD.

Helping to reduce financial losses due to reduced productivity will continue to be an important topic as the workforce ages and chronic conditions become even more prevalent in the American workplace. The outcomes of this research can prompt discussions about how interventions to increase employee medication adherence may ultimately help employers minimize losses due to missed work days.



Employees with chronic conditions who were adherent to their prescribed medications had up to seven fewer days away from work annually than those who were not adherent.

³ Carls GS, Roebuck MC, Brennan TA, Slezak JA, Matlin OS, Gibson TB. Impact of Medication Adherence on Absenteeism and Short-Term Disability for Five Chronic Diseases. *JOEM* 2012. 54:792-805.

⁴ Gallup Healthways. The Working Population Gallup Healthways Well-Being Index. April 28th Hill Briefing; 2008. Available at: <http://www.wellbeingindex.com>. Accessed May 8, 2012.

⁵ DeVoi R, Bedroussian A. An Unhealthy America: The Economic Burden of Chronic Disease Charting a New Course to Save Lives and Increase Productivity and Economic Growth. Santa Monica, CA: Milken Institute; 2007.

Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending

Published in *Health Affairs*, January 2011⁶

It seems like an obvious conclusion – people who are adherent to medications for chronic diseases (meaning they take their prescription drugs as directed by their doctor) have lower overall health care usage and costs. However, previously published studies have not been able to provide compelling evidence of the direct connection between medication adherence and cost savings and many questions have remained:

- > **Are these patients' health care costs lower because they are adherent, or do they have lower costs and use fewer health care resources because they are simply healthier individuals who make good lifestyle choices (e.g., healthy diet, regular exercise)?**
- > **How much lower are health care costs for adherent patients?**
- > **Does the reduction in health care costs make up for the increase in pharmacy costs due to patients taking their medications regularly, and therefore taking more medication?**

We know that almost half of all Americans, approximately 133 million people, have at least one chronic disease.⁷ In addition, studies have found that one-third of patients do not take their medications as prescribed and an even higher percentage of people with chronic conditions stop taking their medications within a year of diagnosis.⁸ Given these facts, CVS Caremark researchers evaluated integrated medical and pharmacy claims data and applied a disciplined methodology to better understand and analyze the impact of medication adherence for health plan sponsors. The research results were published in the January 2011 issue of *Health Affairs* and definitively establish that adherent patients who take medications as directed do indeed cost the health care system less. The study quantified these savings for patients with congestive heart failure, high blood pressure, diabetes and high cholesterol, indicating that adherent patients may save the health care system as much as \$7,800 per patient annually.

Patients who were adherent to their medications achieved savings as the result of fewer emergency department visits and fewer in-patient hospital days. In reviewing each of the four chronic conditions studied, the researchers found that adherent patients saved the following amounts compared to nonadherent patients:

Congestive heart failure patients saved \$7,823 per year

High blood pressure patients saved \$3,908 per year

High cholesterol patients saved \$1,258 per year

Diabetes patients saved \$3,756 per year

So what does this mean for the health care system in the coming years?

As health care reform is implemented and the Affordable Care Act expands access to medical care, players throughout the health care arena are all looking for ways to balance improved health outcomes with reduced spending.

This research indicates that, even with increased pharmacy spending, medication adherence provides substantial medical savings due to reductions in hospitalizations and emergency department use. CVS Caremark believes that, moving forward, plan sponsors, government payors and patients should make programs that actively encourage medication adherence, such as value-based insurance design and pharmacist-led counseling, a top priority.

⁶ Roebuck MC, Liberman, JN, Gemmill-Toyama M, Brennan TA. Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending. *Health Affairs*. 2011; 30:191-99.

⁷ Centers for Disease Control and Prevention. Chronic Diseases and Health Promotion. Atlanta (GA): CDC; 2010 Jul 7 [cited 2011 April 1]. Available at: <http://www.cdc.gov/NCCdphp/overview.htm>

⁸ New England Healthcare Institute. Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease. August 2009.

The Use of Generic Drugs in Prevention of Chronic Disease is Far More Cost-Effective than Thought, and May Save Money

Published in *Health Affairs*, July 2011⁹

Despite compelling evidence that medication adherence improves health outcomes, until recently there has not been an available body of published data to support the theory that improving adherence can also reduce overall health care costs. Furthermore, previously published studies in health care journals used the costs of branded medications in their calculations, and while they concluded that patients taking their medications as directed improved health outcomes, questions arose as to whether medical costs actually decreased.

This study, published in the July 2011 issue of *Health Affairs* concludes that preventative care for chronic diseases in 2011 is significantly less costly than previous reports calculated, because generics are now more broadly available for most chronic diseases. This is in line with current research indicating that generic medications can help patients stay adherent

because they are more affordable and cost has been identified as a barrier to adherence. Patients who are adherent to their medications save the system money because they face fewer emergency department visits and fewer inpatient hospital days.

The researchers reviewed a previous study published in 2008, which looked at prevention of cardiovascular disease using branded medications. This research estimated the cost of treatment to lower LDL cholesterol at more than \$83,000 per quality adjusted life year (QALY), a financial measure to evaluate the impact of improving the quality of life for a patient with a chronic disease. Today, recalculating for the same treatment protocol using generics, the comparable cost for treatment would be just over \$17,000 – or 20 percent of the original estimate. There were even more dramatic cost savings identified in the research, including a comparison of glucose control for diabetes that was estimated to cost

almost \$49,000 per QALY using branded medications, compared to only \$1,022 (just two percent of the originally calculated cost) per QALY, using readily available generics.

Given that more than 70 percent of all health care costs in the U.S. are spent treating patients who have one or more chronic diseases, this study shows that cost-effective generic medications are changing the economics of treating chronically ill patients. The researchers recommended that health care providers should focus on keeping patients adherent using available generic medications in order to help reduce medical costs while simultaneously improving care quality. Specific to the issue of cardiovascular disease, the researchers said cost implications for treatment need to be central to any policy discussions about reducing overall health care costs, because there are 80 million Americans spending approximately \$475 billion annually to treat heart disease.

⁹ Shrank WH, Choudhry NK, Liberman JN, Brennan TA. The Use of Generic Drugs in Prevention of Chronic Disease is Far More Cost-effective than Thought, and May Save Money. *Health Affairs*. 2011; 30(7).

The researchers included recommendations for policy makers to consider, including:

- > Promoting the use of generic medications in Accountable Care Organizations as part of health care reform.
- > Limiting the use of prescription writing practices such as “dispense as written,” where doctors and patients require the prescription be filled as a specific brand, and amending state Medicaid statutes that require patient consent before generics can be substituted, because those practices cost the system billions of dollars annually.
- > Ensuring that e-prescribing practices encourage the use of more cost-effective medications.

- > Developing education programs for patients and physicians around the effectiveness of generics to offset existing biases that result in generics not being prescribed.

- > Promoting consumer incentive programs through pharmacy benefit management and health plan programs that promote the use of generics over brand medication.

No matter who holds the financial risk of paying for health care – the patient, employer or government health plans – using generic medications should be a key part of managing the treatment of chronically ill patients because the use of cost-effective medications is a practical solution that can be implemented quickly.



Cost-effective generic medications are changing the economics of treating chronically ill patients.

SECTION II

CONTRIBUTING FACTORS TO MEDICATION ADHERENCE

The Implications
of Therapeutic
Complexity on
Adherence to
Cardiovascular
Medications

Published in *Archives
of Internal Medicine*,
January 2011¹⁰

Chronic diseases represent a major and growing health care issue. In fact, it is predicted that by the year 2030 more than 170 million people in the U.S. will be affected by one or more chronic diseases.¹¹ Further complicating this issue is the fact that most people living with a chronic disease take multiple medications to manage their condition and related co-morbidities, see more than one physician and may visit multiple pharmacies to fill their prescriptions—factors which make it more difficult for these patients to be adherent to their medications.

CVS Caremark, Harvard University and Brigham and Women's Hospital researchers looked at the impact of complex drug therapy regimens on adherence for patients taking medications to manage chronic cardiovascular conditions and published their findings in the online issue of the *Archives of Internal Medicine* in January 2011. While there is a body of research available that looks at the negative impact of drug regimen complexity—defined as the number of daily doses a patient must

¹⁰ Choudhry NK, Fischer MA, Avorn J, Liberman JN, Schneeweiss S, Pakes J, Brennan TA, Shrank WH. The Implications of Therapeutic Complexity on Adherence to Cardiovascular Medications. *Archives Int Med*. Published on-line Jan 10, 2011. doi:10.1001/archinternmed.2010.495

¹¹ Wu, Shin - Yi et al. Projection of Chronic Illness Prevalence and Cost Inflation. RAND Corporation. 2000.

take—this study is the first to broaden the definition of therapeutic complexity to also include patterns of prescribing (numbers of different prescribers) and patterns of medication fills (using multiple pharmacies and not synchronizing refills to minimize visits to the pharmacy). As a result, the researchers found that during the 90-day study period, 10 percent of the patients in the study had 23 or more prescriptions from four different prescribers, used two different pharmacies and made 11 or more pharmacy visits.

Not surprisingly, this level of complexity had a real impact on medication adherence, with those patients who had a larger number of prescriptions, more visits to multiple pharmacies and lower refill consolidation demonstrating the worst medication adherence. As an example, those patients with multiple medications who did not consolidate their medication refills (patients who filled the fewest medications per pharmacy visit) had adherence rates that were 8.4 percentage points lower than patients with multiple medications who consolidated their refills (patients who filled multiple medications at a pharmacy at one time).

Because medication nonadherence is associated with negative health outcomes, the inherent complexity related to treating many chronic conditions may ultimately undermine chronic disease management. **As a result, the researchers suggest a variety of ways that health care providers and payors can begin to address this issue, including:**

1 CREATE A CENTRALIZED “PHARMACY HOME” – similar to the concept of a medical home – where a patient’s pharmacy care is evaluated and renewals and refills are better synchronized and managed. This could include providing patients with financial incentives for filling prescriptions at a single pharmacy, so that a single health care professional has a full view of the patient’s needs and care.

2 DEVELOP PROGRAMS THAT REDUCE COMPLEXITY of both filling and taking medications by streamlining the number of trips it takes for patients to fill their prescriptions (e.g., encouraging programs such as 90-day versus 30-day prescriptions and coordination through mail order pharmacies).

3 EXPERIMENT WITH PROGRAMS AND TECHNOLOGIES that may make it easier for patients to better organize their medications.

Adherence to Medication Under Mandatory and Voluntary Mail Benefit Designs

Published in *American Journal of Managed Care*, July 2011¹²

A critical challenge in designing pharmacy benefits for health plan sponsors is to find a balance between access to essential medications and the cost of those medications. Through the years pharmacy benefit managers have leveraged both voluntary and mandatory mail order plans in an attempt to provide more cost-effective coverage. In general, voluntary mail order plans provided access, but did not always deliver

on cost savings if members did not move to mail order; while mandatory plans could deliver the cost savings, but initially caused member disruption and a perceived lack of access during implementation. As the cost of health care rises, plan sponsors have become even more attentive to how different plan designs impact medication adherence rates within their workforce.

The objective of this study was to compare patient medication adherence rates under voluntary and mandatory pharmacy mail order plans. The researchers reviewed pharmacy claims for more than 27,000 members in both mandatory and voluntary mail order pharmacy benefit plans. The results showed that when members are required to transition from filling prescriptions at a retail pharmacy location to a mail order pharmacy, some may prematurely discontinue their medications because of the steps

involved in changing over to mail order. This unintended consequence results in a reduction in medication adherence and the potential for increased medical expenses.

The data indicates there is a need for pharmacy benefit managers to pay special attention to potential barriers to medication access during the time period when a prescription must be transferred from a retail pharmacy to a mail service pharmacy. Properly managing this transition can enable PBMs to find ways to improve medication adherence at this critical transition point and enable both members and health plan sponsors to reap the full benefits of mandatory mail order plan designs. In particular, one group of patients that should be closely monitored during this transition period are those who have no prior experience with mail pharmacies as they are most susceptible to stopping their medications.

Trouble Getting Started: Predictors of Primary Medication Nonadherence

Published in *American Journal of Medicine*, November 2011¹³

Most studies on the topic of medication adherence evaluate behavior among patients who have filled their first prescription as researchers could not evaluate how many initial prescriptions were never actually delivered to the

pharmacy. For the first time, electronic prescribing (e-prescribing) provides the opportunity to track primary nonadherence – initial prescriptions that are issued electronically and filled, but never picked up by the patient – an area of nonadherence that may have been previously undetected. This study evaluated more than 423,000 e-prescriptions written in 2008 by 3,634 doctors for more than 280,000 patients in all 50 states. The researchers either matched the e-prescriptions with resulting claims data or, in the case of those not picking up their prescription, used the lack of a claim within six months to identify primary nonadherence. The results of the review show that

nearly a quarter of patients given a new medication prescription by their doctor did not pick up their initial prescription, results that reflect slightly higher primary non-adherence figures than previous studies. The researchers note that this group of patients, who never start taking their medications, miss an opportunity to improve their health and are at risk of developing long-term complications.

¹² Liberman, J., Hutchins, D., Shrank, WH, Slezak, J and Brennan, TA. Adherence to Medication Under Mandatory and Voluntary Mail Benefit Designs. *Am J Manag Care*. July 2011; 17(7).

¹³ Fischer MA, Choudhry NK, Brill G, Avorn J, Schneeweiss S, Hutchins D, Liberman JN, Brennan TA, Shrank WH. Trouble Getting Started: Predictors of Primary Medication Nonadherence. *Am J Med*. Nov 2011; 124(11).

Predictive factors for primary nonadherence identified by the researchers include:

Out-of-pocket cost of medications. Patients who received prescriptions for medications that were not included on their formulary – and were therefore more expensive because copays would be higher – are more likely not to fill their first prescription.

Integration of the doctors' health information systems. Prescriptions sent directly to pharmacies or mail order systems are more likely to be filled than prescriptions that doctors print out and give to patients.

Socio-economic factors. By reviewing zip codes and census data, the researchers determined that patients who live in higher income areas are more likely to fill prescriptions for new medications.

Type of medications. Prescriptions written for infants are almost always filled and antibiotics are filled at a rate of 90 percent. Medications for high blood pressure or diabetes saw primary nonadherence rates in excess of 25 percent.

The Epidemiology of Prescriptions Abandoned at the Pharmacy

Published in *Annals of Internal Medicine*, November 2010¹⁴

Much of the research on medication adherence has been based on the assumption that patients fill their initial prescriptions. Researchers have traditionally relied on prescription refill rates, patient self-reporting about how they take their medication and data from high-tech tools such as electronic pill bottles that track how often and when the bottle is opened. However, important gaps remain in our understanding of the causes of medication nonadherence and the best ways to intervene. One such gap is an understanding of why prescriptions are abandoned at the pharmacy—those prescriptions which are submitted by the prescriber and filled by the pharmacist, but are never picked up by the patient—a segment of medication nonadherence that represents an actionable opportunity for intervention.

To gain insight into this issue, researchers at CVS Caremark, Harvard University and Brigham

and Women's Hospital reviewed de-identified data (data from which an individual's personally identifiable information, such as name, age, address, etc. is removed) from CVS Caremark's pharmacy benefit management business and the national CVS/pharmacy retail chain over a three-month period between July 1 and September 30, 2008. The results were published in the November 2010 issue of the *Annals of Internal Medicine* and provide key insights into why and how often people do not pick up their initial prescriptions. Based on their findings regarding the percentage of prescriptions abandoned during the study period (3.27 percent over three months) and the fact that more than 3.6 billion prescriptions were filled in the U.S. in 2008,¹⁵ the researchers extrapolated that more than 110 million prescriptions are abandoned at U.S. pharmacies each year, costing pharmacies approximately half a billion dollars annually.

The researchers found a direct correlation between the amount of a patient's out-of-pocket copay and the likelihood of abandonment. Patients with a copay of \$50 were nearly four times more likely to abandon a prescription at the pharmacy than patients paying \$10. This result reinforces the widely studied correlation between out-of-pocket patient costs and medication adherence, while quantifying for the first time how often this factor results in an abandoned prescription.

The research also found correlations between:

- > **TYPE OF PRESCRIPTION**
New prescriptions were almost three times more likely to be abandoned than previously filled prescriptions.
- > **PATIENT AGE** Seniors were 45 percent less likely to abandon prescriptions than young adults (18-34 years).
- > **CO-MORBID CONDITIONS**
Patients with multiple conditions abandon prescriptions at higher rates than those with fewer conditions.

This study evaluated a discrete event in the full continuum of the prescription drug delivery process – prescription abandonment at a retail pharmacy – which could represent an opportunity for health care providers to intervene and better support medication adherence. The researchers recommend that one way to help improve medication adherence is for prescribers and pharmacists to become familiar with the characteristics associated with higher rates of abandonment and suggested a simple prediction rule with four elements that can help rapidly assess risk and identify who could benefit from additional counseling or the selection of a less expensive medication option.

These elements include:

¹⁴ Shrank WH, Choudhry NK, Fischer MA, Avorn J, Powell M, Schneeweiss S, et al. The Epidemiology of Prescriptions Abandoned at the Pharmacy. *Annals Int Med.* 2010; 153(10): 633-640.

¹⁵ Kaiser Family Foundation. United States: prescription drugs. Accessed at www.statehealthfacts.org/profileind.jsp?sub=66&rgn=1&cat=5 on 13 March 2010.

1 REVIEW

the individual's benefit plan and tiered copays to help identify the most affordable option, as cost can be a factor in prescription abandonment.

2 UNDERSTAND

past pharmacy behavior. Is this prescription a new one or a refill?

IDENTIFY the patient's age, as younger patients are more likely than older patients to abandon their medications.

3

4 DETERMINE

if it is an electronic vs. a hand-written prescription, as electronic prescriptions are more likely to be abandoned.

SECTION III

MEDICATION ADHERENCE INTERVENTIONS

Impact of Patient-Centered Pharmacy Care and Intervention in a High-Risk Group

Published in *Journal of
Managed Care Pharmacy*,
April 2013¹⁶

Taking medication daily should be part of the routine for patients who have a chronic disease, but it's not always as easy as it sounds. Drug interactions, side effects, cost and a person's social or economic situation are just a few of the factors that may deter them from taking the drug therapies they need to manage their condition.

Medication Therapy Management (MTM) involves coordinated, personalized outreach to patients with chronic conditions to promote better adherence. The use of MTM programs not only helps improve outcomes for patients by helping them stay adherent to their medications, but also, according to recent research, can help save on overall health care costs.

This study, conducted by CVS Caremark researchers, identified high-risk members of a large employer group who had hypertension, high cholesterol, diabetes, depression and asthma and invited them to participate in an MTM program. The research followed 2,250 patients who received MTM via a telephone-based pharmacy outreach program with a clinical pharmacist and a matched control group of 2,250

¹⁶ Moore JM, Shartle D, Faudskar L, Matlin OS, Brennan TA. Impact of Patient-Centered Pharmacy Care and Intervention in a High-Risk Group. *J Manag Care Pharm.* April 2013; 19(3).

who did not receive interventions. The study reviewed outcomes for the 12 months prior and 12 months following the one year intervention period. Results showed that MTM interventions decreased total health care plan-paid costs by up to \$977 (10.3 percent per patient); decreased inpatient visits by up to 18.6 percent per patient; and significantly increased medication adherence.

The MTM group received an initial telephonic consult with a clinical pharmacist to review the patient's medical conditions and medications, address the patient's primary drug therapy concerns and discuss any major drug therapy issues identified during the review. Following the initial appointment, the clinical pharmacist prepared an individualized care plan for the patient including drug therapy issues

discussed, specific recommendations for therapy and any action items for the patient to share with their health care provider. Follow-up telephone appointments with the same clinical pharmacist were scheduled to meet the needs of the individual patient and usually included two or more additional visits over the course of a year. Patients were also encouraged to call their clinical pharmacist with questions or concerns, especially questions pertaining to newly prescribed medications.

Other key findings reviewed hospitalizations between the two groups showing a decrease among the members receiving MTM of 18.6 percent vs. an increase of 24.2 percent among the control group. In terms of medication adherence, the Medication Possession Ratio (MPR) for MTM

intervention group patients with hypertension and high cholesterol showed significant increases, rising by 2.3 percent and 2.1 percent respectively. In addition, the average days supply for the MTM group increased by 72.7 days over baseline, while the control group's average days supply decreased by 111.1 days. There were no significant differences in emergency room visits between the control and intervention groups for any disease category.

Overall, this study found that patients who participated in a high-touch MTM program were able to significantly increase their medication adherence levels, while reducing their use of in-patient hospital services. These improvements in adherence were further supplemented by a significant decrease in total health care costs for the patients' health plan sponsor.



Patients who participated in a high-touch MTM program were able to significantly increase their medication adherence levels.

Targeting Cardiovascular Medication Adherence Interventions: A Systematic Review

Published in *Journal of the American Pharmacists Association*, May/June 2012¹⁷

Ensuring that preventative health care messages reach the right people at the right time is easier said than done. Patients' communication preferences and their receptiveness to interventions are diverse, and the methods used to relay important health information can vary from broad-based public health campaigns to personal, customized outreach. As health care providers strive to reach patients who may be most at-risk for becoming nonadherent, determining the most effective approach for engagement can be a challenge, especially when resources are limited.

Researchers at CVS Caremark and Brigham and Women's Hospital identified differences in adherence rates when various methods were used to communicate and intervene with patients. The team looked at three separate approaches:

(1) focused interventions targeted exclusively to people not adherent to medications, (2) broad interventions targeted to an entire population of medication takers and (3) dynamic interventions targeted at all medication takers using real-time adherence information that identified and targeted those who were not adherent.

Based on a review of 59 articles, the researchers found that interventions using focused or dynamic methods had a greater impact on adherence, and that these types of interventions may have advantages over broad-based approaches. More than one-third of interventions targeted to nonadherent patients resulted in improved medication adherence as compared to 18 percent of broad interventions. This is because an essential "feedback loop" exists in focused and dynamic interventions where data, whether self-generated or

electronically monitored, alerts health care professionals to a patient's medication adherence patterns. Broad interventions, on the other hand, did not provide health care professionals with access to an individual's specific adherence behavior.

The researchers concluded that targeting patients who are nonadherent to their cardiovascular medications may lead to better adherence, but more research is needed to determine how best to identify and intervene with nonadherent patients. The accuracy, cost and reproducibility of methods for identifying target populations should be a central consideration in future studies, especially in an environment where resources are limited and health care professionals and payors need to identify the most cost-effective and impactful ways to make positive behavior changes.

¹⁷ Cutrona SL, Choudhry NK, Fischer MA, Servi A, Stedman M, Liberman JN, Shrank WH. Targeting Cardiovascular Medication Adherence Interventions: A Systematic Review. *JAPhA*. May-June 2012; 52.



As health care providers strive to reach **patients who may be most at-risk for becoming nonadherent**, determining the most effective approach for engagement can be a challenge, especially when resources are limited.

Enhanced Active Choice: A New Method to Motivate Behavior Change

Published in *The Journal of Consumer Psychology*, October 2011¹⁸

Patients' behaviors regarding how they make health care choices and decisions can ultimately impact medication adherence and health outcomes and can even have implications on cost. Active choice communication represents a scenario where a patient is forced to make an explicit choice among several options in a health care setting. The alternative to "active" choice is a more passive "opt-in" or "opt-out" choice, where the most common choice made is usually a default position where the consumer does not have to take any action.

CVS Caremark created the Behavior Change Research Partnership in 2010 to help advise the company on how to develop practices to improve patient medication

adherence through communications that encourage healthy behavior. The partnership is overseen by behavioral economists from the Tuck School of Business at Dartmouth College, the School of Medicine and the Wharton School of Business at the University of Pennsylvania, and Carnegie Mellon University. This study published in *The Journal of Consumer Psychology* represents some of the outcomes of the partnership as it examines the effectiveness of an "active choice" communication alternative presented to consumers regarding their health care behavior.

The researchers looked at results from four different consumer tests involving three different decision tasks: intention to get a flu shot;

requesting a reminder to get a flu shot; and enrollment in an automatic prescription refill program. The study compares the results of these tests, which presented innovative and personalized communications programs where patients needed to make a direct choice. The tests sought to determine if requiring consumers to make an active choice resulted in that person being more committed to continuing the behavior they selected; the results demonstrated that presenting an active choice increases compliance with the desired behavior indicating there are real advantages to forcing a decision. Ultimately, providing consumers with an active choice produced higher participation rates in the desired behavior in a health care setting.

¹⁸ Punam, A.K., Hariam, B., Loewenstein, G. and Volpp, K.G. Enhanced Active Choice: A New Method to Motivate Behavior Change. *Journal Consumer Psych.* October 2011; 21(4).



Active choice communication represents a scenario where a patient is forced to make an explicit choice among several options in a health care setting.

SECTION IV

SOCIAL AND DEMOGRAPHIC FACTORS CONTRIBUTING TO MEDICATION ADHERENCE

Gender and Racial Disparities in Adherence to Statin Therapy: A Meta-analysis

Published in *The American Heart Journal*, May 2013¹⁹

The medical community is well aware of the health issues, lifestyle issues and genetic factors that can put people at risk for developing high cholesterol. Over time, a large body of research had become available documenting differences in health outcomes for patients with high cholesterol based on the patient's race, ethnicity and gender. However, while long-term medication adherence has appeared lower in racial subgroups and among women, there has been limited attention paid to quantifying the overall impact of these factors on adherence.

This study, conducted by researchers at CVS Caremark and Brigham and Women's Hospital, shows that lifestyle factors related to social and cultural behaviors associated with gender and race may affect medication adherence for statin medications used to control cholesterol levels. The researchers found that non-white patients had 50 percent greater odds of nonadherence to statins compared to white patients, while women had 10 percent greater odds of nonadherence to statins compared to men. Although it has long been known that socio-demographic

¹⁹ Lewey J, Shrank WH, Bowry AD, Kilabuk E, Brennan TA, Choudhry NK. Gender and Racial Disparities in Adherence to Statin Therapy: A Meta-analysis. *Am Heart J.* May 2013; 165(5).

characteristics are associated with nonadherence, this study was the first of its kind to look at the scale and scope of this association.

The study consisted of a literature review of more than 50 publications focused on gender and racial disparities associated with medication adherence and included more than 1.7 million patients. Of note, the finding that nonadherence was higher based on the patient's gender or race held true even in those studies that adjusted for income, insurance status, co-payment amounts and other clinically important factors that could contribute to nonadherence.

The researchers stated that there were a number of potential reasons

for nonadherence among women and non-white patients pertaining to demographic characteristics. For example, active prevention of cardiovascular disease may not be a priority for women and their health care providers because of the common misconception that women are less at-risk than men. In addition, women also frequently serve as informal caregivers for family members and the difference may be further impacted by the fact that caregivers frequently have lower rates of medication adherence.

The reasons that non-white patients may be nonadherent are more complex. As an example, the researchers noted that non-white patients are less likely to have a consistent relationship with a

primary care provider than white patients, which can impact chronic care and adherence. Along with differences correlated with social factors, differences in health and health status among women and non-white patients may also play a role. Both women and various racial and ethnic minorities may be more likely to experience side effects from statins, a commonly cited reason for early discontinuation or poor adherence.

These findings help advance an understanding of the effect of demographic factors on medication adherence, which support CVS Caremark's efforts to identify and design interventions that reduce nonadherence and improve health outcomes.



Lifestyle factors related to **social and cultural behaviors** associated with gender and race may affect medication adherence.

Association Between Different Types of Social Support and Medication Adherence

Published in *American Journal of Managed Care*,
December 2012²⁰

The elements that affect an individual's likelihood to remain adherent to their medications are diverse. Economic variables, geographic variables, and, according to research from CVS Caremark and Brigham and Women's Hospital, social variables, play a large role in patterns of adherence. These non-clinical factors are sometimes overlooked but can be very important in helping health care practitioners to understand the bigger picture of medication adherence.

The researchers involved in this study reviewed 50 peer-reviewed articles which directly measured the relationship between medication adherence and some form of social support. Four categories of social support for patients were identified and evaluated, including:

- > **Structural support – including marital status, living arrangements and size of the patient's social network**
- > **Practical support – helping the patients by paying for medications, picking up prescriptions, reading labels, filling pill boxes and providing transportation**

> **Emotional support – providing encouragement and reassurance of worth, listening and providing spiritual support**

> **Combination support – any combination of the three support structures listed above**

The results indicated that greater practical support was more consistently associated with improved adherence to medication, with the majority of studies that looked at this type of support identifying a significant (67 percent) association with improved medication adherence.

The research suggests that leveraging a patient's existing social contacts and networks to help them with the practical aspects of being adherent, such as providing transportation to the pharmacy or picking up medications for them, could help improve their adherence. While more research is needed to identify how to best apply these findings to patient care, the research affirmed the important role that social networks have in helping to manage care for patients with chronic disease.

²⁰ Scheurer D, Choudhry N, Swanton KA, Matlin O, Shrank W. Association Between Different Types of Social Support and Medication Adherence. *Am J Manag-Care*. December 2012; 18(12).

Are Caregivers Adherent to Their Own Medications?

Published in *Journal of the American Pharmacists Association*, July/August 2011²¹

More than 65 million Americans describe themselves as family caregivers, a self-identified group made up of people who provide some level of care to another family member. Given the physical and emotional demands experienced by family caregivers, there have been questions raised about the impact that caring for another may have on the caregiver's own level of medication adherence. This study took a look at this issue by tabulating the results of an online survey of retail pharmacy customers, in which 38 percent of the people responding described themselves as family caregivers. The researchers found a compelling relationship between caregiving and the potential for a lack of medication adherence, primarily because caregivers are more focused on making sure their family members get proper care.

This research indicates that caregiving status is an important characteristic that can identify a potentially nonadherent patient. Health care providers and pharmacists can look for family caregiver status as an identifier among their patients in order to target those individuals and encourage them to stay on their own medicine. The study suggests that for pharmacists in particular, family caregivers represent an opportunity for proactive adherence counseling as pharmacists may frequently see caregivers in the store as they pick up medicine for others in the family.

Of the self-identified caregivers:

- **45% said they somewhat or strongly agree they are more likely to fail to take their own medicine, even though they provide medicine in a timely fashion to other family members.**
- **46% of the caregivers said it is more important that they take care of their family members than themselves and 52% said they are willing to sacrifice their own health to make sure family members receive proper care.**
- **The study also found that if there is limited money for medications, caregivers will buy medicine for the people they are taking care of before purchasing it for themselves.**

²¹ Shrank WH, Liberman JN, Fischer MA, Kilabuk E, Girdish C, Cutrona SL, Brennan T, Choudhry NK. Are Caregivers Adherent to Their Own Medications? *JAPhA*. Jul-Aug 2011;51(4).



Caregiving status is an important characteristic that can identify a potentially nonadherent patient.

SECTION V

ROLE/IMPACT OF HEALTH CARE PROFESSIONALS

An Integrated
Pharmacy-Based
Program Improved
Medication
Prescription and
Adherence Rates in
Diabetes Patients

Published in *Health
Affairs*, January 2012²²

In 2007 an estimated \$174 billion was spent treating the diagnosed diabetes population. Because of the growing prevalence of diabetes, patients who are nonadherent to their medications, and physicians who fail to initiate use of appropriate medications to treat diabetes, represent a substantial cost to the U.S. health care system. In response to increasing costs, CVS Caremark initiated Pharmacy Advisor®, an integrated pharmacy-based program to improve patients' adherence rates as well as doctors' initiation rates for concomitant medications used to treat people with diabetes. The intervention consisted of phone or face-to-face counseling from both mail order and retail pharmacists who had specific information about the patient's treatment and had been trained to counsel patients about managing their diabetes.

This study found that the company's Pharmacy Advisor program increased both patient medication adherence rates and physician initiation of prescriptions, thereby improving care for diabetes patients and resulting in savings for health plans. The study provided further illustration of the central role pharmacists can play in improving the health of their

²² Brennan TA, Dollear TJ, Hu M, Matlin OS, Shrank WH, Choudhry NK, Grambley W. An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients. *Health Affairs*, January 2012; 31(1).

patients. While ensuring adherence and appropriate treatment has long been the domain of primary care providers, as time demands on these health care providers increase, interventions carried out by pharmacists can complement their efforts. Pharmacists are also in a unique position to be able to monitor patient adherence and effectively intervene when needed. The study also provided insights into the problem of time-limited health care interventions because the data showed that patients stayed on their medications while they were being actively counseled, but once those pharmacist-patient conversations ended, adherence rates quickly fell.

To conduct the study, researchers analyzed the pharmacy claims data of benefit members at a large Midwest manufacturing company and focused on interventions with diabetic patients between October 2009 and April 2010. The study included an intervention group of 5,123 people who were proactively counseled by retail and call center pharmacists and a control group of 24,124 patients with diabetes who did not receive specialized counseling. The researchers measured gains in patient adherence and medication initiation rates of concomitant therapies for diabetes, such as statins, angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs).

The contacts by pharmacists with the patients and their doctors increased therapy initiation rates by as much as 39 percent for the full sample with an even higher increase of 68 percent for the group counseled at retail stores. Overall medication adherence rates increased by 2.1 percent, with face-to-face interventions by retail store pharmacists resulting in adherence rate increases of 3.9 percent. While

expenditures for the counseling in the study totaled \$200,000, the employer saved more than \$600,000 through health care cost avoidance with the intervention group, a return on investment of \$3 for every \$1 spent on additional counseling.

In a health care system eagerly seeking programs that can reduce costs and improve care, this type of straight-forward, pharmacist-based counseling program that can improve adherence to existing medication regimens, encourage initiation of missing therapies and save money should be of great value.

Patterns of Medication Initiation in Newly Diagnosed Diabetes Mellitus: Quality and Cost Implications

Published in *American Journal of Medicine*, March 2012²³

Type-2 diabetes has emerged as one of the most significant health issues worldwide. In the U.S. alone, more than 20 million people have diabetes and the number of Americans with the disease is expected to increase by 165 percent by 2050. Treatment of the disease in the U.S. is estimated to cost \$200 billion annually.

Six classes of oral medications have been approved by the U.S. Food and Drug Administration for the treatment of Type-2 diabetes. Although all the medications are effective at lowering blood glucose,

the evidence supporting their impact on other clinical events varies. In 2006 the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), issued evidence-based consensus guidelines recommending metformin, a generic drug, as the agent to be used as first-line therapy for patients newly diagnosed with Type-2 diabetes. This study, evaluated the pharmacy claims for more than 250,000 newly diagnosed diabetes patients who initiated oral medications between January 1, 2006 and December 31, 2008 to determine how doctors are adhering to the recommended guidelines. The study highlighted gaps between treatment recommendations and actual prescription protocols for Type-2 diabetes. In fact, while 65 percent of the patients studied received care consistent with the consensus guidelines, physicians in 35 percent of cases did not follow these guidelines for recommended first-line treatment.

This study is also among the first to define the fiscal implications of therapeutic choices in a large population of patients with diabetes, with the researchers noting that in addition to potential quality of care implications, patients, payors and the health care system could be paying an additional \$420 million annually. This is due to physicians prescribing more expensive branded medications although the guidelines recommend use of generic medications. With the prevalence of diabetes increasing quite dramatically, the potential savings from improved adherence to these treatment guidelines could even exceed these estimates.

²³ Desai NR, Shrank WH, Fischer MA, Avorn J, Liberman JN, Schneeweiss S, Pakes J, Brennan TA, Choudhry NK. Patterns of Medication Initiation in Newly Diagnosed Diabetes Mellitus: Quality and Cost Implications. *Am J Med.* March 2012; 125(3).

Physician Perceptions About Generic Drugs

Published in *The Annals of Pharmacotherapy*, January 2011²⁴

When evaluating the factors that contribute to medication nonadherence, one factor that frequently comes up is the cost of drugs. It appears that the more expensive a drug is, the more likely it will be that the patient will be nonadherent. As a result, generic medications seem to offer one solution to managing rising drug costs and could help encourage people to stay on their medications. Yet, despite a large body of research that points to the safety and effectiveness of generic medications, they remain underused by some doctors.

The researchers at CVS Caremark, Harvard University and Brigham and Women's Hospital believe that

understanding how physicians perceive generics could help identify potential barriers to increasing generic medication use. In order to better understand physician perceptions related to generic drugs and identify characteristics associated with those physicians who have negative perceptions about generics, the researchers surveyed more than 2,700 physicians and analyzed the responses received as reported in the January 2011 issue of *The Annals of Pharmacotherapy*. While the majority of physicians surveyed were comfortable with the efficacy of generic medications and were comfortable using generics themselves, almost one-quarter of those surveyed have negative perceptions about the effectiveness and quality of generic drugs, which may lead to physicians prescribing unnecessarily expensive medications.

The researchers found that age was a factor in a physician's perception of generics, with physicians who were 55 years of age or older being 3.3

times more likely to have negative perceptions about generic drugs. In addition, the doctors surveyed said they were aware that some of their patients struggle with prescription drug costs and that many of their patients do not fill prescriptions due to cost. Surprisingly, despite this insight, the researchers did not find a relationship between the doctors' perceptions of cost burden and their perceptions of generics.

Given the significant cost savings that can be achieved by increasing the use of appropriate generic drugs, and the large number of widely-used brand drugs that are expected to "go generic" over the next few years, negative physician perceptions about generic drugs can be a barrier to increasing generic use and could contribute to elevated prescription drug costs for patients and payors.

As a result, there is a real need for finding effective ways to educate physicians to make them more comfortable with the safety, quality and efficacy profile of generic drugs.



Generic medications seem to offer **one solution to managing rising drug costs** and could help encourage people to stay on their medications.

²⁴ Shrank WH, Liberman JN, Fischer MA, Girdish C, Brennan TA, Choudhry NK. Physician Perceptions About Generic Drugs. *Annals of Pharmacotherapy*. 2011; 45:31-38.

Physician Effectiveness in Interventions to Improve Cardiovascular Medication Adherence: A Systematic Review

Published in *Journal of General Internal Medicine*, May 2010²⁵

There is a great deal of existing research that points to the fact that nonadherence to drugs used to treat chronic conditions is a common and often perplexing issue. While medication nonadherence has been shown to increase overall health care costs and worsen health outcomes, there are still no definitive answers about why patients don't take their prescribed medications and what interventions can help address the issue. Furthermore, little is known about which health care professionals are best able to deliver adherence interventions and what role the patient's physician should play in encouraging patient behavior to improve medication adherence.

In an attempt to better understand and quantify the physician's role in directing medication adherence, researchers at CVS Caremark, Harvard University and Brigham and Women's Hospital conducted a systematic review of interventions to improve adherence to medications for heart disease and diabetes. The research, published in the May 2010 issue of the *Journal of General Internal Medicine* reviewed and compared the effectiveness of interventions that relied on physician involvement, those interventions that relied on other health care professionals (e.g., nurses or

pharmacists) and those that did not involve any health care professionals. Overall, the researchers found that existing physician-based adherence interventions have been less effective than strategies which rely on other health care professionals with specialized skills in pharmaceutical counseling or expertise in behavioral interventions.

The data indicated that, although small, physician-involved interventions did produce a positive effect on adherence, which may be attributed to the patient's perception of the physician's expertise or in the trust built through long-term doctor-patient relationships. The researchers suggest that referral networks linking physicians to other adherence experts could leverage the strengths of the physician's relationship with the patient, while limiting the demands placed on the physician's time and the related costs. While more research is needed to better understand the role of the physician in improving patient adherence in a cost-effective manner and how physicians can best collaborate with other health care professionals, the analysis suggests that non-physician health care professionals, such as pharmacists and nurses, can play an important role in improving adherence.



Researchers suggest that **referral networks linking physicians to other adherence experts could leverage the strengths of the physician's relationship with the patient**, while limiting the demands placed on the physician's time and the related costs.

²⁵ Cutrona SL, Choudhry NK, Stedman M, Servi A, Liberman JN, Brennan TA, Fischer MA, Brookhart MA, Shrank WH. Physician Effectiveness in Interventions to Improve Cardiovascular Medication Adherence: A Systematic Review. *JGIM*. May 2010; 25:1090-1096.

Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence

Published in the *American Journal of Managed Care*, December 2010²⁶

We have become accustomed to seeing certain health care professionals ranked high on Gallup's annual Honesty and Ethics survey. The results announced in December 2010 were no exception with nurses at the top of the list and pharmacists ranked at number three. In the study of medication adherence, however, there has been very little research that compares the effectiveness of the "modes of delivery" for adherence interventions. So, while we know who Americans trust, thanks to Gallup, we don't know the best format to deliver information about adherence, who would be the most effective messenger or where patients are most open to hearing and acting on this information.

To help broaden the body of knowledge available about medication adherence, researchers at CVS Caremark, Harvard University and Brigham and Women's Hospital conducted a systematic review of adherence interventions for patients with heart disease and diabetes, focused on how (in person, on the phone, written or electronically), by whom (physician, nurse or pharmacist) and where (hospital, pharmacy, clinic or home) the information was

transferred to patients. The results, which were published in the December 2010 issue of the *American Journal of Managed Care*, found there is no substitute for a face-to-face session with a trusted health care provider. Pharmacists at a retail drug store were found to be the most influential voice in encouraging patients to take their medication as prescribed, followed by nurses at hospitals as patients are released.

The researchers found that interventions using mail, fax or brochure-type communications that were not personalized had a relatively low impact on promoting patient adherence. Those programs that use electronic communications, such as videos and interactive technology, showed promise, but were determined to only have medium impact on increasing adherence among patients. The highest impact programs featured those which included pharmacists counseling patients in a retail drug store, followed by nurses talking face-to-face with patients who were leaving a hospital. In addition, face-to-face discussions between pharmacists and patients in a store were twice as effective at boosting adherence rates as programs where pharmacists talk with patients on the telephone.

²⁶ Cutrona SL, Choudhry NK, Fischer MA, Servi A, Liberman JN, Brennan TA, Shrank WH. Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence. *Am J Manag Care*. 2010; 16 (12): 929-942.

This analysis is just a first step at better understanding the impact and influence that different communication vehicles and different messengers can have on delivering adherence information. The researchers recommend several areas of focus for future research on adherence, including:

1 Reviewing the impact of life events on increased patient receptiveness to the adherence message (i.e., hospital stays, particularly after a serious cardiac event).

2 Evaluating psychological factors during an acute illness and hospital stay and how they may impact a patient's willingness to modify adherence behavior.

3 Delivery of in-person pharmacist counsel when a patient comes to pick up their medication.

4 New and innovative ways to take advantage of electronic technologies and tap into emerging social networks run by patients rather than health care professionals.

SECTION VI

ROLE/IMPACT OF TECHNOLOGY

Variations in Structure and Content of Online Social Networks for Patients with Diabetes

Published in *Archives of Internal Medicine*, September 2011²⁷

As patients increasingly use social media as a health care tool and resource, a survey by Harvard University, Brigham and Women's Hospital and CVS Caremark researchers demonstrated that there is great variability in the standards used to ensure sites effectively provide information and answers to health-related questions. The researchers examined diabetes-related social media sites and found they all use different communication and financing structures, vary in how they facilitate participation by experts and have little in common when it comes to oversight of content and membership criteria.

Study authors said it is clear that online social networks are playing an increasing role in health education. Factors causing patients to look for support online include the fact that primary care physicians have less time to spend with individual patients as they see increasing numbers of patients and have limited time for telephone consultations to answer questions related to chronic disease management. In addition, as the population that is familiar with using the web ages and begins to develop chronic diseases, they are looking to familiar on-line channels to help them cope with their disease.

²⁷ Shrank WH, Choudhry NK, Swanton K, Jain S, Greene MD JA, Harlam B, Patel KP. Variations in Structure and Content of Online Social Networks for Patients with Diabetes. *Archives Int Med*. Sep 26, 2011; 171(17).

The researchers focused on web sites that primarily provide information about diabetes.

They began their review by identifying 300 online diabetes-related sites through a Google search. They narrowed that number to 23 web sites that were not attached to any news organizations or academic institutions. The final study reviewed 15 web sites in depth, ranging in size from 3,074 members to more than 300,000, with the majority having more than 10,000 members. Eighty percent of the sites linked to Facebook, while two-thirds networked through Twitter.

The researchers said that information required for site membership was minimal and only one site required an extensive profile be sent to the site administrator for approval.

Physicians were available to answer questions **on only 33%** of the sites, while **67% of the sites** called for site administrators to review content.

On **13% of the sites** there was no apparent policing of information posted.

Industry advertising is allowed on all but three of the sites. **Half of the sites** that featured advertising had information from pharmaceutical manufacturers, **67%** had ads from diabetes device manufacturers, and **13% published ads** purchased by insurance companies.

Two-thirds of the sites allowed advertisements related to diet and exercise for diabetics.

Social media represents an important health care tool of the future so it is important to determine best practices for development as well as how these vehicles can be used to disseminate the right information to help patients treat their chronic disease. While social media is attractive to people looking to share information and find support and strategies for living with chronic disease, the authors said there is a long way to go before we can be confident patients are receiving high quality, accurate information about their conditions through this medium.

Online Social Networking by Patients with Diabetes: A Qualitative Evaluation of Communication with Facebook

Published in *Journal of General Internal Medicine*, October 2010²⁸

The Internet changed the way people search for health care information, and new social media networking sites like Facebook has changed the way many people connect and interact. These new technologies also impact how individuals learn about health or build a community of patients who share clinical information and provide support. With more than 500 million registered users worldwide, Facebook is a destination and meeting place for social networking and disease-specific sites have appeared on Facebook as sources of information, support and engagement for patients with chronic diseases. However, very little research has been done to understand the content and sources of health-seeking behavior and information-sharing on popular social networking sites such as Facebook.

Researchers at CVS Caremark, Harvard University and Brigham and Women's Hospital examined the 15 largest Facebook communities dedicated to diabetes and published their findings in the November 2010 issue of the *Journal of General Internal Medicine*. The researchers found what they classified as "tentative support" for the proposed health benefits of social media in the management of chronic disease. On the other hand, they also found that because of the inability to verify the identity of the individual or group posting information, when someone posts about a positive experience with a product or service it is difficult to know whether it is an authentic and

unbiased claim or a marketing pitch. On the positive side, members of online diabetes communities gain positive benefits from their participation in these forums. These patients receive interpersonal and community support from wall posts and discussion threads, can access specialized knowledge on disease management from their peers and have the opportunity to participate in a positive way with a community of their peers. Despite these positives, the researchers recommend that members of these communities use caution as they identified numerous incidences of surveys, marketing pitches and efforts to recruit patients for clinical trials where the true identity of the poster could not be confirmed.

The dynamics of the social networking environment hold promise for patients, providing a place where they can find a community of peers offering support and education, but also carrying the perils of an unregulated environment, which allows for substantial and non-transparent promotional and data-gathering activities. Clinicians should be aware of these strengths and limitations to help them better counsel their patients about sources of information and support about chronic disease. In addition, policymakers could begin to consider how to assure transparency in promotional activities in these online social networks. Finally, patients may consider seeking out social networking sites developed and patrolled by health professionals to promote an accurate and unbiased exchange of information.

²⁸ Greene JA, Choudhry NK, Kilabuk E and Shrank WH. Online Social Networking by Patients with Diabetes: A Qualitative Evaluation of Communication with Facebook. *JGIM*. 2010; 26:287-292.

Healthcare Information Technology Interventions to Improve Cardiovascular and Diabetes Medication Adherence

Published in the *American Journal of Managed Care*, December 2010²⁹

The application of Healthcare Information Technology (HIT) has been linked to a variety of benefits for health care cost and quality. Electronic Medical Records (EMRs) hold the promise of portability, ensuring that all of a person's relevant health care information is available no matter where, or by whom, they are treated. E-prescribing can make it faster and more convenient to get and track prescriptions. With all this promise, researchers and clinicians are beginning to look at the role HIT could play in facilitating medication adherence interventions, but to

date, there has been little rigorous evaluation of the effectiveness of HIT-driven adherence interventions.

As part of their focus on adherence, researchers at CVS Caremark, Harvard University and Brigham and Women's Hospital conducted a systematic review of the existing literature on HIT interventions designed to improve medication adherence in cardiovascular disease and diabetes. In looking for published studies that address how electronic communications can improve adherence in these two disease areas, the researchers combed

through more than 7,000 articles published since 1966, but only found 13 articles that met their criteria. Their analysis, published in the December 2010 issue of the *American Journal of Managed Care*, highlights the current scarcity of prospective data on the effectiveness of HIT interventions to improve adherence and a lack of compelling evidence to guide the development and implementation of future interventions. **The researchers identified some key points for consideration in future research and investigation into this area, including:**

Studies indicated that **simple reminder systems were consistently successful**. These reminder systems are unique compared to other HIT interventions in that they can be seamlessly integrated into the patient's daily routines without requiring additional effort on the part of the patient.

Studies examining the **use of interactive HIT for education and counseling were less successful**, indicating that the electronic delivery of education does not necessarily make it more effective.

While the researchers expected to find that HIT enhanced the effectiveness of adherence interventions by generating real-time adherence feedback to the health care providers, the **results did not find a substantial improvement** compared to reminder interventions alone.

Previous literature has indicated that patient engagement in care is associated with improved adherence to treatment. Although several of the studies reviewed aimed to create an interactive system for patients, they generally did so by gathering data from patients through relatively basic mechanisms (e.g., touch-tone keypad) and sending back automated, albeit customized, feedback designed to educate and counsel. **Furthermore, these studies required a substantial degree of patient motivation, which may be unrealistic or pose a barrier.**

While HIT interventions look like promising tools in the effort to improve medication adherence, more research is needed to fully understand and identify best practices. In reviewing the analysis, simple HIT interventions, such as reminder systems, appear effective, and efforts to implement them broadly would seem to be an efficient and relatively low-cost approach to improve adherence. However, reminders alone will not solve the problem. The researchers call for innovative systems to further engage and motivate patients to adhere to their medications. Few published studies describe sophisticated, interactive interventions that expand the functionality and capabilities of electronic health systems to provide patients and providers with more valuable and timely information, leaving us with limited evidence to guide the development and implementation of HIT adherence interventions.

²⁹ Misono AS, Cutrona SL, Choudhry NK, Fischer MA, Stedman MR, Liberman JN, Brennan TA, Jain SH, Shrank WH. Healthcare Information Technology Interventions to Improve Cardiovascular and Diabetes Medication Adherence. *Am J Manag Care*. 2010; 16 (12 Spec No.): SP82-SP92.

POLICY CONSIDERATIONS FOR IMPROVING PHARMACY CARE

Beneficiaries with
Cardiovascular
Disease and
the Part D
Coverage Gap

Published in *Circulation:
Cardiovascular Quality and
Outcomes*, May 2012³⁰

When Medicare Part D came into being, the term “donut hole” took on a new meaning and became a controversial topic. Referring to the Medicare Part D coverage gap that impacts beneficiaries once they reach a certain spending threshold, the donut hole exposed beneficiaries to the full price of prescription medications for a period of time. This led to higher out-of-pocket costs for patients, but there was little evidence to show that exposure to these costs affected behaviors like medication adherence or had an adverse impact on health.

In a study conducted by researchers at CVS Caremark and Brigham and Women’s Hospital and published in the journal *Circulation: Cardiovascular Quality and Outcomes*, the impact of the Medicare Part D coverage gap on medication adherence and outcomes was directly reviewed. The researchers found that when individuals with cardiovascular conditions experienced a gap in their Part D coverage (i.e., the “donut hole”), adherence rates dropped as patients were unable to afford out-of-pocket costs associated with full-priced prescription medications.

³⁰ Polinski JM, Shrank WH, Glynn RJ, Huskamp HA, Roebuck MC, Schneeweiss S. Beneficiaries with Cardiovascular Disease and the Part D Coverage Gap. *Circ Cardiovasc Qual Outcomes*. May 2012; 5(3).

The study also found that patients who entered the donut hole were no more or less likely to switch to a cheaper, generic medication during that time period.

The study found that beneficiaries with cardiovascular conditions who had no financial assistance during the donut hole were 57 percent more likely to discontinue their

cardiovascular medications than those beneficiaries who had consistent drug coverage. Sudden exposure to 100 percent of drug costs led to abrupt discontinuation of essential medications. While the study concluded there were no significant adverse health effects in the short-term related to this drop in adherence, the long-term health consequences could not be assessed.

This research contributes to a growing body of evidence that urges policymakers to be sensitive to the effects of the donut hole coverage gap on drug discontinuation. As part of the Affordable Care Act, policy changes were enacted to eliminate the coverage gap by 2020, making drugs more affordable to seniors and other Medicare beneficiaries.

Warnings Without Guidance: Patient Responses to an FDA Warning About Ezetimibe

Published in *Medical Care*, June 2012³¹

FDA warnings about issues related to drug efficacy and safety can help health care providers and patients make informed decisions about their health care. However, when a communication about a drug's effectiveness does not include specific information about appropriate treatment alternatives, there can be a negative effect on patient adherence – especially when the medication in question treats a chronic condition that requires ongoing care.

In a study published in *Medical Care*, researchers from CVS Caremark and Brigham and Women's Hospital reviewed drug discontinuation rates and rates of switching to alternative therapies following an FDA communication about the effectiveness of the cholesterol-lowering drug ezetimibe that made

headlines in January 2008. This FDA communication was issued after results from a clinical trial indicated that adding ezetimibe to a cholesterol-lowering regimen did not appear to improve patient outcomes, raising questions about the effectiveness of the drug. In this case, the FDA warning highlighted questions about the drug's effectiveness, but did not recommend patients stop taking the drug and did not provide specific guidance about appropriate substitutions for patients taking ezetimibe. The research team's goal was to better understand how such communications may affect medication adherence rates.

The researchers reviewed de-identified claims data for more than 860,000 patients who were new users of ezetimibe between January 2006 and August 2008. Trends in discontinuation rates of ezetimibe were estimated for three time periods: 1) before the FDA communication (January 2006 – December 2007), 2) during the transition period when the FDA communication was issued (December 2007 – January 2008), and 3) after the FDA communication (January 2008–July 2008).

The research indicated that the monthly level of patients who

stopped filling their prescription for this drug increased by nearly six percent. Of those patients who stopped taking the drug after the FDA warning, only 16.5 percent switched to another clinically appropriate therapy. The researchers also found that several patient characteristics were associated with the discontinuation rates seen after the FDA warning. For example, patients who resided in lower-income areas had a 12.9 percent lower rate of discontinuation compared with patients living in the highest income areas; female patients had a 6.9 percent lower rate of discontinuation compared with male patients; and patients ages 18–34 had lower rates of discontinuation compared with patients over 65 years of age.

Overall, a substantial decrease in ezetimibe adherence rates was found after the FDA communication and related media attention, with only a small proportion of patients making a clinically appropriate switch after stopping the medication. The researchers recommended there be further consideration into how these types of warning messages are communicated in order to encourage the appropriate response on behalf of patients rather than simply a reduction in use of the drug.

³¹ Shrank WH, Choudhry NK, Tong A, Myers J, Fischer MA, Swanton K, Slezak J, Brennan TA, Liberman JN, Moffit S, Avorn J, Carpenter D. Warnings Without Guidance: Patient Responses to an FDA Warning

Changes in Direct-to-Consumer Pharmaceutical Advertising Following Shifts from Prescription-Only to Over-the-Counter Status

Published in *Journal of the American Medical Association*, September 2012³²

Access to information is a vital component of the medical decision-making process for patients. As individual accountability and engagement become increasingly important topics in the health care cost debate, the need for patients to become informed consumers about their treatment options is vital.

However, not all changes taking place in the health care space are helping patients become more informed. According to research published in the *Journal of the American Medical Association* in 2012, the transition from prescription to over-the-counter status for drugs means that patients may not receive as much information as they did when the drug was available by prescription only.

Researchers from CVS Caremark and Brigham and Women's Hospital found that advertisements for over-the-counter (OTC) versions of drugs contained significantly less information about risks associated with the medication. Only 11 percent of ads discussed potential risks for OTC drugs, compared to 70 percent of ads discussing risks when the drug was available by prescription only.

This study highlights an important factor: When prescription drugs move to OTC status, regulatory oversight of advertising shifts from the Food and Drug Administration (FDA) to the Federal Trade Commission (FTC), an agency with more lenient restrictions around advertising and marketing of the product. The FTC applies a

“reasonable consumer” standard of truthfulness and non-deception to marketing that does not require any balancing of potential harms.

This research calls for continued dialog about how to determine the amount and type of information about OTC drugs that should be shared with patients to inform decisions.

According to the researchers, “Pharmaceuticals do not lose their capacity for harm after moving from behind the pharmacist’s counter to in front of it; misuse of OTC drugs remains a major cause of emergency department visits, hospitalization, and death. Closer attention should be paid to how such drugs are promoted to consumers.”



The transition from prescription to over-the-counter status for drugs means that patients may not receive as much information as they did when the drug was available by prescription only.

³² Greene JA, Choudhry NK, Kesselheim AS, Brennan TA, Shrank W. Changes in Direct-to-Consumer Pharmaceutical Advertising Following Shifts from Prescription-Only to Over-the-Counter Status. *JAMA*. Sept 2012; 308(10).

The Consequences of Requesting “Dispense as Written”

Published in *American Journal of Medicine*, March 2011³³

States have adopted a variety of generic substitution laws as one way to help reduce medication costs. However, physicians and patients may override the generic substitution process by directing that a branded prescription be “dispensed as written” (DAW). Until recently, very little was known about how often and why these DAW requests occur and what impact they may have on medication adherence.

While advocates for DAW may argue that providing prescribers and patients with the opportunity to request that a medication be

dispensed as written provides greater choice and the potential for improved adherence, research conducted by CVS Caremark, Harvard University and Brigham and Women’s Hospital found that DAW requests are actually associated with excess costs and that patients are less likely to fill these medications. The research, published in the March 2011 issue of *The American Journal of Medicine*, found that for patients with a chronic condition who were starting on a new therapy, those with a DAW prescription were 50 to 60 percent less likely to fill the more expensive brand medication than those who

were able to fill the generic drug. Furthermore, the researchers calculated that eliminating DAW for appropriate generic substitutions could save patients as much as \$1.2 billion annually and reduce health system costs by as much as \$7.7 billion each year.

During the study period approximately five percent of all prescriptions had a DAW designation and that request was pretty equally split between the physician and the patient. In addition, specialists, older physicians and patients between 55 to 74 years of age were all more likely to request DAW.



Eliminating DAW for appropriate generic substitutions could **save patients as much as \$1.2 billion annually and reduce health system costs by as much as \$7.7 billion** each year.

So, how can we address the unintended negative impact of DAW?

The first step is building awareness. Physicians and patients should be aware that dispense as written designations not only increase costs to the patient and the whole health care system, but often can discourage patients from taking their medications because of increased out-of-pocket costs. Among those populations identified in the study as being more likely to request DAW, targeted educational efforts about the safety and efficacy of generics can also help raise awareness that generic drugs are good alternatives to brand-name drugs. In addition, educational efforts should focus on patients who need to initiate medications for chronic conditions, because these patients are less likely to purchase their medications if they are dispensed as written and a less expensive option is not offered.

³³ Shrank WH, Liberman JN, Fischer MA, Avorn J, Kilabuk E, Chang A, Kessleheim AS, Brennan TA, Choudhry NK. The Consequences of Requesting “Dispense as Written.” *Am J Med.* March 2011 (124).

State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid

Published in *Health Affairs*, July 2010³⁴

As health care reform is implemented – with the goal of providing broader health care access and reducing the number of uninsured Americans – it is estimated that by 2019 more than 32 million Americans who currently do not have health coverage will gain coverage. More than half of these newly insured Americans are expected to be covered through Medicaid, with the Centers for Medicare and Medicaid Services (CMS) projecting a 34 percent enrollment increase in Medicaid and the Children’s Health Insurance Program (CHIP) in 2014.

With this increase of Medicaid beneficiaries, it will become increasingly important to find ways to manage costs for the federally funded program while continuing to promote positive health outcomes. A study conducted by CVS Caremark, Harvard University and Brigham and Women’s Hospital, published in the July 2010 issue of *Health Affairs* found opportunities for state Medicaid programs to save

more than \$100 million simply by revising state laws to allow for easier and faster generic drug substitution (i.e., when a less expensive, but equally effective and chemically-identical generic medication is substituted for a more expensive branded drug).

Individual states are able to pass legislation regulating how they apply generic substitution laws for Medicaid beneficiaries and as a result the practice of generic substitution can vary widely. Some state boards of pharmacy have adopted mandatory generic substitution laws in which pharmacists are required to substitute a generic for a brand-name medication if the prescriber does not specify that the brand drug should be dispensed. Other states have enacted generic substitution laws that give pharmacists more discretion by allowing, but not requiring, pharmacists to substitute generics. In addition, some states require patient consent prior to generic drug substitution, while other states do not. The mandatory substitution and patient consent laws are separate statutes and states can adopt one, both or neither.

In this first-of-its-kind study, the researchers reviewed differences between existing generic substitution state policies and their impact on the uptake of generic simvastatin (brand-name Zocor®)

for the treatment of high cholesterol, in the 18 months following Zocor’s patent expiration in June 2006. They found that states requiring patient consent lagged by approximately 25 percent in the rates of generic substitution for Zocor. Based on this information the researchers estimated that, nationwide, Medicaid programs could have saved approximately \$19.8 million in the 15 months following the patent expiration of Zocor if all states had adopted policies that did not require patient consent for generic drug substitution. Furthermore, the researchers calculated that if the savings experienced by states that do not require patient consent were extended to states that currently require it, state Medicaid programs could see savings of up to \$100 million for three widely used brand medications – Lipitor®, Zyprexa® and Plavix® – in the year after their respective patents expire.

This study illustrates that revising state regulations to allow pharmacists to make a generic drug substitution without direct patient approval following patent expiration was the most impactful on the rate of generic uptake. Given the large number of widely used brand-name medications that are expected to go generic in the next few years, one way states can manage Medicaid drug costs without compromising quality is to explore opportunities to modify current generic substitution policies.

³⁴ Shrank WH, Choudhry NK, Agnew-Blais J, Federman AD, Liberman JN, Liu J, et al. State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid. *Health Affairs*. July 2010; 29: 1383-1390.

Changes in Drug Use and Out-of-Pocket Costs Associated with Medicare Part D Implementation: A Systematic Review


Published in the *Journal of the American Geriatrics Society*, September 2010³⁵

Medicare Part D, the government-backed pharmacy benefit program for elderly Medicare beneficiaries, was implemented January 1, 2006 to improve access to prescription medications for older adults. To better understand the impact of the implementation of Medicare Part D on changes in drug use and out-of-pocket costs, the researchers at CVS Caremark, Harvard University and Brigham and Women's Hospital conducted a review to evaluate all medical journal literature from January 2006 to October 2009 focused on the effect of the Part D program. The resulting study, published in the September 2010 issue of the *Journal of the American Geriatrics Society*, is a systematic review of 552 articles published in the nearly three-year study period. While 42 articles met criteria for full evaluation, ultimately 26 peer-reviewed articles were included for discussion in the study. Of these studies, 13 described drug use and out-of-pocket costs after the Part D program was implemented,

seven discussed use and cost by beneficiaries in transition into the new program and six discussed the impact of the coverage gap (or donut hole).

The studies showed, as expected, that the inception of Part D was associated with a consistent overall increase in drug use and a decrease in out-of-pocket costs for enrollees. The research also showed that the transition to Part D went smoothly for many dual-eligible patients, but there were some vulnerable populations that experienced difficulties with the advent of the new coverage. For example, the studies reviewed around the Part D coverage gap showed that when beneficiaries reached the uninsured portion of the Medicare Part D program their experiences were associated with less drug use and higher out-of-pocket costs.

This analysis is a first step at better understanding the impact of the Part D program on Medicare beneficiaries and the authors of the study will continue further analysis on this topic. The researchers note that the conclusions from this systematic review must be interpreted with caution. For instance, although the research found that elderly patients fill 97 percent of their prescriptions within a single pharmacy chain, studies that rely on retail prescription claims may miss prescriptions of patients who use more than one chain. The researchers added that while discussions continue around Part D among policymakers and as changes to the coverage gap are considered, there is also a need to review data about the effects the program is having on health outcomes.



Medicare Part D was associated with a consistent overall increase in drug use and a decrease in out-of-pocket costs for enrollees.

³⁵ Polinski JM, Kilabuk E, Schneeweiss S, Brennan TA, Shrank WH. Changes in Drug Use and Out-of-Pocket Costs Associated with Medicare Part D Implementation: A Systematic Review. *JAGS*. September 2010; 58 (9): 1764-1779.



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