# The 21st Century Intelligent Pharmacy Project:
# The Importance of Medication Adherence

**Saving Lives and Saving Money by Improving Medication Adherence through a Coordinated Approach to Integrated Healthcare**

*A white paper released by the Center for Health Transformation's 21st Century Intelligent Pharmacy Project*



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**Overview of the Problem**

As former Surgeon General Dr. C. Everett Koop said, "Drugs don't work in patients who don't take them."[1] Prescription medications are only effective when they are taken. In many pharmacy circles, the term medication "adherence" and medication "compliance" are used virtually interchangeably. However, in more recent years, the pharmacy profession and pharmaceutical industry have gravitated more toward medication adherence as the term of choice. Adherence to a medication regimen is generally defined as "the extent to which patients take medications as prescribed by their healthcare providers."[2]

Non-adherence is a tremendous problem in the United States, causing thousands of premature deaths and demanding care that would otherwise have been unnecessary. The estimated annual cost of patients not taking their medications as prescribed approaches $290 billion.[3] Other non-adherence statistics are shocking:

- Approximately **125,000** Americans die annually (**342** people every day) due to poor medication adherence;
- Ten to **25 percent** of hospital and nursing home admissions are caused by the inability of patients to take their medications as prescribed and directed;[4]
- The rates of non-adherence to prescription medication therapy have remained stagnant over the past **three decades**, and recent reviews have shown that as many as **40 percent** of patients still do not adhere to their treatment regimens[5] and up to **20 percent** of all new prescriptions go unfilled.[6]

As we search for strategies and solutions geared toward improving patient adherence to prescription drug therapy, it is imperative to involve pharmacists. While physicians, nurses and other healthcare professionals can have an impact on improving adherence, pharmacists, as the medication experts have demonstrated the ability to inform, problem-solve and provide performance support directly to and with patients. And, pharmacists are one of the most accessible healthcare professionals in the United States.[7]

Though healthcare practitioners cannot supervise or accompany patients through each day of the medication adherence process, they can play a unique and important role providing patients a good start at implementing behavior changes. Solutions should not only help design scientifically-based, proven intervention strategies, but also reduce the time and cost involved with implementing these strategies in various healthcare settings.

Behavior change requires different strategies for different people. Trust, hope, fear, motivation, knowledge, literacy, skills, tools, rehearsal, reinforcement, feedback, confidence and competence are key concepts in the literature of medication adherence. The problem of non-adherence often defies isolated efforts and tactics, but studies have shown that multi-disciplinary approaches work well, multiple channels work better than single channels, and a longer time horizon is more realistic than a short one. Indeed everyone is different, and everyone changes over time.

**"While no single strategy will guarantee that patients will fill their prescriptions and take their medicines as prescribed, elevating adherence as a priority issue and promoting best practices, behaviors, and technologies may significantly improve medication adherence in the U.S."**

*- Enhancing Prescription Medication Adherence: A National Action Plan*
National Council on Patient Information and Education, August 2007

The Center for Health Transformation (CHT) created the 21st Century Intelligent Pharmacy Project to identify those significant issues within the realm of pharmacy and advance best practices and transformational solutions which improve health and lower costs. Medication adherence is among those issues.

This white paper will investigate why patients neglect their medicines and how important patient engagement is to ultimately manage and control disease and disorders. In addition, this white paper will reveal successful strategies, emerging new solutions and transformational best practices aimed at improving patient outcomes by increasing medication adherence.

**Finding Best Practices and Transformational Solutions:**
Determining best practices and transformational solutions seems somewhat problematic. There are any number of disease-specific strategies aimed improving patient adherence. The most well known examination is "The Asheville Project," which is detailed in this white paper. Originally conceived for patients with diabetes, the model was subsequently expanded to other diseases after the success in managing patients with diabetes.

According to the National Council on Patient Information and Education (NCPIE), although the challenge of poor medication adherence "has been discussed and debated for at least three decades, these problems have generally been overlooked as a serious public health issue and, as a result, have received little direct, systematic, or sustained intervention. As a consequence, Americans have inadequate knowledge about the significance of medication adherence as a critical element of their improved health."[8]

So, clearly, those programs that increase awareness of the importance of taking medications properly and in the manner in which physicians and other healthcare professionals prescribed are essential elements of any successful solution to improve patient adherence. However, education alone rarely works. A fully integrated approach with support resources and innovative tools appears to be the best approach.

NCPIE further states that adherence rates suffer from a fragmented approach by which hospitals, healthcare providers and other parts of the health delivery system interact with patients and caregivers. According to NCPIE, "many leading medical societies are now advocating a multidisciplinary approach through coordinated action by health professionals, researchers, health planners and policymakers."[9]

NCPIE convened a panel of nationally recognized experts to develop consensus on priorities that could have the greatest impact on improving patient adherence in the United States, saying that "these recommendations serve as a catalyst for action across the continuum of care — from diagnosis through treatment and follow-up patient care and monitoring."[10]

Additionally, NCPIE believes that the healthcare system needs to elevate patient adherence as a critical healthcare issue. Medication non-adherence is a problem that applies to all chronic disease states; affects all demographic and socio-economic strata; diminishes the ability to treat diabetes, heart disease, cancer, asthma and many other diseases; and results in suffering, sub-optimal utilization of healthcare resources and even death.

To that end, one recommended strategy would be to create a unified national education campaign to make patient adherence a national health priority. The campaign should be specifically designed to motivate patients and healthcare professionals to take steps to improve medication adherence, compelling, actionable messages must be communicated as part of a unified and sustained public education campaign.

AlignMap.com, an online resource dedicated to improving medication adherence, believes that the empowerment of patients "has the potential to improve treatment adherence and healthcare in general, but only if that empowerment is accomplished in the context of a therapeutic alliance with the goals and values of patients, clinicians and the system though which care is provided in alignment. The empowerment of patients without such alignment endangers rather than enhances healthcare on both the individual and systemic level."[11] In other words, align the incentives and then empower patients and healthcare professionals to make medication adherence an essential part and a clear priority in the treatment plan.

Tackling the problems of patient non-adherence takes teamwork. NCPIE calls for the development of a multidisciplinary approach to adherence education and management.[12] AlignMap.com believes that a desire to cooperate on the part of all those involved in a given case — patients, clinicians and healthcare administration — is a good starting point, but effective implementation of treatment requires knowledge and skills, as well as motivation. Healthcare situations are dynamic and all parties involved must continuously update their ability to cooperate.

The best patient care outcomes occur when patients, clinicians, payers and healthcare administrators learn quickly, implement solutions rapidly, incorporate best practices seamlessly and embrace continuous learning. Accelerating this process is a key responsibility of healthcare professionals. There is a growing recognition that a multidisciplinary approach to understanding patient behavior is necessary for patient adherence to be sustained.

One of the most effective ways to address and to improve patient adherence is through the creation of a body of knowledge about what works and what does not. Whether it is through white papers, such as this publication or other innovative ways to share information about best practices in adherence education and management, we should collect data and report on best practices in the assessment of patient readiness, medication management and adherence interventions, incentives that produce quality outcomes from adherence interventions and measurement tools, and we should share this information across specialties and healthcare facilities.

**"For every complex problem, there is a solution that is simple, neat, — and wrong."**

*- H. L. Mencken*

Furthermore, we should develop a curriculum on medication adherence for use in medical schools and allied healthcare institutions. These types of courses are already part of a pharmacist education, but the lack of awareness among other clinicians regarding basic adherence management principles and their effective application remains a major reason that adherence has not advanced in this country.

Patients respond differently to different physicians, therapies and motivational factors. Teachers acknowledge the need to individualize education as much as possible. Yet, the medical literature dealing with patient adherence often expresses perplexity, frustration and, on occasion, amazement that a given intervention (whether that intervention is patient education, cues and reminders, free medical services, easy access to services… ) improves compliance among some but not all patients. Different patients react in different ways to healthcare recommendations and compliance-enhancing efforts.[13]

Creating a culture which embraces patient adherence can be a win-win-win situation. While there is no such thing as a "free lunch," adherence enhancement strategies may be the source of that equally elusive goal, the *win-win* outcome. In fact, successful patient adherence strategies really result in *win-win-win* game.

- Clinicians (physicians and pharmacists) win because treatment plans are implemented;
- Administrators win because they can achieve the lower costs; and
- Patients win because they get well faster and avoid unnecessary delays in recovery, relapses and side-effects.

Complacency about patient adherence directly leads to the failure of medical treatment plans. A reasonable rule of thumb is to assume, lacking proof that the situation is otherwise, that 50 percent of patients do not comply with treatment recommendations. Non-adherence can result in devastating consequences, including:

- Ten to 25 percent of all hospital and nursing home admissions, resulting in 340 deaths per day;
- Twenty percent of unintentional pregnancies in the United States at a cost of $2.6 billion annually;
- Three times as many doctor visits and $2,000 per year per non-adherent patient in additional costs compared to patients who follow treatment plans;
- Thirty-three to 69 percent of all medication-related hospital admissions in the United States at a cost of more than $100 billion annually.

While some of these recommendations are currently in various stages of implementation, we know this much: Prescription medication adherence is a problem of national importance to patients and their caregivers, health plans, employers, physicians, pharmacists and health systems. Strategies directed toward improving patient care should always incorporate programs which draw attention to and improve patient adherence.

**Medication Adherence Best Practice Summary:**
**Mirixa: Reversing the Trend**

As noted in this paper, the numbers tied to medication non-adherence are staggering: $290 billion annually in increased medical costs, with $100 billion annually in costs resulting from medication-related hospitalizations. These high-dollar amounts are the result of hundreds of thousands of patients not following their prescribed medication regimen.[14]

Mirixa Corporation, founded in 2006 by the National Community Pharmacist Association (NCPA), believes that pharmacists can play a leading role in reversing this trend through patient care services that are delivered directly *by* a pharmacist *to* the patient. The combination of a pharmacist's clinical expertise, the opportunity for direct contact with patients (whether face-to-face or voice-to-voice), and the availability of educational materials can start a relationship of shared focus on health and wellness between the pharmacist and patient.

Mirixa provides technology-enabled solutions for the delivery of medication-related services. Pharmacy benefit management companies (PBMs), health plans, pharmacies and employers use the web-based MirixaPro℠ platform and Mirixa's network of over 40,000 pharmacies, to administer patient care programs such as Medication Therapy Management (MTM) and adherence, to targeted population groups nationwide.

Client research has shown that patient non-adherence to medication regimens results from three basic factors: lack of trust on the part of the patient in the healthcare system, lack of patient education and lack of funds. Client research has also shown that MTM and adherence programs achieve the highest return when delivered by a pharmacist (as opposed to a general healthcare professional or a call center employee).

Mirixa solutions enable pharmacists to deliver patient care services that identify, assess and resolve medication-related problems – such as care gaps, duplicate therapies, omissions in care and drug-to-drug interactions. Among certain populations adherence programs are effective with as many as half of the patients participating and having no adherence issues later. Additional outcomes of the service are greater patient health awareness and improved collaboration between the patient, pharmacist and physician.

*Medco-Driven Collaborative Program*
Mirixa is involved in an innovative collaboration lead by Medco Health Solutions and includes the State of Illinois, the Illinois Pharmacists Association (IPhA), and the University of Illinois at Chicago (UIC) College of Pharmacy. The study aims to determine the effectiveness of training community pharmacies, using an advanced networked safety system, to identify medication-related issues and provide clinical interventions to improve patient health outcomes and lower costs.

The UIC College of Pharmacy has trained more than 100 community pharmacists on the most effective means to identify and address underlying patient barriers to closing clinical gaps. The MirixaPro platform delivers Medco-defined alerts that are transmitted in real-time to community pharmacies through a secured system. The study tracks the success of these pharmacists in closing gaps by counseling patients and coordinating care with physicians. The study's results are planned for release in early 2011.

*Workflow Tips for Pharmacists*
Mirixa also provides best practices for administering adherence programs on its website (www.mirixa.com). Many pharmacies are stretched thin for resources and by utilizing some of the suggestions proposed in our web-based training and available on the site – recruitment of pharmacy students and consulting pharmacists to help deliver patient care services, for example – pharmacies can establish a consistent adherence program.

The healthcare reform law, signed in March 2010, includes some important provisions related to medication adherence, including grant and pilot programs in MTM. Pharmacists are optimally positioned to deliver adherence counseling. Mirixa solutions enable pharmacists to go beyond dispensing and deliver clinical services that improve patient outcomes and drive down healthcare costs.

For more information, contact Mirixa Corporation at 11600 Sunrise Valley Drive, Suite 100 in Reston, VA 20191 or call (703) 865-2035.

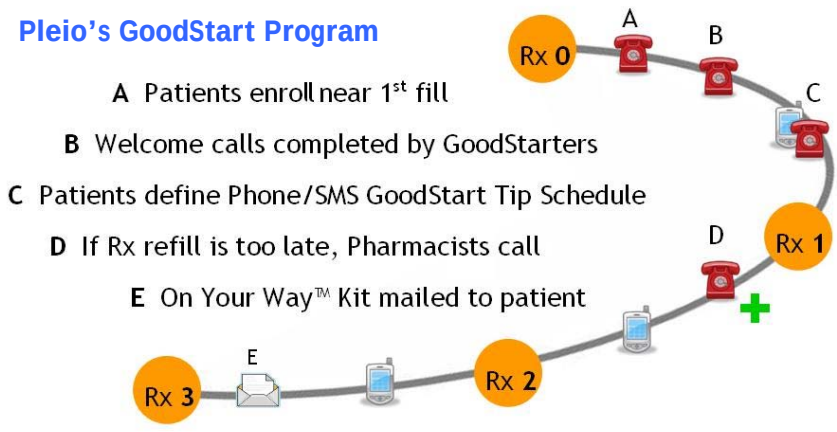
**Medication Adherence Best Practice Summary:**
**The Pleio GoodStart™ Follow-Up Service**

According to a 2009 study conducted by the *New England Healthcare Institute*, an estimated one-third to one-half of all patients in the United States do not take their medications as prescribed, resulting in as much as $290 billion annually in increased medical costs.[15]

*Background*
For most patients, getting a good start with a new medication is easier said than done: accepting their disease, understanding dosing instructions and creating a new habit are just a few of the barriers that await them after they have left the pharmacy, prescription in hand. Inhaled and injected medications can be challenging to administer properly, but even blood pressure pills can become a low priority when people do not understand how they work or what they do. For most people, there is no silver bullet that will suddenly cause them to become completely compliant, as adherence is a complex process.

Prescription refill records prove that the first few months on a new medication are the most challenging. In fact, Pleio Health Support Systems has observed that, for many drugs, most patients become non-compliant with dosing instructions within just 5 days of picking up their prescription. So connecting with patients as soon as they fill their first prescription and staying with them during the adoption phase is a good fit for pharmacists, who normally see patients more than any other healthcare provider during this critical adoption phase.

*Solution*
Until recently, adherence expertise was hard to find, assemble and empower. Pleio Health Support Systems began bringing people together to create an adherence solution in 2006. They have worked closely with innovative pharmacy chains, pharmaceutical manufacturers and more than a dozen technology and database providers, to build a platform that provides patients a variety of medication adherence support services when they need them, how they want them and where they want them. Pleio GoodStart™ offers a variety of resources to help people get off to a good start on new prescriptions, so that they can get the most of their medication.

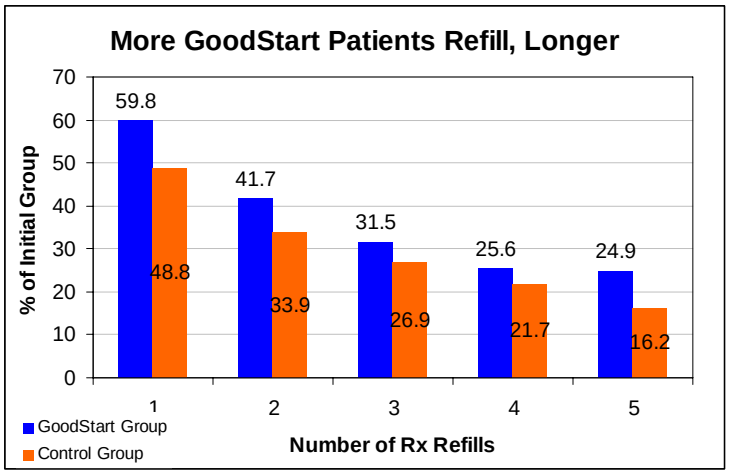



Pleio GoodStart™ is one of the first programs to connect multiple tactics on a single platform to guide patients through a process that builds adherence. In addition to phone and in-person pharmacist encounters, a series of GoodStart™ discussions are designed to identify the patient's greatest needs, develop a customized action plan and provide feedback and encouragement. Key concepts and

words from these conversations are then reinforced through GoodStart Tips™ delivered via the medium of their choice. If patients have a support buddy, they can receive Pleio BuddyTips™ by e-mail text or phone message as well. Finally, patients are provided a toolkit to help them maintain their good habits once those habits are in place.

*Impact*

GoodStart has been very well-received: 70 percent of participants say that it helped them with their medication regimen. Prescription refills have increased by 29 percent (or two extra refills) over patients' first 9 months of therapy.




*2009 Analysis of 1,678 Patients on GoodStart Program compared to a 950 – patient control group (20-day gap)*

Through the support of pharmaceutical manufacturers, the service is offered free to pharmacies, as well as their patients.

Pleio continues to observe significant persistence past the 1-year mark among patients who participate in the program. For more information, please visit www.pleio.com.

**Medication Adherence Best Practice Summary:**
**The Asheville Project and Diabetes Ten City Challenge**

In the mid-1990s, the City of Asheville in North Carolina searched for a way to curb a trend of ever-rising healthcare expenditures for their employees. After many meetings and discussions, a healthcare program was conceived between a local pharmacy association, hospitals, local pharmacies and local physicians. This model, now dubbed the "Asheville Project," proved itself to be successful in improving the health of patients through a coordinated care collaboration of healthcare practitioners. The Asheville Project was successful in not only providing better patient health, but it also demonstrated a reduction in healthcare spending and became a beacon of coordinated care practice for future models and pilots in healthcare.

*Background*
In 1997, the City of Asheville, North Carolina took a non-conventional approach to better manage their overall healthcare costs. The City, a self-insured employer, was facing increasing annual costs spent on providing their employees and their family members' healthcare coverage. In a partnership with the North Carolina Center for Pharmaceutical Care (NCCPC) and Mission–St. Joseph's Health System (MSJ), the City created a pharmaceutical care services (PCS) program for their employees and their family members. The program sought to improve employee health and reduce the bottom-line healthcare spending on employees and beneficiaries through continual management of patients with diabetes. Over time, many patients who enrolled in the diabetes management program learned to better manage their condition and meet nationally established diabetes goals. The project not only benefited the patients in terms of quality of life, but also significantly reduced the overall costs spent on healthcare. The City of Asheville also discovered that employee productivity increased and the number of employee sick-days was reduced. Although diabetes was the only chronic condition initially targeted through the Asheville Project, it was realized that the framework of coordinated care that the Asheville Project provided could be transposed onto other chronic conditions. Since the birth of the original project in 1997, similar PSC programs have sprouted up across the nation and have expanded into other conditions such as asthma and hyperlipidemia.

Although the City of Asheville funded employees' and dependents' participation in the PCS benefit, most of the healthcare collaboration and management of the program was conducted by healthcare professionals. Assisted by the NCCPC, MSJ and community institutions of higher education, local pharmacists were educated and trained on in-depth diabetes treatment skills. Patient enrollment into the PCS program was strictly voluntary and the City of Asheville agreed to also provide financial incentives to enrollees to encourage participation. These incentives included a free blood glucose meter, which stored daily readings for tracking purposes; a waiver for all co-payments for all diabetes-related medications and supplies; self-care education in diabetes; and consultations with the pharmacists. Patients in the program were allowed to have a monthly consultation session with a community-based pharmacist of their choice from a selection of 12 local pharmacies. The pharmacists provided counseling for patients on their diabetes, provided education, set treatment goals and monitored progress. In addition, the pharmacist also provided information on the importance of adherence and home glucose meter training, and performed physical assessments of patients' blood pressure, feet, weight and skin.

Pharmacists also referred patients to a physician or diabetes education center (DEC), if deemed necessary. Neither pharmacists nor patients were required to adhere to a specific protocol. Like the patients, pharmacists in the program administering the PCS program were also provided financial incentives. More specifically, pharmacists were reimbursed for their services on a fee-for-service basis by the City of Asheville.

The Asheville Project was initially conceived as a patient-centered program with the pharmacist playing the pivotal role in managing the wellness of patients with diabetes. However, as the program progressed, this simple model changed to involve a triage of other stakeholders while still maintaining its patient-centered focus. No one healthcare practitioner has the skills or ability to manage everything a patient needs or requires. The Asheville Project confirmed however that what is needed is coordinated approach to care.

The Asheville Project model linked various different types of stakeholders, promoting communication between pharmacists, physicians, diabetes educators, health systems and other healthcare professionals. This cross-collaboration between and among different professionals allowed the program to meet the needs of each individual patient.

Though pharmacists were at the forefront of the Asheville Project, by meeting with patients regularly to help guide and coach them on their treatment and care, many healthcare providers had a stake in the care and treatment of patients. For example, a diabetes educator helped fill gaps in patient education and understanding. A payer helped furnish necessary resources for the patient such as prescription medications and services. Hospital providers were able to provide self-care programs for patients regarding their condition. Primary care physicians assisted in the coordination of care between different professionals and stakeholders. Throughout the administration of all of these services, these healthcare professionals corresponded with each other regarding the patient to help drive better health outcomes and fill gaps in an individual patient's care. Although not initially designed this way, the Asheville Project promoted coordinated care by linking different resources such as health systems, pharmacists, diabetes educators, etc. together during its initial phases.

**"The Diabetes Ten City Challenge offers and opportunity to transform healthcare delivery in local communities and drive fundamental change in the U.S. healthcare system."**

*- William Ellis, CEO, APhA Foundation*

The Asheville Project was a success because of the use of locally based pharmacists and the involvement of a diverse group of stakeholders, creating cross-collaboration. Regular visits with pharmacists allowed for effective coaching of patients to maintain medication adherence and a healthy lifestyle. The regular face-to-face meetings also allowed for continual tracking of progress which in turn allows for appropriate, timely interventions. In addition, pharmacists tended to spend as much time as needed with patients, which ensured that patients were fully educated. These extended care visits with pharmacists helped demonstrate the value of such meetings to patients which supported the importance of subsequent follow-up visits.

Since the inception of the project, several studies have been published on short-term and long-term clinical and economic results. A long-term study conducted by Cranor et al. and published in 2003 in the *Journal of the American Pharmacists Association* (JAPhA), showed the value of the project in both a clinical and economic sense after a period of 5 years. In the study, laboratory values from the year prior to a patient's enrollment were taken as the baseline value for comparison. Clinical outcomes of the program were measured as changes from baseline values of A1c, low-density lipoprotein (LDL) and high-density lipoprotein (HDL). Optimal A1c was defined in accordance to the then American Diabetes Association guidelines of less than 7 percent. Optimal LDL was defined as less than 100 mg/dL and HDL as greater than 45 mg/dL and 55 mg/dL for men and women respectively.[16]

The Asheville Project clearly showed improvement in clinical outcomes. Mean hemoglobin A1c decreased at every follow-up; with each follow-up, 57.7 to 81.1 percent of patients demonstrated an improvement in A1c from baseline. In addition, the number of patients with optimal A1c values increased. Mean LDL decreased at every follow-up by a small amount after each follow-up; 50.0 to 66.7 percent of patients demonstrated improved LDL values with each subsequent follow-up. Similarly, mean HDL increased; 53.3 to 75.0 percent of patients experienced improved HDL after every follow-up. Furthermore, there was a general increase in the number of patients who achieved optimal HDL level from baseline demographics.[17]

Similar to clinical outcomes, favorable economic outcomes were also demonstrated. Results published from various articles indicate that the project had a four-to-one return on investment; that it saved the City $4 for every $1 investment. While overall costs were lower, upfront costs rose due to increased prescription utilization and program expenses. Mean prescription costs were increased by $2,188 in the fifth year of the program. However, mean medical cost decreased by $6,502 in the same year. Patients also were more productive at work and utilized less sick days; the mean number of sick days taken by patients decreased by half, dropping from 12 to 6 days.[18]

The success of the Asheville Project garnered much attention nationwide. The project demonstrated successful coordinated care leading to better patient outcomes with cost savings. This pioneering project provided the foundation and impetus for later initiatives, such as the Patient Self-Management Program (PSMP) Diabetes, Raising Energy program, Awareness, and Campus Health (REACH) program and the Ten City Challenge and continues to be a much referenced example of the power of pharmacists in care-coordination. [19]

In 2005, with the support of GlaxoSmithKline, the American Pharmacists Association (APhA) Foundation started a program that would further test the patient self-management/pharmacist coach model in ten communities across the United States. This came to be known as the Diabetes Ten City Challenge (DTCC). The DTCC was implemented in Charleston/Spartanburg, Cumberland, Chicago, Colorado Springs, Dalton, Honolulu, Los Angeles, Milwaukee, Pittsburg and Tampa

Bay. The DTCC was formed through a partnership of the city governments and private employers in these ten cities, the APhA foundation and pharmacists.

The main goal of the DTCC was to fundamentally change the way chronic disease is managed and paid for through a value-based benefit design model. The model used in the DTCC improved the benefit/incentive structure for participants related to obtaining anti-diabetic medications and education services of a pharmacist essential to managing the disease. The overall results of the DTCC were very encouraging. The data collected from 573 patients who participated in the DTCC showed both positive clinical and economic outcomes.

Patient satisfaction in the program was as impressive as the improvement in key health metrics. One employee said, "The Wellness Program and the Diabetes Ten City Challenge offered by the City of Charleston are truly helpful. Without these wonderful programs, my cholesterol medication, diabetes medications along with test strips and lancets, would total about $270 per month or $3,200 per year. The support provided by these programs is invaluable. The continued advice, and programs that you offer to City employees throughout the year is great. Also my pharmacist coach, Cecily DiPiro, helps me with her advice regarding my blood testing readings, diet, and exercise. The concern that Mayor Riley has for healthy City employees is instrumental in making this all happen and I thank him. We all have illnesses in our lives, but with programs such as these and caring people, the task is a little easier to cope with."

*Objectives and Methods*
The objectives of the DTCC were to: (1) Implement an employer-funded, collaborative health management program using community-based pharmacist coaching, evidenced-based diabetes care guidelines and self-management strategies designed to keep patients with diabetes healthy and productive; (2) Implement the patient self-management training and assessment credential that equips patients with the knowledge, skills and performance-monitoring priorities needed to actively participate in managing their diabetes; and (3) Assess participant satisfaction with overall diabetes care and pharmacist care provided in the program.

The program was offered in community independent pharmacies, community chain pharmacies, ambulatory care clinics and at on-site workplace locations to allow sufficient flexibility in the delivery of care. Characteristics of these sites including the following: private area for patient consultation, management support freeing pharmacists for patient care activities, access to internet for recording and tracking patient care interventions, availability of one or more pharmacist coach with demonstrated communication skills and specialized training or certification in diabetes management and participation in local and/or regional pharmacist service delivery network that contracted directly with the participating employer.
The employers participating in the DTCC were self-insured and therefore "at risk" for medical and prescription costs for their employees and other beneficiaries under the established health plan. The employer and health plan agreed to invest in incentives for patients and pharmacist providers. At a minimum, these incentives included waived copayments for medications and certain supplies for employees who enrolled in the program. Some employers offered additional incentives including counting participation toward wellness points and waiving copayments for education classes and/or laboratory tests.

All of the patients participating in the DTCC were volunteers. The patients were assigned to a pharmacist coach in their geographic area by a local network coordinator. Services were provided in a local pharmacy or at the participant's workplace. During visits, pharmacists applied a prescribed process of care that focused on clinical assessments and progress toward clinical goals and worked with each patient to establish self-management goals. Pharmacists also worked with other healthcare providers to recommend adjustments in the patients' treatment plans when appropriate. Participating pharmacists were required to complete a training program in diabetes care offered by a provider of continuing pharmacy education accredited by the Accreditation Council on Pharmacy Education or to have otherwise been certified for diabetes care. Over the course of the patients' care, the pharmacists and the patients' physician communicated as necessary to coordinate the best care for the patients.

*Results*

Overall, both the economic and clinical outcomes from the DTCC were positive. Results from the program were based on 573 patients who were in the program for an average of 14.8 months. When compared to projected costs if the DTCC had not been implemented, the mean total healthcare cost per patient per year was reduced by $1,079. The data also showed an average savings of $593 per patient per year through employer incentives like waived co-pays on their diabetes medications and supplies. Overall, both employers and patients saw a reduction in costs when compared with the projected medical costs. Using the employer and patient payment amounts from the economic analysis in this population of 573 patients, compared with projected costs, averted costs were estimated at $278,512 for employers and $339,875 for patients during the first year of the program's implementation.

Aside from the drop in healthcare costs, the patients' health also saw improvement after the first year. There following are the percent improvements in patients achieving national HEDIS goals: 23 percent blood glucose (HbA1c<7%), 39 percent blood pressure (<130/80 mmHg), and 11 percent cholesterol (LDL-C <100 mg/dL). Moreover, the patients involved in the DTCC saw a rise in the preventative actions they were taking. Flu vaccinations increased from 32 to 65 percent, eye exams increased from 57 to 81 percent, and foot exams increased from 34 to 74 percent.

*Conclusion*

The DTCC results support the collaborative care model to manage diabetes effectively in diverse locations and among different employers. Utilizing this model can improve healthcare delivery in local communities and facilitate change in the U.S. healthcare system by encouraging employers to invest in helping their employees better manage their chronic conditions, reduce healthcare costs and improve health outcomes.

**Medication Adherence Best Practice Summary:**
**MWV Packaging to Improve Medication Adherence**

MWV provides packaging solutions for the healthcare industry that are specifically designed to improve patient adherence and compliance. The company's industry experience, combined with market insights, innovation and state of the art production and support, enable MWV to deliver solutions that meet the needs of pharmacists, brand managers, healthcare providers and most importantly, patients.

*Background on Pass-Through Packaging*
The nation's current prescription-filling process typically involves repackaging of pills from bulk manufacturer bottles into unit of use vials for patients. This process presents some major challenges including:

- Counting and repackaging medications is somewhat time consuming and can limit the amount of time pharmacists can spend interacting with patients, answering questions and providing essential patient counseling; and
- The repackaging and handling process of medications often results in counting errors and medication contamination.

The following statistics detail the issue:

- According to a report in the American Journal of Health-System Pharmacy, approximately 60 percent of all medications require repackaging by the pharmacy.[20]
- In a study by Mott et al., "…the proportion of pharmacists personally dispensing greater than 160 prescriptions daily increased from 23 percent in 2000 to 36 percent in 2004...it is questionable whether any pharmacist can personally dispense 160 prescriptions daily in a safe manner and also give appropriate attention to patient counseling, even with the aid of technology."[21]
- In the same study by Mott et al., 54 percent of responding pharmacists rated the workload at their pharmacies as high or excessively high, and 58 percent reported that workload had increased or increased greatly compared with the previous year. [22]
- The authors of a 2003 national observational study by the American Pharmacy Association, studied prescription dispensing accuracy and safety, and concluded that pharmacy dispensing errors are a problem on a national level, at a rate of about four errors per day in a pharmacy filling 250 prescriptions daily. Each year, an estimated 51.5 million errors occur during the filling of 3 billion prescriptions.[23]
- Every dollar spent on pharmacists' patient care services realizes healthcare savings of $16.70.[24]

*Solution and Impact: Pass-Through Packaging*
Over the past 7 years, MWV has developed a portfolio of pass-through pharmaceutical packages for both branded and generic medications. With these solutions, the medication arrives at the pharmacy in a unit-of-use format, ready to be labeled, verified and "passed-through" to the patient. These solutions can:

- Improve pharmacy efficiency;
- Reduce time spent counting medications;
- Speed visual verification process – no need to pour and verify;
- Free up pharmacy time to focus on patient counseling to improve adherence;
- Serve as a conversation starter between pharmacist and patient about the importance of adhering to the prescribed regimen;
- Reduce costs that can increase patient access.

Pass-through packaging is best suited for medications that have a standard regimen or pill count. For example, an antihypertensive that is almost always prescribed as 1 tablet daily can easily be pre-packaged in a 30-count format, eliminating the need for the pharmacy to transfer 30 pills from a bulk bottle to a patient vial. With medications for which dosing frequently varies between patients or where the amount of pills covered varies by insurance provider, efficiencies achieved with pass-through packaging are diminished. Where appropriate, the creation of a standard packaging format with standardized coverage would increase efficiencies and would likely lead to improved developments in "pass-through" packaging formats. A standardized prescription format can also result in space-saving efficiencies and ease distribution by the healthcare professional at the pharmacy counter.

*Image of gravity-fed dispenser holding pass-through packages. Dispenser enables simple stocking and easy identification of medication.*

By improving pharmacy efficiencies and reducing the need for repackaging, the amount of time pharmacists can spend counseling patients and addressing questions increases, which in turn improves overall patient outcomes.

*Background on Patient Adherence Packaging*
The nation's current bottle-based prescription dispensing process presents several major challenges including:

- Traditional medication bottles incorporate no design features specifically intended to improve patient adherence and compliance. Using traditional bottles, consumers are often unable to determine whether or not a dose has been taken, or when they need to refill their prescriptions, without physically counting the medications remaining inside.
- Traditional medication bottles provide little protection from moisture, spilling and contamination. Medication contained in traditional bottles is exposed to the elements each time a bottle is opened.
- Traditional medication bottles can be less than user-friendly. Child-resistant caps on traditional medication vials are often difficult for older adults to open.

- Traditional medication bottles are not designed to reduce patient confusion.
- Bottles and vials generally have a standard look and feel which can make it difficult for patients to distinguish between different medications.
- Bottles and vials are generally round, making it difficult for patients to read important label information.
- Important printed information provided by the pharmacy, such as patient leaflets or required medication guides, cannot be conveniently affixed to bottles which reduces the likelihood that patients will keep the information with the medication for the duration of therapy.

According to a recent Deloitte Study, only four in 10 Americans say they take their medications as directed.[25] The NACDS Economics Department estimates that up to 20 percent of all new prescriptions go unfilled and that the rate is much higher for prescription refills. Consumer research conducted by MWV revealed that patients value discretion when taking medication in public, and standard prescription vials, because of the appearance and the noise created by medications rattling, were considered to be a less-than-discreet alternative. This unmet desire for discretion may prompt some patients to delay taking medication when they are in public surroundings. Many patients participating in MWV consumer research also admitted that they generally threw away printed patient information once they returned home from the pharmacy, thus reducing the important value of pharmacy communications.

*Solution*
MWV has developed a portfolio of branded and generic pharmaceutical packages designed to enhance patient adherence to medications. These packs typically have calendars printed on the medication cards, or "blisters," which are designed to help patients follow their drug regimen. Upon quick examination, patients or caregivers can determine:

1. when medications need to be taken next;
2. if medications have already been taken; and
3. when refills will be needed.

*Calendared packs are also designed to help simplify complex regimens, particularly those where titration is needed.*


A simple printed calendar on a medication card has been shown to improve adherence to medication by helping patients track their medication regimen and refill on time.[26] In addition to helping patients track medication, MWV's blister packs provide several other advantages over medication traditional bottles and vials:

- MWV's blister packs are viewed by patients as more hygienic because the pills are not exposed to the elements until right before they are taken.
- The individually-sealed blisters prevent medication from being spilled, lost or damaged.
- The child-resistant features of MWV's blister packs rely on cognitive abilities rather than physical strength to open. Patients, especially those with arthritis, often find traditional child-resistant closures on bottles to be difficult to open.
- The blister pack's large flat surface provides a more easily-read location for important on-pack patient education information.
- Many of the blister packs contain pouches that can be used for storing patient leaflets, ensuring that important information is kept with the medication for the duration of therapy.
- Blister packs can be designed with a unique and distinctive look for different medications, helping patients differentiate between them.

*Packing medication in individually-sealed blisters with a child-resistant outer "shell" better protects the medication from spilling, crushing, contamination and moisture.*



*A printed inner card with color blocking can empower patients to manage complex regimen or titration, while plenty of printable space and a pocket ensure that important patient education information stays with the medication for the duration of therapy.*

*Impact*

Data collected across a range of therapeutic categories indicates the positive impact that calendarized blister packaging can have. The benefits of calendarized blister packaging include education, information and confidence. The visual demonstration to patients of whether they have taken their medication, when they need to take their next dose of medication and when they need to refill has a significant impact on their routines and their adherence to medical regimen.

*Results*
Specific studies with targeted patient populations show the adherence benefits of calendarized blister packaging. An Ohio State University (OSU) study of 85 patients, age 65 and over, taking lisinopril for diagnosed hypertension illustrated the importance of calendarized blister packaging as a tool to improve patient adherence. The control population was provided with the medication in traditional prescription vials as opposed to the study group which received a calendarized blister packaging.

The percentage of on-time refills was significantly higher for the study group than the control group. Adjusting for age and gender (using analysis of covariance, which did not alter the results), the percentage of on-time refills was 13.7 percent higher in the study group than the control group.

Medication possession ratio (MPR) was significantly higher for the study group than the control group, though the absolute difference was small (6 percent). After adjusting for age and gender using a statistical model, a significant difference remained in MPR between the two groups, with the mean MPR for the study group being 6.2 percent higher than the control group.

*Clinical Outcomes*
Twelve patients (48 percent) in the study group had a lower DBP by the 12-month visit, compared with 4 patients (18.2 percent) in the control group ($P = 0.0313$), despite the wide variation in DBP seen throughout the study.

Adjusting for initial DBP and visit in a longitudinal model, the average decrease over time in DBP was significantly lower in the study group than in the control group ($P = 0.0104$).

No significant differences were observed between the two groups in any of the long-term outcome measures (i.e., angina, MI, renal function, emergency department visits, hospitalization) for the 6- and 12-month visits.

*Conclusion of OSU Study*
Providing medications in a package that identifies the day each dose is intended to be taken and provides information about proper self-administration can improve adherence to treatment regimen and treatment outcomes in elderly patients being treated for hypertension. There were some limitations to the study. There were a relatively small number of patients, tracking of only one disease state and a short time frame relative to some of the long-term outcomes measured. However, the impact on overall patient adherence was revealing.

The FAME study, published in the Journal of the American Medical Association, showed that blister packaging of blood pressure medication combined with pharmacist counseling improved adherence among elderly patients by nearly 40 percent compared with regular vials and no counseling. As a result, these patients experienced statistically significant reductions in their systolic blood pressure.[27] Researchers concluded that "provision of blister-packed medications was a key component of the medication adherence program."

MWV has conducted extensive consumer research involving their pharmaceutical packaging solutions. In general, consumers are overwhelmingly in favor of the calendarized, unit-dose format. MWV is conducting a thorough and extensive analysis of both publicly-available and Shellpak®-specific data in order to validate the compliance benefits that patients receive from MWV packaging solutions.

For more information on either the "pass-through" solution or the calendarized blister packaging, visit www.mwvhealthcare.com or contact, 800-864-2685.

## Conclusion: Critical Nature of Medication Adherence

As explored in this white paper, medication non-adherence is costly in terms of health, time and money. Fortunately, there are a number of best practices available for exploration and replication. Healthcare consumers and providers can turn towards education, management, technology and even packaging as avenues to provide support to patients in an effort to increase adherence. The best types of care models empower patients to control their health, while recognizing the vital roles that physicians and pharmacists can play. By utilizing some of the best practices detailed here, stakeholders can create a system in which patients are supported and can easily navigate their own care.

Pharmacists are the critical piece for elevating the discussion of medication adherence – with both other medical professionals and directly with patients. These highly trained professionals are among the nation's most respected professional and among the most accessible to consumers. According to Gallup's annual "Honest and Ethics" poll, in 2009, Americans found that pharmacists were very honest and ethical, second only to nurses and rating just ahead of doctors.[28] Employing pharmacists as solution providers is essential to the success of virtually every patient adherence program.

As CHT's 21st Century Intelligent Pharmacy Project continues to examine issues of importance to patients, healthcare professionals, health plans and employers, medication adherence is an issue that deserves more attention. With upwards of 40 percent of patients exhibiting non-adherent behavior to their treatment regimens and procedures[29], it is a problem that can no longer be ignored.

For more information on the **21st Century Intelligent Pharmacy Project**, please visit: www.healthtransformation.net.

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