Thinking Outside the Pillbox

Medication Adherence and Care Teams

A Call for Demonstration Projects



New England Healthcare Institute

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About Thinking Outside the Pillbox

Thinking Outside the Pillbox is a continuing series of reports stemming from NEHI's research into improving medication adherence for patients with chronic disease. This report, Medication Adherence and Care Teams: A Call for Demonstration Projects, is the third in the series. The first two in the series, A System-wide Approach to Improving Medication Adherence for Chronic Disease followed by A System-wide Approach to Improving Medication Adherence for Chronic Disease for Chronic Disease: Roundtable Highlights, were published in 2009.

About The New England Healthcare Institute

The New England Healthcare Institute (NEHI) is a nonprofit, health policy institute focused on enabling innovation that will improve health care quality and lower health care costs. Working in partnership with members from across the health care system, NEHI brings an objective, collaborative and fresh voice to health policy. We combine the collective vision of our diverse membership and our independent, evidence-based research to move ideas into action. For more information, visit <u>www.nehi.net</u>.

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Table of Contents

| Call to Action1 |
|--|
| Executive Summary |
| The Problem5 |
| The Role of Care Teams in Promoting Adherence6 |
| The Need for New Demonstration Projects |
| What to Test: Objectives for New Demonstration Projects |
| Objective 1: Test Multi-component Adherence Strategies |
| Objective 2: Overcome the Limitations of Prior Studies and Demonstration Projects 21 |
| Objective 3: Demonstrate the Adaptability of Strategies to Diverse Care Settings |
| Objective 4: Achieve Integration with National Health Care Reform |
| Conclusion |
| Notes and References |

Call to Action

Poor medication adherence in all its manifestations costs the United States upwards of \$290 billion per year in unnecessary health care spending, not to mention illnesses and deaths that could be otherwise prevented. Unless we discover innovative ways to address the adherence crisis, these negative impacts will likely worsen.

Clinicians are increasingly looking toward the use of care teams as a costeffective way to provide coordinated, patient-centered medical care in a high-cost, resource-constrained environment. As such, medication adherence services delivered by care teams could be an important part of the solution to the adherence crisis. Care teams are comprised of both physicians and nonphysician caregivers, including professionals such as community pharmacists who operate outside the physician practice.

Care teams bring great strengths to the task of improving patient medication adherence, but more empirical evidence is needed to demonstrate their clinical and cost effectiveness. This gap in evidence should be remedied by a robust series of demonstration projects that will show how care teams can be deployed to improve patient medication adherence in a wide variety of practice settings throughout the country. Potential funding vehicles for these projects could come both from private investments, as well as from complementary programs created by the Patient Protection and Affordable Care Act, such as programs to promote medical homes, chronic care coordination, and the meaningful use of health care information technology (IT).

Executive Summary

Now is the time for the U.S. health care system to address one of its most persistent problems – the failure of patients to take medications as prescribed, or "patient non-adherence" – by experimenting with medication adherence strategies delivered by patient care teams. It is time to test adherence solutions through teamwork.

Now is the time because poor medication adherence is exacting a heavy toll in the form of unnecessary illness, disability and premature mortality, particularly among the burgeoning number of chronically ill patients in the U.S. Poor medication adherence in all its manifestations costs the U.S. upwards of \$290 billion per year in unnecessary health care spending. Unless we discover innovative ways to address the adherence crisis, it will likely worsen. An aging population and the rising prevalence of chronic conditions such as diabetes and hypertension create will result in both a greater need for treatment by prescription medication and, if nothing is done, greater non-adherence -- ultimately creating poor health outcomes and spurring unnecessary medical spending at a time when we can afford neither one.

The time is also right because the U.S. health care system appears poised to embrace system-changing innovations, such as the increased utilization of health care IT, which will facilitate the introduction of interventions to improve patient medication adherence. Many provisions of the nation's new health care reform law, the Patient Protection and Affordable Care Act, will support active experimentation with approaches such as the patient-centered medical home and accountable care. It is hoped that these innovations will reward health care providers for sustaining good patient health outcomes, and thus increase the attention and focus on good patient medication adherence.

If the U.S. is to improve patient medication adherence, many experts believe that care teams will need to play a major role. Evidence suggests that discrete, "rifle shot" adherence interventions have a limited impact on improving adherence across broad populations. Significant improvement will depend upon the coordinated implementation of both multiple steps and multiple interventions. Care teams may prove essential, if only because they will bring more than one set of hands to bear on the complex challenge of improving patients' capability and willingness to adhere to their prescription regimens.

Care teams, which can include both physicians and non-physician caregivers, may also prove to be an essential element in improved medication adherence given other pressures within our health care system that are leading to greater use of non-physician staff. The ongoing national shortage of primary care physicians is likely to increase pressure for the utilization of non-physician staff of all types, including professionals such as community pharmacists, who may not work within the physician practice itself, but serve as part of a "virtual care team."

Existing medical evidence supports the idea that team-based care can provide superior treatment of chronic conditions. Care teams are integral to the patient-centered medical home, and to other models of improved patient care that are designed to improve efficiency, affordability and, ultimately, patient outcomes.

Yet despite the evidence that care teams provide overall superior treatment for the chronically ill, the evidence base specifically supporting the use of care teams in deploying adherence strategies is thin. As NEHI revealed in its 2009 report *Thinking Outside the Pill Box: A System-wide Approach to Improving Medication Adherence for Chronic Disease,* several leading health care organizations are now actively experimenting with adherence improvement through the use of care teams, but these efforts remain at an early stage. Many are not designed explicitly to measure adherence improvement; robust performance metrics have only recently been designed and validated to routinely measure medication adherence across large patient groups, and demonstration projects have only recently begun to utilize those metrics. Thus, there are very few findings available from experience in the field that lend themselves to broad application.

Fortunately, many ongoing initiatives for health care reform and improvement (for example, initiatives for payment reform, patient-centered medical care, and health care IT deployment) now give us the ability to mount a series of demonstrations that can be designed to explicitly test the effectiveness of medication adherence services delivered by care teams in a variety of typical practice settings, and to evaluate their effectiveness using a common set of metrics.

Given the enormous impact of poor medication adherence on patient outcomes and the health care system, and given the importance of physician-led care teams to health care reform, it is time for health care stakeholders to create a broad portfolio of new demonstration projects showcasing the use of care teams to improve adherence in a wide variety of practice settings across the health care system.

NEHI recommends that this new portfolio of demonstration projects should:

- **Demonstrate multi-component strategies**, since non-adherence has multiple causes and providers need to be prepared to coordinate multiple services in order to change the behavior of individual patients.
- **Encompass core elements** that have shown promise in the existing literature, including:
 - Techniques for patient identification and screening, since targeting patients is likely to prove necessary to achieve cost effectiveness;
 - Medication review, medication reconciliation and overall optimization of each patient's medication regimen;
 - o Interventions to reduce cost barriers for individual patients; and

- Patient education and engagement techniques.
- Overcome limitations of the existing evidence base by:
 - Utilizing adequate sample sizes, rigorous performance metrics and other study designs that yield findings of broad applicability; and
 - Identifying key organizational, process and regulatory barriers to the adoption of care teams and the use of medication adherence strategies.
- Demonstrate the adaptability of medication adherence strategies to diverse care settings, including the "virtual care teams" created by linking smaller physician practices to community-based pharmacists and other external professionals.
- Demonstrate the integration of medication adherence strategies with other elements of health care reform, including:
 - The deployment of electronic medical records, feedback loops and data sharing systems that will allow the safe, secure and private exchange of patient medication-related data among care team members such as physicians and pharmacists;
 - The use of standard performance metrics; and
 - Innovations in payment that will enable and reward investment in delivering medication adherence services through care teams (both physician practice-based and "virtual" teams), including the cost of capital investment required to deploy comprehensive, effective strategies.

Government policymakers, health care providers, payers, and the pharmaceutical and the pharmacy industries alike should now seize the opportunity to pursue the use of care teams in improving medication adherence by building a robust portfolio of demonstration projects throughout the country.

The Problem

Chronic disease is now recognized as both the leading threat to good health and the leading driver of increased medical spending in the U.S., accounting for over 75 percent of total health spending¹. About half of all Americans have at least two chronic diseases or conditions, a number that is only expected to increase in the coming years.²

Treatment of chronic disease invariably entails prescription medication, but 30 to 50 percent of Americans on medications for chronic illnesses do not fully take their prescription regimens as prescribed – an issue referred to as "medication nonadherence." The resulting costs are significant. NEHI estimates that medication nonadherence, along with inadequacies in diagnosis, the prescribing process and patient medication management may result in as much as \$290 billion per year in avoidable medical spending, or 13 percent of total health care expenditures. Poor medication adherence significantly increases the risks of hospitalization and mortality among patients with diabetes, hypertension and heart disease, including an estimated 89,000 premature deaths per year among hypertension patients alone.³

Medication non-adherence is a complex and multi-faceted problem that defies simple solutions. For instance, the problem manifests itself in several ways. Some patients prove to be non-adherent from the outset by failing to fill prescriptions, or filling some prescriptions and not others. Patients may discontinue their prescriptions prematurely; studies show that patients with newly prescribed medications are at high risk for premature discontinuation. Patients may skip required doses of medicine, or weaken their medication through pill splitting.

Not surprisingly, research points to multiple causes for non-adherence. Inadequacies in diagnosis and in the act of prescribing may lead to treatment regimens that are unnecessarily complex or burdensome for patients, or may create unnecessary side effects. Most patients are sensitive to high out-of-pocket costs for prescription drugs, and high costs have been shown to reduce adherence, particularly when multiple prescriptions are involved. Limited health literacy and poor communication from providers may limit patients' understanding of their illness and the need to maintain adherence. Depression, other emotional factors and a simple lack of belief in the efficacy of treatment may reduce adherence as well.⁴

The complex, multi-faceted nature of patient non-adherence has contributed to the difficulty in identifying effective interventions to improve adherence. It underscores the need for strategies that identify the specific, most important cause of non-adherence among specific groups of patients, and the need to apply interventions that target the specific needs of those patients.

The Role of Care Teams in Promoting Adherence

Why should care teams matter to the improvement of patient medication adherence?

Evidence emerging from literature and directly from the field suggests that, for most patients, improved adherence will require care providers to devise coordinated strategies that encompass multiple components. These multi-component strategies entail identifying, evaluating, motivating and actively monitoring patients in ways that require the physician's overall supervision but would impose an excessive burden on most physicians.⁵

Then again, the utilization of physician-led care teams in general is proving more important for a multitude of reasons. Several trends point to greater utilization of non-physician staff in health care in the years ahead, either within physician practices, or within looser or "virtual" care team arrangements in which external professionals coordinate their efforts with physicians.

The complexity of medical treatments has grown greatly over the last 40-50 years, as has the complexity of managing a physician practice. The sheer size of physician practices has grown as well, with individual physicians frequently compelled to maintain patient panels of upwards of 2,000 in order to break even financially. These pressures contribute to a long-term trend towards greater delegation of tasks by some physicians and physician groups to non-physician clinicians.⁶

The growing scarcity of primary care physicians is another factor. Declining numbers of new primary care doctors is prompting a harder look at wholesale reforms of the primary care practice model, including a team approach in which nurses, nurse practitioners, physician assistants and other professionals take on more extensive roles in treating patients.⁷

The growing demand for treatment of chronically ill patients is intensifying this interest in team-based care. Studies show that a primary care physician with a typical patient panel would need 10.6 hours per day to deliver effective, high quality care to chronic disease patients.⁸ A strong body of evidence suggests that team-based care represents the most clinically effective way to address chronic disease, with or without a looming physician shortage.⁹

Care team concepts are now woven through several provisions of the new federal health care reform law (the Patient Protection and Affordable Care Act or ACA). Perhaps the most prominent concept embodied in the ACA is the patient-centered medical home (PCMH), which is generally defined as a model of health care delivery in which teams of professionals are physician-led, but bear a collective responsibility for patient care and

good patient outcomes.¹⁰ Several measures of the ACA authorize federal support for new PCMH demonstrations or promote direct deployment of the PCMH throughout the country. Other provisions of the ACA support deployment of variations on the PCMH that link physicians with external, community-based providers in the "virtual" care team concept. These provisions include a program to allow states to place Medicaid recipients in "health homes" that may be "free standing or virtual" and utilize a diverse group of professionals, including community-based pharmacists. The bill also authorizes grants to states for the creation of "community health teams" comprised of community-based clinicians acting in support of physician-led primary care practices.¹¹

This broad range of care team concepts in the ACA reflects the reality that many, if not most, physician practices are likely to move only slowly and incrementally towards transformative models of care such as the PCMH, if they move at all. Smaller and poorly resourced practices might benefit more immediately from the creation of effective alliances with external, "virtual" care team members such as community-based pharmacists.

Pharmacists and commercial pharmacies are ubiquitous and easily found in communities where the typical physician practice may be small and without extensive resources. Many patients have more frequent contact with their pharmacists than with their physicians and their physicians' staff, and patient surveys indicate that patients trust pharmacists highly for advice and counsel on medications and medication management.¹² An increasing proportion of U.S. pharmacists graduate with advanced degrees (such as a PharmD degree) that qualify them to provide advice on medications directly to patients.

The utilization of non-physician professionals brings with it significant management challenges that have real implications for the quality and effectiveness of patient medication adherence strategies. The PCMH and other care team models are physician-led, but on a day-to-day basis it is unlikely that physicians will coordinate the details of medication adherence services. The delegation of tasks from physicians to others, particularly to clinicians who operate outside the physician practice, risks fragmentation of services and may dilute the patient's sense that the physician is truly invested in his or her care. Expert observers have noted that disease management (DM) programs have often been less than effective because patients do not believe DM providers to be speaking with or for the patient's physician. As one observer put it, "the patient must believe that the doctor is watching."¹³ For this reason, one of the most important objectives of new demonstration projects on care teams and medication adherence is to determine which adherence-related tasks should be reserved for prescribing physicians, and which tasks can and should be assigned to other professionals, including pharmacists, nurses, physician assistants and others.

The Need for New Demonstration Projects

Unfortunately, relatively little of the current evidence base illuminates the potential role of care teams in improving patient medication adherence in a cost-effective manner. In fact, evidence regarding all modes of health care delivery and medical practice models as factors in patient medication adherence is limited in scope and rigor.¹⁴

This is not to say that leading physician practices and their care teams have turned a blind eye to adherence as an issue. Recent case studies developed by Avalere Health and NEHI in 2009 show that a number of leading organizations are actively managing patient medication adherence, with promising results.¹⁵ But despite these innovative programs, few organizations have undertaken rigorous evaluations that specifically track medication adherence improvement measures and correlate these measures to specific interventions or strategies. Also, findings from leading, highly integrated health care systems may not prove to be easily transferable to the great majority of health care practice settings that are smaller, less integrated and may be more dependent on community-based resources to provide patients with adequate support.

The evidence that does exist suggests that attempts to improve adherence through use of care teams has proven to be expensive and yielded uncertain results. University of Southern California health economist Dana Goldman and colleagues have noted that "even the most successful interventions [do] not result in large improvements in adherence and generally [rely] on complicated, labor-intensive regimens of uncertain effectiveness."¹⁶

Because conditions have changed as a result of health reform legislation, the environment is now favorable for new care team experiments to demonstrate how care teams can achieve significant and measurable results, at costs that are likely to prove acceptable to health care payers and purchasers. Health care providers not only need to know that care teams can work, they need to know whether care teams can be integrated within or alongside their existing organizations and processes, and whether the cost of deploying teams to improve medication adherence will fit within new health care payment models such as global payment or accountable care models.

Several initiatives lay the groundwork for these demonstrations, starting with the ACA. As noted, the law creates new programs and incentives for demonstration of the PCMH, as well as for experimentation with health care payment reform. Existing innovations in payment and care coordination, such as the Community Care of North Carolina program and Blue Cross Blue Shield of Massachusetts' Alternative Quality Contract, already provide some early guideposts. These and other payment reform plans call for a transition to outcomes-based reimbursement, in which clinicians will be rewarded for measurable improvements in patient health, rather than for the volume of services provided. In theory,

these payment systems will create incentives for clinicians to prevent disease progression and to sustain good health outcomes in their patients. In many cases, this will require an important focus on medication adherence.

The critical question is whether the incentive payments or care coordination fees likely to be available under health care payment reforms will match the costs of providing effective chronic care coordination, including effective medication adherence services. There is little data or practical experience available to predict these costs or to set appropriate fees, so the need for active experimentation is clear. The cost of providing effective medication adherence services is likely to vary according to the characteristics of the patients served, the type and complexity of medication regimens involved, the resources available to providers (including external resources such as community pharmacies), practice patterns of medical providers, the mode of health care delivery in a given region and the interventions used. New experimental projects should be devised to demonstrate how effective strategies can be deployed at realistic levels of cost.

Health Care Reform: Opportunities for Patient Medication Adherence and Care Teams

Several provisions of the Patient Protection and Affordable Care Act (ACA) and the American Recovery and Reinvestment Act (ARRA) could spur demonstrations of medication adherence strategies deployed through care teams.

Center for Medicare and Medicaid Innovation (CMI): CMI will sponsor "models" of innovation in health care reimbursement. Models of payment for medical homes, accountable care and medication therapy management could be devised to incorporate medication adherence services delivered by care teams.

The Patient-Centered Medical Home: Subject to appropriation, Section 3502 of ACA provides grants or contracts for "community health teams" that support patient-centered medical homes. A similar provision (Section 2703) authorizes state Medicaid programs to support patient-designated "health homes," including "freestanding or virtual" homes providing coordinated care of chronic illness delivered by physicians, nurses, physician assistants, pharmacists and a broad range of community-based professionals.

Hospital Readmissions: By 2012 the Centers for Medicare and Medicaid Services (CMS) will reduce payments to hospitals with excessive readmissions of certain chronically ill patients. Poor medication adherence is closely linked to preventable readmissions and preventable mortality in conditions such as coronary heart disease.

The ACA also authorizes funding for collaborations between hospitals and communitybased organizations that create care transition programs for Medicare beneficiaries with repeated hospital readmissions. Comprehensive medication reviews and medication management, including medication counseling and self-management support, are among the interventions eligible for program support. The program begins in January 2011 and is authorized for 5 years.¹⁷

Health Care IT: The ARRA provides \$30 billion in financing for the adoption of electronic medical records and other forms of health care IT in clinical practice, provided that clinicians demonstrate "meaningful use" of the technology. Criteria for meaningful use promulgated by the government place a priority on the demonstration of health care IT to improve medication adherence.¹⁸

Medication Therapy Management: The Secretary of HHS is authorized to sponsor grants or contracts for medication therapy management (MTM) services to patients with multiple chronic diseases, or who are at high risk of medication-related problems. The program is subject to appropriation.

Comparative Effectiveness Research (CER): The ACA creates a permanent CER entity (the Patient Centered Outcomes Research Institute) that will commission federally supported CER studies. In 2009, the Institute of Medicine ranked research on medication adherence initiatives among the top 25 percent of high priority CER topics.

What to Test: Objectives for New Demonstration Projects

New demonstration projects need to yield results that are both robust and capable of application to a wide variety of practice settings in the health care system. NEHI research, expert interviews and discussions with practitioners suggest several key objectives for demonstration projects:

- **Objective 1**: Test multi-component strategies, not single ('rifle shot') interventions; multi-component strategies should be built from components that are supported by existing literature and the current experience of practitioners in the field.
- **Objective 2**: Overcome the limitations of prior studies and demonstration projects, through study designs that:
 - Feature adequate sample sizes and rigorous performance measurement; and
 - Identify common barriers to adoption of multi-component adherence strategies, including organizational, process and regulatory barriers.
- **Objective 3**: Demonstrate adaptability to diverse care settings.
- **Objective 4**: Be designed to achieve integration with critical elements of national health care reform.

Each objective is discussed in greater detail in the sections that follow.

Objective 1: Test Multi-component Adherence Strategies

Clinicians naturally tend to think in terms of discrete interventions when solving clinical problems, but solving the problem of poor medication adherence is best thought of as a matter of employing good interventions through an overall strategy. Much of the existing evidence base on improvement of adherence focuses narrowly on specific interventions (a specific telephone reminder system, for example) and not on overall strategies, and this is a likely reason why prior demonstrations projects and trials have yielded limited results.

NEHI's research and insights from experts suggest that multi-component adherence strategies should encompass four key elements: patient identification, medication regimen review and optimization, reduction of cost barriers, and patient education and engagement. Each element reinforces the others, and each element is closely aligned with ongoing health care reform implementation such as deployment of health IT and the creation of patient-centered treatment processes.

Patient Identification

In an ideal world, clinicians would work with all of their patients to ensure appropriate medication adherence. In reality, adherence interventions are typically targeted at patients with the most severe needs and those most likely to benefit. Given constraints of time, money and efficiency, most clinicians are likely to need to carefully choose the patients who will receive help. Identification of patients can be seen as a process both of targeting patients on medical grounds and screening for their likelihood of adherence to prescription medication. These criteria can be tested through new demonstrations of effective patient medication adherence.

Targeting by disease state

Disease management programs and many employer-sponsored benefit plans target services by major disease state. From the standpoint of medication adherence, the presence of perceptible disease symptoms (symptomatic disease) or the absence of symptoms (asymptomatic disease) may be an important distinction for testing in demonstration projects.

Patients with symptomatic conditions (such as poorly controlled diabetes, heart disease or asthma) may be more inclined or more motivated to adhere to medications, more likely to be incurring medical costs and at higher risk of needing more intensive medical services. Thus, the short-term opportunity to improve health and avert new health care spending through improved medication adherence may be higher with these conditions than in cases where patients are asymptomatic.

Asymptomatic diseases (diseases in which symptoms are not present or perceptible to the patient) frequently manifest a prolonged latency period, so that improved medication

adherence among asymptomatic patients is less likely to result in measurable short-term improvements in health and consequent reduction in health care spending. Nevertheless, improved adherence among large numbers of asymptomatic patients (among large employee populations, for example) can have a very significant impact on improved population health and help avert health care spending.¹⁹

Targeting by risk level

Targeting health services and interventions by risk level has become popular among larger employers who sponsor comprehensive employee health management programs. Typically, employee health risk data is forwarded to third-party data aggregators and analysts in order to preserve employee confidentiality and to comply with applicable privacy laws such as HIPAA. Employers receive aggregated data on major health risks present among their employees, and use the information to create targeted health improvement programs, including programs that aim to improve patient medication adherence. Methods to target patients by disease state or by direct evidence of nonadherence (see below) more directly identify patients in need of assistance. Nevertheless, many large employers are drawn to targeting by risk level because it identifies employees/patients on the cusp of "risk transitions" from a state of low health care need to more intense needs. Successful identification and treatment of these employees/patients is a step towards averting higher health care spending and thus controlling health care costs.

Targeting by evidence of non-adherence

Perhaps the most straightforward approach to targeting patients would be to identify any patient who has clearly failed to adhere to his or her medication regimen. For instance, upwards of seven percent of patients abandon their prescription at the pharmacy – a number that is growing as out-of-pocket costs rise – consequently exacerbating the issue of non-adherence.²⁰ Unfortunately, most physician practices do not have easy access to data that indicates non-adherence, such as pharmacy claims data (from health plans or prescription benefit managers) or prescription fill and refill data, which is increasingly available within retail chain pharmacies. Expanded adoption of e-prescribing services that offer feedback loops to the physician practice (a service now offered by SureScripts, the dominant e-prescribing service), coupled with the use of electronic medical records and data sharing, should greatly enable the targeting of patients on the basis of straightforward non-adherence.

Targeting by other high opportunity patient segments

Several patient segments present particularly promising opportunities to achieve improved outcomes and future cost savings through medication adherence strategies.

• *Patients with new prescriptions:* Research clearly shows that patients with new prescriptions are at the greatest risk of poor adherence and the discontinuation of medications. Patients frequently drop their medications within the first 30-60 days of initial prescription. Among patients who are prescribed statin drugs, for example,

upwards of 40 percent fail to adhere within the first three months of initial prescription.²¹ Within the first 30 days, rates of medication discontinuation are significantly higher for patients newly prescribed a class of drugs compared to patients who had been prescribed a drug of the same class within the last 180 days.²² The high rate of non-adherence among new prescribers suggests that medication adherence interventions designed to routinely target newly prescribed patients will be promising.

- *Patients with behavioral health issues*: Research suggests that identifying patients with poor mental health and co-morbid chronic conditions such as diabetes could be an effective targeting strategy for improved medication adherence. Published literature suggests an association between poor medication adherence and poor mental health, a finding that supports the observations of many practicing clinicians, although much of the relevant published research is based on studies that were not primarily designed to test adherence.²³ Research does suggest a significant association between poor medication adherence and depression, anxiety or related disorders among patients with Type 2 diabetes.²⁴ Patients who are actively treated for psychiatric disorders frequently exhibit adherence problems with psychiatric medications, and with medications for co-morbid conditions such as diabetes.²⁵
- *Co-morbidities and poly-pharmacy*: Patients with multiple chronic conditions have complex issues related to adherence; targeting patients by the complexity of their regimens and by the presence of multiple prescriptions (poly-pharmacy) represents a promising avenue for focusing medication adherence strategy. Data indicate that as the number of pills patients are required to take each day increases, adherence decreases.²⁶ Patients with multiple chronic conditions --- those likely to have multiple prescriptions are the target of the Medicare medication therapy management (MTM) benefit, first authorized as part of the Medicare Part D legislation in 2003. Provisions of the newly-enacted federal health care reform law (Patient Protection and Affordable Care Act) will further standardize MTM services eligible for Part D reimbursement, and will also create new grants to demonstrate the wider application of MTM services to patients with multiple chronic conditions or are at high risk of medication-related problems.
- *Care transitions:* Transitions in care, particularly the transition between hospitalization and home, or hospitalization and other care settings, are increasingly recognized as periods when patients are extremely vulnerable to relapse and rehospitalization. Poor medication adherence is highly correlated to increased relapses and rehospitalizations.²⁷ To reduce unnecessary hospital readmissions, targeting patients who are undergoing care transitions should be a high priority.

Screening

A fundamental insight from recent work on patient medication adherence is that the proclivity of patients to adhere varies considerably among individuals based on health literacy, personal preferences, limitations, beliefs and lifestyle. Further, adherence variability persists even if the prescription regimen is perfectly appropriate and optimized for the patient, and even if cost barriers are reduced or eliminated. These insights have created momentum for the development of accurate, easy-to-use tools for screening patients that require a minimum of training and can be administered by a range of non-physician staff.

One of the best documented screening tools is the Patient Activation Measure (PAM), a 22-item survey that measures patient knowledge, skill and confidence (hence "activation") for self-management of disease. The PAM was developed by Dr. Judith Hibbard of the University of Oregon, one of the leading U.S. researchers in the area of patient health literacy, motivation and engagement. The PAM is not specific to medication adherence questions, although patient results on the PAM are highly correlated with a patient's likelihood to adhere to his or her medication regimen. Thus the PAM, or similar broad measurement tools, may be useful to physicians and care teams wrestling with complex issues of patient engagement and behavior change. Administration of a patient assessment tool is part of the Geisinger Health System strategy for medication adherence (outlined in a NEHI case study), and is also a component of the Latino Health Initiative of the Joslin Diabetes Center.²⁸

Alternative screening tools focus specifically on adherence. A recently developed tool, notable for its brevity in comparison to others, is the Adherence Estimator developed by researcher Colleen McHorney of Merck & Company, a three-item tool that has shown promise of being highly predictive of medication adherence performance.²⁹

Screening tools such as these give providers information with which to tailor their interactions with patients in ways that will improve the patients' motivation to maintain adherence. The screening of chronically-ill patients for their level of activation might also be tied to other clinical objectives that involve patient behavior change, such as changes in diet and fitness that are frequently indicated for chronically ill patients.

Medication Review, Reconciliation and Regimen Optimization

Researchers have had a difficult time quantifying the impact of medication review and reconciliation on improving patient outcomes.³⁰ Nevertheless, many experts (including members of NEHI's working group) believe strongly that a significant portion of medication adherence problems could be corrected if adequate medication review and reconciliation is done on a routine basis. Ideally, the patient's medications should not be simply reviewed and reconciled with one another, but the overall regimen should be adjusted to achieve an optimal regimen that reflects factors such as the patient's personal preferences, patterns of work and home life, and personal finances. The need to optimize

patient medication regimens will only grow as greater numbers of patients are diagnosed with chronic diseases and related, co-morbid conditions, and find themselves with multiple medications prescribed by multiple physicians.

At least two challenges inhibit routine administration of patient medication reviews and reconciliation.

The first is lack of data. Physicians have records of prescriptions they order for individual patients, but most physicians do not have regular access to data on prescriptions ordered by other physicians for the same patient, much less data on whether the patient has filled and refilled prescriptions on a timely basis. Filling these data gaps will require implementation of a supportive health IT data infrastructure that links e-prescribing data, electronic medical records, pharmacy-related health insurance claims, and prescription fill and refill data, and enables the sharing of this data across provider settings, including virtual care team settings like community-based pharmacies. The federal government has encouraged this implementation by taking steps such as including medication-related data as a key element in the "meaningful use" criteria for the adoption of electronic medical records and development of a health care data infrastructure under the federal HITECH act creates significant opportunity for the design of new medication adherence demonstration projects.

The second challenge is that of determining how care team members are best deployed to carry out medication review, reconciliation and optimization to achieve clinical and cost effectiveness. In the physician practice, medication review and reconciliation is frequently an "orphan process," according to members of NEHI's working group. Often, no one staff member is best suited to perform all relevant tasks in the most cost-effective manner. Basic tasks such as initial reconciliation can be, and frequently are, assigned to medical assistants or less costly staff, but final judgments must be rendered by physicians or under their direct supervision and review. Clinical pharmacists may be retained, particularly to resolve complex or difficult medication issues, but relatively few physician practices do so.

Innovative programs such as the Community Care of North Carolina program have addressed this gap by hiring clinical pharmacists to serve networks of physicians, operating either from space within physician offices or directly from community pharmacies. Physician networks within the Community Care of North Carolina system retain the services of clinical pharmacists based on their own local needs and preferences, and underwrite the services with care coordination fees paid by the state Medicaid program through Community Care of North Carolina.

Medication review, reconciliation and optimization are also core functions of medication therapy management (MTM), and the Medicare Part D MTM benefit provides another platform for demonstrations of medication adherence strategies that incorporate MTM

functions, at least for Medicare beneficiaries. The MTM benefit authorizes reimbursement for patient counseling services rendered by clinical pharmacists, acting either within physician practices or other health care provider organizations, or within community pharmacies. The Medicare benefit remains restricted to patients who have multiple, serious chronic conditions, who take multiple drugs covered under Part D, and whose total prescription drug expenditure exceeds a pre-determined limit. Congress did not expand eligibility for the MTM benefit in the Affordable Care Act, but it did authorize HHS to make grants and contracts available to providers implementing MTM programs (subject to appropriation), and models of payment for MTM services could become priorities of the newly created Center for Medicare and Medicaid Innovation (CMI). Thus, despite ongoing limitations on federal support, MTM services could serve as an element of new demonstration projects on medication adherence and the use of care teams, particularly projects targeting seriously, chronically ill patients with multiple conditions.

Reduction of Cost Barriers to Improved Adherence

For some patients, out-of-pocket costs can be a significant barrier to adherence, and research has shown that reducing out-of-pocket costs is an important element in improving the medication adherence of individual patients.³¹ Data suggest that patients trust physicians and pharmacists more than other sources to give them information about drug efficacy and drug costs, but that such information often is not relayed.³² There are several limitations on the ability of physicians, pharmacists and other care team members to counsel patients on medication costs or to intervene and lower costs.

Lack of data is, once again, a serious limitation. Physicians and other prescribers need direct access to a patient's specific formulary to know how much a patient will pay for a particular medication, and whether lower-cost, equally effective options are available. Currently, many physicians have little or no access to this information or must task staff to investigate it. The federal HITECH program addresses this gap through its "meaningful use" criteria: Physicians seeking incentive payments for adoption of electronic medical records will find that the capability to access formulary information through an EMR is a core criterion for incentives.

Even if medication cost data become more readily available to prescribing physicians, the physician or, likely, other care team members, must be delegated to carry out the several steps necessary to make use of the information, starting with formulary "look ups" and appropriate counseling of patients on their medication costs. Like the various tasks involved in medication reconciliation, these are actions that are not routinely carried out today; an important objective of new demonstration projects with care teams, then, will be to discover how cost-related tasks should be defined, what care team members should carry them out, and how they should be managed and reimbursed within an overall medication adherence strategy.

Once again, while the prescribing physician may likely delegate most routine tasks to other care team members, there are still important clinical reasons for ensuring that the physician receives timely feedback on the patient's drug costs and ability to pay. Physicians may want to consider the patient's ability to pay in designing an overall medication regimen that will enhance the patient's ability to adhere (cost considerations could play a role in designing dosing regimens and forms of drug delivery, for instance). Feedback to the physician on the patient's sensitivity to costs is thus one element of patient-centered care.

Patient Education and Engagement

A patient's ability to pay for medication is far from the only factor determining the patient's medication adherence; ongoing research also points to a number of idiosyncratic factors that influence a patient's likelihood of adherence. They include fundamental literacy, as well as health literacy (the ability to comprehend health and health care-related concepts); the patient's understanding of his or her condition, the nature of the treatment regimen and prescribed medications; the patient's ability to navigate the health care system; personal beliefs and preferences; and the patient's sense of engagement with his or her health and health care.³³ Changing the patient's mindset about medication adherence is an issue of behavior change, as is the case with many other issues in the management of chronic disease, such as behavior change relative to diet and fitness.

The tools and techniques for patient education and engagement are core components of an overall adherence strategy for patients, in order to overcome the above mentioned factors. Relevant tools and techniques include:

• *Patient education tools:* Some clinicians provide patients with educational materials on conditions and treatment regimens in the hope that patients will improve their treatment adherence as they become better educated about their condition. Patients have increasing opportunities to educate themselves through materials available on the Web through patient information sites such as WebMD or social networking sites that attract patients with similar conditions.

Evidence on the effectiveness of static educational materials such as educational brochures is inconclusive at best.³⁴ It is likely that the patients most apt to be motivated by teaching themselves about their condition are patients most apt to be adherent to treatment in the first place.

As a result, innovative stakeholders are turning to more active ways to educate patients, and active approaches should be part of any care team demonstration project that makes patient education part of its core strategy.

For example, various stakeholders are now turning to mechanisms that "push" targeted messages to patients on the basis of a "right patient, right information, just in time" approach. Messages that synthesize the best available medical evidence can be pushed to targeted patients by employers through employee health benefit web portals, or by health plans through subscriber web portals, the mail or over the phone. Patient education messages can be pushed towards customers by chain pharmacies through automated phone and e-mail reminder systems.

Physician practices can push appropriate messages as well, and physicians may well be the best positioned to deliver an effective message given their special relationship with the patient. "Information therapy" is a concept developed by physician-researchers in which physicians teach patients about their conditions and treatment options at points when patients are likely to make the best decisions by being fully informed (or have "the right information at the right time"). Key information therapy concepts are incorporated in the meaningful use guidelines promulgated by the Department of Health and Human Services and the Office of the National Coordinator.³⁵

• *Patient engagement tools:* The significance of "patient activation," namely the patient's capability and motivation to manage his or her health, has become increasingly apparent in recent years.³⁶ Steps to screen patients for their level of activation could prove to be an important element of patient medication adherence strategies. Likewise, interventions that directly motivate the "unactivated" patient to change medication adherence behavior could be an important tool in improving adherence.

The most widely discussed tool for patient motivation is motivational interviewing (MI), a technique developed and tested by behavioral psychologists that is now taught in schools of pharmacy throughout the country. Providers trained in MI take patients through a series of questions designed to reveal a patient's ambivalence towards medication adherence and to motivate the patient to change their behavior.³⁷ A complete training module for motivational interviewing typically takes two-and-a-half days. MI is frequently associated with pharmacists and pharmacy educators but the technique can be employed by any trained professional, including case managers and other non-physician staff within physician practices.

• *Reminder technologies:* Estimates suggest that forgetfulness and confusion account for anywhere from 10-30 percent of poor medication adherence.³⁸ The incidence of poor adherence due to forgetfulness may well increase in the future as Baby Boomers age and an increasing number suffer from both chronic disease and age-related forgetfulness or dementia. Reminder technologies range from devices

including pillboxes, cell phones and personal computers that can be preprogrammed with reminders, to devices embedded with cell phone or Internet connectivity that provide adherence messages to patients and feed adherence data back to caregivers. Utilization of reminder technologies in demonstration projects will require close coordination with overall health IT strategies.

Objective 2: Overcome the Limitations of Prior Studies and Demonstration Projects

Limitations of the existing evidence base include:

- Incomplete evidence on the prevalence of poor adherence, a result of a lack of systematic means to collect and share data; and
- Design limitations of existing studies, including small sample sizes, nonstandardized adherence measures and heterogeneous patient populations.

Many of these weaknesses can be overcome with adequate funding and a commitment by federal funding agencies and private funding sources to develop a truly robust portfolio of medication adherence experiments and demonstration projects. In particular, the new federal initiative for comparative effectiveness research is well positioned to commission studies of adequate scale that will directly compare competing strategies for adherence. The cost and effort to conduct rigorous data collection and performance tracking should be alleviated by designing demonstration projects that conform to the meaningful use guidelines for electronic medical record adoption promulgated under the HITECH Act, and thus make use of HITECH financial incentives. Demonstration projects should also fully incorporate robust performance metrics such as those promulgated by the Pharmacy Quality Alliance (PQA) industry partnership (detailed below).

Metrics

The evidence base on adherence interventions remains weakened by studies that rely on relatively small sample sizes and limited follow-up or longitudinal monitoring.³⁹ To ensure that demonstration projects generate robust and scalable results, new projects should:

- Include organizations with sufficiently large patient pools to yield valid samples; smaller physician practices should be studied within the context of larger networks.
- Utilize performance metrics that are emerging as standard in the field, such as the metrics developed by the PQA and endorsed by the National Quality Forum. Forty current PQA measures include metrics of adherence to hypertension, diabetes, heart disease and asthma medications.
- Report on metrics, beyond improved outcomes, that align with the interests of key stakeholder groups and potential demonstration project underwriters:
 - *Employers, health plans and government payers* -- Demonstration of averted medical spending, including the reduction of per capita health care spending (health care spending reduced across an entire population) below the baseline projected growth.
 - *Pharmaceutical and pharmacy industries* -- Demonstration of improved prescription fill, re-fill and medication possession rates.

Objective 3: Demonstrate the Adaptability of Strategies to Diverse Care Settings

Adherence strategies must be adaptable to a wide variety of care settings. Physician practices in the U.S. are mostly small, although physicians themselves are somewhat evenly distributed among small and large practices. Calls to redesign and revitalize the primary care system in the U.S. have gained strength in recent years and are now supported by several provisions of the ACA. However, even if such reforms prove successful, it is likely that physician practice settings will remain very diverse in the years ahead. Medication adherence strategies must be adapted accordingly to work in both large and small, urban and rural settings.

Practice Size

Data from the National Center for Health Statistics illustrates the great degree of variation among U.S. medical practices in terms of practice size and breadth of specialty. About one half of all office-based physicians in the U.S. practice alone or with one partner, and these solo and two-doctor practices represent over 80 percent of all physician practices. A majority of physicians and physician practices are organized as single-specialty practices (solo practices included). Only one in five physicians practice in a multi-specialty group.

The wide variation among physician practice settings reflects an equally wide variation in the capabilities and resources related to improved medication adherence. There is wide disparity, for example, in the adoption of electronic medical records, including EMRs with features that are relevant to medication adherence.

| Diverse Size, Unequal Resources Within U.S. Physician Practices | | | |
|---|-----------------|----------------|--|
| Practice Size | % of Physicians | % of Practices | |
| Solo | 36.8 | 69.4 | |
| Partner | 12.1 | 11.4 | |
| 3-5 | 27.8 | 14.4 | |
| 6 or more | 23.4 | 4.9 | |
| Specialization | % of Physicians | % of Practices | |
| Solo or single-specialty group | 78.8 | 90.1 | |
| Multi-specialty group | 20.3 | 8.9 | |
| Unknown | 1.0 | 1.0 | |
| EMR Use | % of Physicians | % of Practices | |
| Full | 12.8 | 9.2 | |
| Partial | 13.7 | 12.7 | |
| None | 73.5 | 78.2 | |
| Adherence-related EMR Feature | % of Physicians | % of Practices | |
| E-prescribing | 11.9 | N/A | |
| Warnings on drug interactions | 14.6 | N/A | |

Source: National Center for Health Statistics, 2005-2006

EMR Use

Adoption of electronic medical records (EMR) by physician practices remains relatively low, although the incentives created by the federal HITECH act promise to accelerate the process. Only 12.8 percent of physicians and 9.2 percent of practices have full EMR systems with roughly an equal number of physicians and practices using a partially electronic system. Not surprisingly, more recent data suggest that only 12 percent of U.S. physicians utilize electronic prescribing (see discussion below). Physicians within large practices are more likely to report both full and partial use of EMR systems than physicians at small practices.⁴⁰ Among those physicians using either full or partial EMR systems, only 11.9 percent have e-prescribing capabilities and only 14.6 percent have a system that provides warnings on drug interactions and counter-indications.

Non-Physician Clinical Staff

Data on the use of so-called 'mid-level providers' (nurse practitioners, physician assistants and other professionals, not including registered nurses) in smaller practices is scant. Nevertheless, according to the most recent data from the National Ambulatory Medical Care Survey (NAMCS), only 11.5 percent of physician practices overall utilize such professional staff. Utilization of mid-level providers is only 20 percent even among physician practices of six or more doctors. Reimbursement for the services of non-physician clinical staff can vary greatly among the states and is the subject of complex regulation at the federal level.⁴¹

At the most basic level, new demonstration projects for medication adherence utilizing care teams might fall into two groups: demonstrations involving larger physician practices and demonstrations involving smaller physician practices.

Larger physician practices – larger physician practices are more likely to employ non-physician staff such as nurse practitioners and physician assistants, and most likely to utilize electronic medical records and other forms of health care IT.

Smaller physician practices – smaller physician practices, due to resource constraints, are less likely to employ non-physician staff and less likely to utilize health care IT. Smaller practices will need resources provided to them by external stakeholders, and may be more likely to require the formation of partnerships with other physician practices and non-physician organizations such as community pharmacies, in order to undertake an effective medication adherence strategy.

Objective 4: Achieve Integration with National Health Care Reform

Several overarching objectives of national health care reform pertain directly to improved medication adherence. New demonstration projects should build upon and knit together these closely related initiatives in order to create comprehensive, multi-component strategies.

Health IT and Data Infrastructure

Medication adherence demonstration projects should be well integrated with ongoing efforts to promote adoption of electronic medical records, promote health care data exchange and adopt other forms of health care IT.

Provider access to timely, accurate and complete medication history data is essential to basic, adherence-related steps such as medication review, reconciliation and the optimization of complex medication regimens.

At present the deployment of health care IT in the U.S. remains low, but the pace is starting to quicken. In 2008, only about 12 percent of U.S. prescribers used electronic prescribing, writing approximately 68 million prescriptions, and only 16 million medication histories were generated electronically for use by e-prescribing providers.⁴² Meanwhile, SureScripts, the leading e-prescribing data network, now claims the capability to provide medication histories for 65 percent of all patients in the U.S.⁴³ The NaviNet network, a web-based health care information exchange service, now claims upwards of 800,000 physician users. Consumer web portals operated by the major drug chains offer consumers the ability to access real-time medication history data as part of a suite of services that includes customer-generated refill orders via web sites.

No system is perfect. As of now, none of the systems in place is able to offer complete information on every patient: important sources of data on patient medication use, such as data on patient utilization of the \$4 generic drugs offered by WalMart's enormous network of stores, is not captured by these databases. More important, none of these services is yet used widely for the improvement of patient medication adherence.

The federal government has made a major commitment to speed physician adoption of electronic medical records and health data interchange. Some \$19 billion in provider incentives are in place as result of the HITECH Act of the 2009 ARRA; the incentives will be paid out between 2011 and 2015 based on demonstration by providers that they have achieved meaningful use of EMRs according to 25 separate criteria announced in December 2009. The criteria include meaningful use of medical records to perform medication reconciliations, and routine maintenance of accurate medication lists.

Robust and routine data exchange could yield benefits for improved medication adherence that go beyond the benefits of medication review and reconciliation. A major goal of new demonstration projects should be to develop innovations in health care IT that drive improvements in all aspects of medication adherence strategy. For example: pharmacy benefit managers (PBMs), community pharmacies, health plans, disease management companies and other organizations are increasingly capable of targeting messages to patients based on alerts set off by surveillance of patient claims data or pharmacy data. In theory, targeted messages from patients' doctors could be pushed to patients, thus tightening the link between the patient and the prescribing physician and reducing the fragmented messaging that has diminished the effectiveness of interventions such as disease management.

The physician community is now debating whether the HITECH Act will provide enough support for physician adoption of health IT before and during deployment for physicians to proceed with their investment in EMRs. From the standpoint of new demonstration projects in medication adherence, two courses of action are needed:

- Close partnerships with state or regional health data exchange organizations to ensure that the software and systems adopted by physicians meet HITECH standards for meaningful use that are relevant to medication adherence; direct involvement of health care data exchanges in the demonstration projects themselves will provide a greater level of assurance.
- Partnerships with organizations that offer physicians and care teams web-based access to patient medication histories across provider settings. Such partners could include health plans and chain pharmacies.

Patient-Centered Care

Patient-centered care has come to the foreground of the national debate over health care reform. The PCMH is the most prominent manifestation of the concept, but the movement towards patient-centered care implies the redesign of many processes in health care delivery. Patient-centered care is generally described as health care that recognizes and respects patient values, preferences and lifestyles, and that involves the patient and the patient's family in managing the patient's health, most particularly by involving the patient in health care decision-making. Patient-centered care is particularly relevant to the care of chronically ill patients. As noted earlier, the newly enacted ACA authorizes funding for a variety of new demonstrations and experiments with patient-centered care and the medical home.

At the same time, the movement towards patient-centered care also exacerbates stresses on the nation's primary care system. Health care reformers envision that these stresses will be relieved by new incentives for the education and training of primary care physicians, by increasing reimbursements to primary care physicians and creating new payment incentives for coordinated care, and by the utilization of non-physician staff operating as care teams.

The move towards patient-centered care creates a special challenge for effective medication adherence strategies. Care teams that make good use of non-physician staff are uniquely positioned to carry out effective adherence strategies. At the same time, the delegation of tasks to non-physician members of the care team raises issues around the fragmentation of service to the patient, and the potential impact of this fragmentation on the patient's proclivity to maintain adherence. Ideally, the patient should feel that the team is an extension of the physician (in that sense, physician-led), and that decisions are reviewed with the patient by professionals such as clinical pharmacists, who are believed by the patient to be credible and trustworthy on these matters. The challenge is to establish workable models for the deployment of medication adherence strategies through care teams that preserve the patient's link to the physician, but make good and efficient use of non-physician staff, including professionals with specialized skills.

The role of pharmacists is a special case in point. An increasing body of literature and field experience point to the ability of pharmacists to command patients' attention and facilitate good medication adherence. Clinical pharmacists directly employed by hospitals and by outpatient clinics have created measurable improvements in care quality and patient outcomes.⁴⁴ However, as pointed out in a recent *Health Affairs* article by a team of authors led by Dr. Marie Smith of the University of Connecticut School of Pharmacy, "less emphasis has been placed on developing new practice models or studying the impact of integrating the pharmacist in primary care practice."⁴⁵

As noted previously, Community Care of North Carolina has addressed the issue by demonstrating the use of consulting clinical pharmacists within physician networks that include small- and mid-sized physician practices serving Medicaid patients. The Asheville Project is the country's best-known example of a model in which community pharmacists are employed in a loose alliance with physician practices to coordinate mediation management for diabetes patients with employer-sponsored health insurance. The community health team and "health home" initiatives authorized by the ACA could demonstrate additional models, but demonstrations are needed to show how one or more of these models for the use of pharmacists outside the physician practice could be scaled up into more routine use in the health care system.

The Health Care Reimbursement System and Payment Reform

U.S. health care reform is moving simultaneously towards payment reform, new models of patient-centered care and improved management of chronic conditions. The hope is that payment reforms will generate funds and incentives to invest in improved patient medication adherence as an essential part of patient-centered care and the management of chronic illness. However, as of now there is no clear understanding as to what types of payment reforms will facilitate the introduction of coordinated medication adherence

strategies, including strategies utilizing care teams. More important, there is little understanding as to the magnitude of capital and operational spending on care teams that will be necessary to make measurable improvements in patient adherence, and what standard of return on investment – in both health and financial outcomes – will be expected by health care payers. Demonstration projects that test competing models of payment should be a high priority.

The payment reform models now commanding attention – such as global payment, accountable care, care coordination and pay-for-performance models – should provide new impetus for the adoption of medication adherence strategies, since they attempt to reward health care providers for sustaining good health and good health care outcomes and penalize providers for poor outcomes deemed preventable. Presumably, these innovations will reward faithful medication adherence because adherence will avert preventable illness and unnecessary medical spending.

Yet as the discussion above illustrates, a comprehensive strategy for medication adherence is likely to require upfront investment by physician practices in staff and practice infrastructure, and perhaps negotiation of alliances with external professionals such as community pharmacists. As of yet, physicians and other providers have little information to rely on in calculating the cost and potential return on investment in adherence strategies, including care team strategies.

At the same time, the existing fee-for-service system is likely to remain in place for many providers for some time to come, so adaptation of the fee-for-service model to support medication adherence could prove to be an essential step towards realistic improvement of medication adherence and chronic disease care. As noted earlier, existing fee-for-service payment systems support reimbursement of the "mid-level," non-physician providers on care teams, but the regulatory environment for their reimbursement is complex and inconsistent in ways thought to inhibit the hiring of non-physician staff.⁴⁶ The MTM benefit supports reimbursement of pharmacists, including pharmacists who act as virtual care team members from within community pharmacies. Pharmacist participation in the MTM benefit has been steadily increasing, according to the National Association of Community Pharmacists: 54 percent of community pharmacists received MTM reimbursements in 2009, a seven percent increase since 2007, suggesting once again that pharmacists are a resource that can be incorporated into new models of care team support for improved medication adherence.⁴⁷

A few, ongoing examples from the field provide some guidance. Community Care of North Carolina, for example, supports its Pharmacy Home Project through a per-member, per-month (PMPM) fee that currently totals \$3.50, although the PMPM underwrites tasks that go beyond adherence promotion. Blue Cross Blue Shield of Massachusetts has created a global payments plan (the Alternative Quality Contract, or AQC) that offers physician groups a global, risk-adjusted payment initially benchmarked to recent medical claims levels, with an inflation rider guaranteed, and a 10 percent pay-for-performance premium offered for achievement of HEDIS and outcomes measures. The performance measures do not, at least to-date, include adherence-specific indicators.

Conclusion

As NEHI President Wendy Everett and Harvard economist David Cutler put it in a recent article in *The New England Journal of Medicine, "*We've known for some time that improved adherence can lead to improvements in health outcomes and reductions in health care spending. What we haven't known is where to start."⁴⁸ Now a starting point is rapidly coming into view.

Accelerated deployment of health care IT, increasing interest in outcomes-based health care payment, the rising need for more effective management of chronically ill patients, and the growing need for team-based care: all of these trends represent critical building blocks for improving patient outcomes through medication adherence. National health care reforms will intensify these trends and could provide important new sources of financial support for the demonstration of effective strategies. Government policymakers, health care providers, payers, and the pharmaceutical and the pharmacy industries alike should now seize the opportunity by building a robust portfolio of demonstration projects throughout the country.

Notes and References

¹ Centers for Disease Control. And Prevention. Chronic Diseases, The Power to Prevent, The Call to Control, At a Glance 2009. <u>http://www.cdc.gov/chronicdisease/resources/publications/AAG/pdf/chronic.pdf</u>

² Anderson G. Chronic Care: Making the Case for Ongoing Care. Princeton, NJ: Robert Woods Johnson Foundation, 2010. Available at http://www.rwjf.org/files/research/50968chronic.care.chartbook.pdf. ³ New England Healthcare Institute. Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease – Summary of Findings. September 2009, Page 2;, Cutler DM, Long G, Berndt ER, et al. The value of antihypertensive drugs: a perspective on medical innovation. Health Aff (Millwood) 2007;26:97-110.

⁴ Osterberg L, Blaschke T, Adherence to Medication, N Engl J Med 353:487;

⁵ An overview of patient medication adherence strategies can be found in Thinking Outside the Pillbox: A system-wide Approach to limproving Patient Medication Adherence for Chronic Disease – Summary of Findings, New England Healthcare Institute, 2009

⁶ Okie S. Innovation in primary care- Staying one step ahead of burnout. N Engl J Med. 2008; 359:2305-2309

⁷ Bodenheimer T, Grumbach K, Berenson R. A lifeline for primary care. N Engl J Med. N Engl J Med 2009; 360:2693-2696

⁸ Østbye T, Yarnall K, Krause K, Pollak K, Gradison M, Michener JL. Is there time for management of patients with chronic diseases in primary care?, Ann Fam Med 3, no. 3 (2005):209-214

⁹ Schuetz B, Mann E, Everett W. Educating Health Professionals Collaboratively For Team-Based Primary Care. Health Affairs 29, NO. 8 (2010): 1476–1480

¹⁰ The Patient Centered Primary Care Collaborative defines the patient centered medical home this way: "The American College of Physicians, the American Academy of Family Physicians, the American Academy of Pediatrics and the American Osteopathic Association have jointly defined the medical home as a model of care where each patient has an ongoing relationship with a personal physician who leads a team that takes collective responsibility for patient care. The physician-led care team is responsible for providing all the patient's health care needs and, when needed, arranges for appropriate care with other qualified physicians." <u>http://www.pcpcc.net/joint-principles</u>

¹¹ Authorization for the Medicaid "health home" program is found at P.L. 111-148, Sec. 2703 defines a team of health care professionals as "physicians and other professionals, such as a nurse care coordinator, nutritionist, social worker, behavioral health professional, or any professionals deemed appropriate by the State". It can "be free standing, virtual, or based at a hospital, community health center, community mental health center, rural clinic, clinical practice or clinical group practice, academic health center, or any entity deemed appropriate by the State and approved by the Secretary".

¹² Authorization for the community health teams is found at P.L. 111-148, Sec. 3502

 ¹³ Views on disease management (DM) and patients' perceptions reflect views expressed in meetings of the New England Healthcare Institute Working Group on Care Teams and Patient Medication Adherence
¹⁴ Gellad W, Grenard J, McGlynn E. A review of barriers to medication adherence: A framework for driving policy options. RAND Health Technical Report, 2009

¹⁵ New England Healthcare Institute, "Beyond the Pill Box" available at <u>www.nehi.net</u>

¹⁶ Goldman DP, Joyce GF, Zheng Y, Prescription drug cost sharing, JAMA 298.1 (2007):61-69.

¹⁷ P.L. 111-148, Sec. 3026

¹⁸ Centers for Medicare and Medicaid. CMS Proposes Definition of Meaningful Use of Certified Electronic Health Records (EHR) Technology. Retrieved March 24, 2010, from

http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3564

¹⁹ Sokol, MC, McGuigan, KA, Verbrugge, RR, Epstein, RS. Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost. *Medical Care;* 2005;43(6):521-530.

²⁰ Wolters Kluwer Pharma Solutions, Inc., *Pharma Insight 2009: Patients take More Power Over Prescription Decisions (March 2010)*, <u>http://www.wolterskluwerpharma.com/Press/Pharma%20Insight%202009%20-%20Media.pdf</u>. ;

Kaiser Family Foundation, Prescription Drug Trends., May 2010

²⁴ Gellad, op cit, and Golden SH, Lazo M, Carnethon M, Berttoni AG, Schreiner PJ, Roux, AVD, Lee HB, Lyketsos C, Examining a bidirectional association between depressive symptoms and diabetes, JAMA. 2008;299(23):2751-2759

²⁵ Osterberg op cit; Katon W, Cantrell CR, Sokol, M, Chiao E, Gdovin JM, Impact of Antidepressant Drug Adherence on Comorbid Medication Use and Resource Utilization, Arch Intern Med, Nov 2005; 165: 2497 - 2503.

²⁶ Claxton AJ, Cramer J, Pierce C. A systematic review of the associations between dose regimens and medication compliance. Clin Ther 2001;23:1296-310.

²⁷ Coleman E, Smith J, Raha D, Min S, Posthospital Medication Discrepancies:

Prevalence and Contributing Factors. Arch Intern Med. 2005;165(16):1842-1847.

²⁸ New England Healthcare Institute, op cit; private communication with Dr. Enrique Caballero, Director, Latino Health Initiative, Joslin Diabetes Center

²⁹ McGorney C, The Adherence Estimator: a Brief, Proximal Screener for Patient Propensity to Adhere. Current Medical Research and Opinion. 25 (1) 2009, 215-238

³⁰ Bayoumi I, Howard M, Holbrook AM, Schabort I. Interventions to improve medication reconciliation in primary care. Ann Pharmacother. 2009 Oct;43(10):1667-75 Epub 2009 Sep 8.

³¹ Chernew, ME, Shah, MR, Wegh, A, Rosenberg, SN, et al. Impact of Decreasing Copaymetns on Medication Adherence Within a Disease Management Environment. *Healt Affairs* 2008; 27(1):103-112. ³² Donohue JM, Huskamp HA, Wilson IB, Weissman J. Who do older adults trust to provide information about prescription drugs? Am J Geriatr Pharmacother. 2009 Apr; 9(2): 105-16. PMID: 19447363; Wilson IB, Schoen C, Neuman P, Strollo MK, Rogers WH, Chang H, Safran DG. Physician-patient communication about prescription medication non-adherence: a 50 state study of America's seniors. J Gen Intern Med 2007; 22:6-12. PMID: 17351835

³³ Osterberg, op cit

³⁴ See literature review in New England Healthcare Institute, op cit

³⁵ A leading information therapy initiative, the IX Alliance, was recently folded into the eHealth Initiative, a national public-private partnership. See <u>http://www.ehealthinitiative.org/2009-11-24.html</u>

³⁶ For an argument on the significance of patient activation in systemic health care reform, see Judith Hibbard and Katherine Hayes, "Second Generation Consumerism: Increasing Consumer Activation to Improve Health Outcomes and Lower Costs for Patients with Chronic Disease," in *The Health Care Delivery System: A Blueprint for Reform,* Center for American Progress and the Institute on Medicine as a Profession, October 31, 2008

³⁷ Rollnick S, Miller, WR. What is motivational interviewing? Behavioral and Cognitive Psychotherapy. 23, 325-334 (1995)

³⁸ Osterberg, op cit

³⁹ New England Healthcare Institute. "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease."

⁴⁰ Hing ES, Burt CW, Woodwell DA. Electronic medical record use by office-based physicians and their practices: United States, 2006. Advance data from vital and health statistics; no 393. Hyattsville, Maryland: National Center for Health Statistics. 2007.

⁴¹ For example, see analysis from the American College of Physicians regarding nurse practitioner services: Nurse Practitioners in Primary Care: An American College of Physicians Policy Monograph, 2009

⁴² Surescripts. "National Progress Report on E-Prescribing." (2008). Available at http://www.surescripts.com/downloads/NPR/national-progress-report.pdf.

⁴³ Surescripts. Superscripts Knowledge Base. Available at <u>http://www.surescripts.com/support/knowledge-base/payerspbms/how-many-patients-can-surescripts-provide-access-to-prescription-benefit-and-prescription-history-information-for-on-behalf-of-connected-payers.aspx.</u>

²¹ Benner JS, Glynn RJ, Mogun H, NeumannPJ, Weinstein MC, Avorn J. Long-term persistence in use of statin therapy in elderly patients. JAMA. 2002 Jul 24-31;288(4):455-61.

²² Vanelli M, PedanA, Liu N, Hoar J, Messier D, Kiarsis K. The role of patient inexperience in medication discontinuation: a retrospective analysis of medication nonpersistence in seven chronic illnesses. Clinical Therapeutics. 2009 31(11); 2682-2652.

²³ Gellad op cit

⁴⁷ National Community Pharmacists Association. 2009 NCPA Digest. 2009.

⁴⁸ Cutler D, Everett W, Thinking Outside the Pillbox — Medication Adherence as a Priority for Health Care Reform. N Engl J Med 2010; 362:1553-1555. April 29, 2010

⁴⁴ Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL, Clinial pharmacists and inpatient medical care: a systematic review. Arch Intern Med. 2006;166(9):955-64.

⁴⁵ Smith M, Bates DW, Bodenheimer T, Cleary PD. Why pharmacists belong in the medical home. Health Affairs 2010; 29:5

⁴⁶ American College of Physicians. Nurse Practitioners in Primary Care: An American College of Physiciains Policy Mongraph. 2009.

Notes

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