In Brief

- Improved patient medication adherence in the U.S. depends in large part on whether adherence interventions can be successfully introduced into routine care processes in the daily practice of medicine.
- For many practitioners this will mean fitting patient medication adherence interventions within medication management processes at a point when medication management as a whole needs to be improved to meet goals for patient safety and therapeutic effectiveness.
- Innovative models of medication management – such as Medication Therapy Management or MTM – have been shown to yield improvements in patient outcomes and in reducing downstream medical costs. But these innovative models have not yet achieved wide-scale adoption.
- To achieve wider adoption of medication management and patient medication adherence interventions, stakeholder groups should coalesce around supportive policies that will help providers target, calibrate and deliver core medication management and patient adherence services to diverse patient groups in diverse ways.
- While stakeholders, particularly payers, may require sustained proof before intensive forms of service (such as MTM) are made available to greater numbers of patients, all stakeholders should rally around more limited goals that could promote patient medication adherence more quickly, such as refill synchronization.

Introduction

Poor patient medication adherence is now widely recognized as a serious problem in U.S. health care. It is the target of a major public awareness campaign (the National Consumers League’s Script Your Future campaign) and advocacy from the U.S. Surgeon General. Some employers are striving for better patient medication adherence by offering employees incentives through value-based health insurance benefits, as evidence has shown that reduced patient cost-sharing can improve adherence, albeit modestly. Recently, as reduction of avoidable hospital readmissions has become a widely-shared goal, improvement in patient medication adherence has come to be seen as an essential step in post-discharge care.\(^1\)

For most patients, prescription drugs are ordered by clinicians in the course of routine or chronic care. It seems unlikely that significant and lasting improvements in patient medication adherence will occur unless community-based providers and the daily practice of...
medicine support good adherence behavior among patients. But for many clinicians, decisions on how to improve patient medication adherence are part of a larger decision-making process on how to improve medication management overall. The decision to invest time, money and staff in interventions to improve adherence must be considered alongside investments in improved patient medication safety, as well as steps to improve effective prescribing and appropriate medication use. Thus, a critical variable in how the U.S. health care system will improve patient medication adherence is how the health care system will improve its use of medications overall.

Many factors are driving the need for community-based providers to take a “big picture” view of medication use. Chief among them is the increasing burden of chronic disease treated by prescription medications, particularly in seniors, as they are among the growing number of patients with multiple chronic conditions. These patients frequently take multiple medications as part of medication regimens that can be highly complex, thus creating more intense demand for good medication management practices, including steps to enhance patient understanding and adherence. Meanwhile, public and private payers are increasingly tying provider reimbursements to performance on quality measures, including many which pertain directly to medication use. Many of these measures are designed to promote evidence-based prescribing and medication safety, but many also hinge, directly or indirectly, on the success of the overall medication regimen, and hence on adherence. Recently, two Medicare programs – Medicare Advantage and the Part D prescription drug program – began to evaluate each of their participating, private-sector partners on the medication adherence rates of member-patients.

Innovative models of medication management, such as Medication Therapy Management (MTM), have been shown to have promising impacts on patient outcomes and on reducing downstream costs. But for the most part they have not yet achieved wide-scale adoption. The good news is that ongoing changes in the health care delivery system could accelerate progress.

Efforts to reduce avoidable hospital readmissions are driving innovative approaches to medication management through the deployment of transitional care services. (These approaches are reviewed in a prior NEHI issue brief.) Other ongoing approaches are creating both infrastructure and delivery vehicles for improved medication management and patient adherence. Among the most important changes are those in Health Information Technology (EMR deployment, health data exchange, electronic prescribing); care coordination (the Patient Centered Medical Home); and quality measurement (adherence-related metrics, such as those of the Pharmacy Quality Alliance). The challenge for health care stakeholders (patients, providers, and payers alike) is how to best exploit the opportunities created by these ongoing changes so as to accelerate progress on patient medication adherence.

NEHI believes that this challenge can only be met if stakeholder groups continue to coalesce around common policy goals and common objectives for performance in the field. For this to happen, stakeholders must also coalesce around a common understanding of the problems in medication management and patient adherence, and a shared understanding of the mechanics of medication management.

Current Models of Medication Management

Thinking on medication practice has evolved considerably over the last 30 years, resulting in numerous terms that may be well understood by one group of stakeholders but not by others. One point to make at the outset is that some concepts pertain to models of care (describing
what gets done for the patient), others pertain to practice models (describing who it is that performs services for the patient), while some pertain to both at once. This is a critical distinction, as a frequent stumbling block to adoption of new medication practices is disagreement on whether or how to assign medication tasks to non-physicians, including nurses and pharmacists.

Two concepts are of particular relevance here:

- Comprehensive Medication Management (CMM) and pharmaceutical care; and
- Medication Therapy Management (MTM)³

**Comprehensive Medication Management**

Comprehensive Medication Management (CMM) is a systematic review of all drugs, both prescribed and over-the-counter, and other substances (such as dietary supplements) taken by an individual patient as prescribed by any and all prescribers. It is an expansive model in which medication review is coupled with a clear action plan, patient counseling and appropriate follow-up care.⁴ The CMM concept received an early test in 2005 in Minnesota, where the state Medicaid program adopted a CMM-inspired program to cover Medicaid beneficiaries with a service Minnesota labels as Medication Therapy Management (MTM), (as distinct from the Medicare MTM benefit.) The Minnesota Medicaid MTM benefit now serves as the model for Comprehensive Medication Management. As defined in statute, these services include the following provided by a licensed pharmacist (or other qualified individual):

1. Performing or obtaining necessary assessments of the patient’s health status;
2. Formulating a medication treatment plan;
3. Monitoring and evaluating the patient’s response to therapy, including safety and effectiveness;
4. Performing a comprehensive medication review to identify, resolve and prevent medication-related problems, including adverse drug events;
5. Documenting the care delivered and communicating essential information to the patient’s other primary care providers;
6. Providing verbal education and training to enhance patient understanding and appropriate use of the patient’s medications;
7. Providing information, support services and resources designed to enhance patient adherence with the patient’s therapeutic regimens; and
8. Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient.⁵

Adherence is one part of the many steps involved in comprehensive medication management, and the CMM model envisions a high degree of coordination among providers and ready access by the pharmacist to complete a patient history as well as a patient’s medication history. In practice, provider organizations and payers have faced a challenge in developing and implementing a business case to fund ongoing CMM.

**Medication Therapy Management**

In creating the Medicare Part D prescription drug program, the Medicare Modernization and Improvement Act of 2003 also created a Medication Therapy Management benefit. The Medicare Part D statutes outline a large menu of goals for Medicare MTM services, and patient medication adherence is one of them. (Medicare MTM "may include elements that promote….increased enrollee adherence with prescription medication regimens."⁶) However,
the Medicare MTM benefit has distinct limitations in eligibility, scope and the intensity of services covered.

The Medicare Modernization Act set minimum thresholds for beneficiary eligibility, and gave Medicare Advantage plans and the newly-created Medicare Prescription Drug Plans (PDPs) flexibility to impose further eligibility thresholds. The plans were required to offer MTM services to eligible patients, but patients had to affirmatively agree (opt-in) to services. The Centers for Medicare and Medicaid Services (CMS) imposed a minimum set of elements on MTM offerings: they were to entail interventions for both beneficiaries and prescribers; include an annual comprehensive review conducted by a pharmacist or another qualified provider; the review could be conducted or communicated in person, or over the telephone; a patient medication action plan and a personal medication list were to be created out of the review; and health plans were to undertake ongoing reviews of targeted patients on a quarterly basis. Beyond this minimal set of elements, plans were given latitude to specify the services that were to be delivered as well as to design the documentation used in providing services to patients.

Several leading pharmacy licensing, industry and professional associations converged on a common definition of MTM services as CMS prepared to launch the MTM benefit, resulting in a “consensus definition” released in 2004. Some of the same organizations have since refined their definitions of MTM even further. These new definitions mostly overlap the Medicare definition but differ in three important respects:

1. Most, but not all, call for face-to-face delivery of MTM services;
2. They generally define good MTM as including not only an assessment of a patient’s existing medication orders, but also a review of the patient’s medical condition sufficient to reveal gaps in therapy and existing medication-related risks; and
3. They call for affirmative steps to resolve any problems identified in the review, either by immediate referral to prescribers or through intervention by the pharmacist themselves.

In short, these definitions of MTM come closer to the vision of comprehensive medication management than what is generally provided in current practice.

Medication Therapy Management in Medicare Part D
While Medicare Advantage and Medicare PDPs have expanded eligibility and intensified services since 2006, the number of Medicare beneficiaries who have received MTM has been low. CMS reported that 2.8 million Part D beneficiaries participated in MTM in 2010 out of approximately 28 million Part D enrollees, representing about a 10 percent eligibility rate. CMS had previously predicted that as many as 25 percent of enrollees would be eligible.

In addition, CMS has not been able to document improvements in the resolution of drug therapy problems (DTPs) or in patient medication adherence as a result of MTM. Program performance reported by CMS shows a wide variation in practices. For example: in 2010, 82 percent of plans offered a written summary of MTM reviews to patients, 58 percent offered a written action plan, and only 27 percent offered face-to-face consultation with patients. All Medicare Advantage and Medicare prescription drug plans (PDPs) reported communicating results of MTM reviews to prescribers, but communication was mostly by fax machine (92 percent). Furthermore, only 17 percent of programs reported sharing patient medication lists with prescribers.

MTM and the Affordable Care Act
The Affordable Care Act mandates a number of changes to the Medicare MTM benefit designed to improve the service and expand its uptake among beneficiaries. Some of these changes
were implemented in 2010, while others go into effect in 2013. Eligible beneficiaries must now affirmatively opt-out of MTM service. In addition, plans must assess at-risk patients not currently enrolled in MTM services on a quarterly basis. Plans must also provide more detailed reports on the actual interventions delivered to patients through MTM and the number of MTM-eligible enrollees who receive an annual comprehensive medication review. This last statistic will become a publicly reported quality measure of each plan in 2013. Finally, all plans will now be required to use a standardized format for both a summary of the patient’s comprehensive medication review and a patient’s medication action plan. For the first time, patients will now see identical documents no matter which health plan or drug plan they choose in a given year.

Commercial MTM and Disease Management
A robust MTM vendor industry segment has grown over the last 15 years. MTM vendors began to sell MTM services to self-insured employers in the late 1990s, well before enactment of the Medicare Part D drug benefit. Estimates of the total MTM market are now over $11 billion.\textsuperscript{13}

A number of other key concepts are reviewed in more detail in Appendix I, including:

- Medication reconciliation – a model of care now largely associated with hospital practice
- Clinical pharmacy – a practice model pertaining to utilization of pharmacists
- Collaborative drug therapy management (CDTM) – a practice model pertaining to physician-pharmacist cooperation
- Pharmaceutical care – neither a model of care nor a practice model, per se, but an overarching concept regarding effective administration and management of medication use
- Disease management – A long-standing care concept (and industry), not specific to medication use, but frequently focused on patient medication use

Increased Adoption of Medication Management and Patient Medication Adherence Interventions: Key Issues

While uptake of medication management practices such as MTM have been limited up to this point, there are promising changes in the field for medication use.

MTM vendors report that as much as 40 percent of their MTM business is with commercial (non-government) payers, such as health plans, prescription drug plans and pharmacy benefit managers. In the Medicare program, both Part D prescription drug plans and Medicare Advantage plans are now rated (through the Star ratings) on the medication adherence performance of subscriber patients; through 2015 the highest-rated Medicare Advantage plans are eligible for performance bonus payments.

Of equal or greater significance is a change in outlook by the Congressional Budget Office. In November 2012, the CBO announced it will henceforth credit increases in prescriptions filled by Medicare patients with offsetting reductions in medical service spending. CBO will credit a 5 percent increase in the number of prescriptions filled with approximately 1 percent in reductions of medical spending.\textsuperscript{14} The Centers for Medicare and Medicaid Services (CMS) has also indicated a willingness to consider approval of new models of payment for the integration of Medicare Part D drug plans with Medicare Accountable Care Organizations (ACOs), in the interest of better and more comprehensive medication use that will act to drive down rates of total or per capita medical spending.\textsuperscript{15}
These changes represent a strengthening commitment by government and private sector payers to pay for the results of improved medication management and patient medication adherence interventions. However, providers still face a complex challenge in determining how to structure and deliver services on a cost-effective basis. Determinations relative to adherence-specific services are particularly challenging, as adherence services may well be a secondary consideration to adopting services that eliminate drug safety, drug interaction and drug-related problem (DRP) concerns, and because the published evidence base on effective patient medication adherence interventions is still viewed as inconclusive.\(^{16}\)

At least three issues are at play in determining cost-effective strategies for medication management that include a strong focus on improved patient medication adherence:

- **Targeting**: Identifying which patients should be offered services from the standpoint of potential benefits to patient health as well as potential medical spending costs that could be averted

- **Comprehensiveness**: Determining how extensive a set of medication management services should be offered to patients, including the breadth of services that target medication adherence (services such as patient and family caregiver counseling, use of reminder technologies, motivational interviewing and other interventions)

- **Intensity**: Determining how intensive services should be for each identified patient, and how long the level of intensity should be maintained. For example, providers need to determine which services should be initiated on a face-to-face basis and how long they should be sustained before they might be transitioned to less costly forms of delivery, such as telephone-based contact.

In order to create further momentum for improved medication management and patient medication adherence, public policy, private sector reimbursement policy and other relevant private sector policies need to coalesce around support to solve the cost effectiveness challenge. Moreover, supportive policy needs to address several different challenges within this problem.

Among the issues identified in NEHI research and by experts at NEHI roundtables are the following:

**Diverse patient populations**: Current health care quality metrics that are pertinent to medication use are mostly targeted at fairly narrow measures of diabetes care, cardiovascular disease care and the use of medications that are specific to those conditions. Patients with multiple chronic conditions and with mental and/or behavioral health issues are among the most seriously ill and potentially costly patients in the U.S. health care system. Medication management and patient medication adherence interventions need to be broadened to address the complexities of care for these patients, including problems of "concurrent" adherence to multiple medications.

**Consistency of standards**: While supportive policy should address broader groups of patients currently at risk, stakeholders should strive to make standards of eligibility for service more consistent across health plan and provider groups, in order to improve awareness and uptake of services by patients and by providers at the point of care (physician teams, community pharmacists, etc.).\(^{17}\)
Diverse providers: Currently health care quality metrics and financial incentives that are specific to patient medication adherence are mostly targeted at drug benefit plans and to pharmacies. Metrics of physician medication practice are, at best, only indirectly related to patient adherence. Stakeholders could jointly examine whether existing physician metrics could be balanced with adherence-specific metrics without unduly burdening physician practices.

Diverse practice settings: At present highly integrated health care systems, such as Kaiser Permanente, offer examples of successful, advanced medication management and care coordination processes. The vast majority of U.S. patients do not receive their care from such highly integrated systems, however, and depend on “virtual” teams comprised of their physicians, physician staff (if any) and external pharmacists for their medication-related care. Stakeholders need to be directly supportive of collaboration among these virtual team members, including direct communication of patient data and prescription orders, and delegation of tasks throughout the team on a clinically-effective and cost-effective basis.

Recommendations from the Experts

Proponents of improved medication management and patient medication adherence generally believe that the health care system should make top-to-bottom improvements that will tighten medication use and create greater accountability among both providers and patients for medication use that delivers the therapeutic value prescription drugs can provide. This would help achieve what University of Connecticut pharmacy educator and researcher Marie Smith, PharmD, has called an improved “medication ecosystem.” Some of the most significant changes, such as expanding patient eligibility for the Medicare MTM benefit, will undoubtedly require greater support from evidence gleaned in the field. Thus, a continuing recommendation heard at NEHI’s roundtable events is a recommendation for expanded research in the field on interventions that are scalable throughout the health care system.

Other important recommendations have also been heard at NEHI’s ongoing series of policy roundtables on patient medication adherence, and include some of the following:

Refill synchronization: Evidence developed by Dr. Niteesh Choudhry and others suggests that synchronizing prescription refills and reducing the number of visits a patient must make to the pharmacy can improve adherence. Refill synchronization could be a goal for care coordination and collaboration among prescribing physicians and dispensing pharmacies.

Face-to-face communication: CVS Caremark Vice President, Anita Allemand, pointed out that face-to-face communication with patients (such as face-to-face communication between pharmacists and patients) has been proven to be as much as three times more effective than telephone communication. Policymakers should consider encouraging face-to-face communication, at least for early, potentially high-impact meetings between patients and providers.

Pharmacy home: Dr. Choudhry and others point to the value of a “pharmacy home,” a single pharmacy point of contact for patients who might otherwise visit multiple pharmacies to fill multiple prescriptions. A “pharmacy home” that centralizes the collection and dissemination of patient medication data is utilized as part of the widely-noted care coordination strategy deployed by North Carolina’s Medicaid program (the Community Care of North Carolina network) to ensure that patients with multiple medications receive coordinated and consistent care.
Patient-Provider relationships: Many practitioners point to the importance of building a trusting relationship between patients and their care teams, including physicians, physician staff, and professionals outside the physician practice, such as community pharmacists. Relationship building takes time. In turn, public policy and private sector practice should support the time necessary to build solid relationships, particularly as many providers are transitioning to models of team-based care, such as the patient-centered medical home (PCMH). Frequent transitioning of patients from one health plan to another may undermine the relationship-building process, at least for some patients.

Value-based prescription drug benefits: Although some patients may prove non-adherent at any medication price, experts pointed to research on private sector health plans showing that value-based plans that lower out-of-pocket costs for patients have been shown to improve medication adherence.

Drug Utilization Review (DUR) and Medication Therapy Management: Former MedPac Commissioner Dr. Bruce Stuart of the University of Maryland encouraged health plans to take a holistic view of drug utilization by merging their drug utilization review processes with internal planning for MTM services, and in turn, optimizing the results of investment in drug therapy.

Improvements to the Medicare MTM benefit: Potential improvements suggested by Dr. Stuart also include: a rigorous re-analysis of MTM eligibility criteria to shift eligibility standards to more scientifically validated criteria; inclusion of each Medicare drug plan’s MTM targeting criteria in their Star ratings reports; inclusion of each plan’s MTM outcomes in their Star ratings; and added reporting by the Medicare drug plans on ongoing results and progress in their MTM programs.

Further investments in research: Practitioners and researchers alike urged that research funding (government and non-government) be directed towards replication studies that will prove out the effectiveness of medication management and patient adherence strategies across diverse practice settings and among diverse populations. Research on patient medication adherence to date has relied mostly on one-off studies that provide insufficient evidence for adoption and reimbursement policy.

Conclusion

Dr. Choudhry, who is one of the nation’s leading adherence researchers, has suggested that successful interventions to promote patient medication adherence will have to “exploit existing care processes and communications channels” in order to be scalable and achieve a broad impact in our health care system. Many, if not most, providers see patient medication adherence as part of the larger process of prescribing and dispensing safe, appropriate and effective medications to meet a patient’s individual medical needs; in turn, they see adherence interventions as part of a process of medication management. The challenge for stakeholders is to identify supportive policies that will allow providers to deliver core medication management interventions that include adherence to diverse groups of patients in diverse settings. This includes the settings that pertain to the majority of U.S. patients, who rely on collaboration (or “virtual teamwork”) among prescribing physicians, non-physician staff and professionals such as community pharmacists who operate outside the physician practice.
Appendix I – Related Medication Management Components

Medication Reconciliation
Medication reconciliation entails compilation of an accurate list of all prescription and over-the-counter drugs, including dietary supplements, ordered for a patient and assessing the final list for potential interactions and safety risks. Long recognized as a best practice, it has only recently been mandated by accrediting bodies. “Med rec” is generally viewed as a practice that can be carried out by any qualified provider (nurse, pharmacist, physician) but under the supervision of a physician unless the physician’s authority is expressly delegated, as through a collaborative practice agreement (see below.)

The Joint Commission made routine medication reconciliation a requirement for hospital accreditation in 2006, but was subsequently forced to suspend enforcement of its standard in 2009 as implementation in the field proved complex and the hospital community could not coalesce around a standard process.

The Joint Commission has otherwise incorporated medication reconciliation into its National Patient Safety Goals (NPSG); an initial goal was replaced and revised within a new goal (NPSG #3) on safe medication use that applies to both hospitals and outpatient care organizations.23

Clinical Pharmacy
“Clinical pharmacy” is not a model of medication management, per se, but the discipline of clinical pharmacy undergirds many if not all of the models of medication management that have emerged in the last 25 years.

Clinical pharmacy refers to pharmacy practices (i.e. actions of trained pharmacists) that involve actual clinical decision-making on behalf of patients, as opposed to simple dispensing of drugs by pharmacists to patients.

This expanded vision of pharmacy practice has completely transformed pharmacy education in the United States. After years of debate, the American Council for Pharmacy Education adopted new standards in 2000 that made a doctoral level (Pharm D.) degree the new “entry level” credential for practicing pharmacists, replacing the bachelor’s (B.S. Pharm) degree. The Pharm D. degree requires six years of schooling, 2000 hours of work in supervised practice settings and a six-month externship. The new standards went into effect in 2003. The PharmD degree specifically trains pharmacists for expanded responsibilities in medication management.

As with the expansion of the Advanced Practice Nursing (APN) and the Physician Assistant (PA) disciplines, the clinical pharmacy field challenges traditional scope-of-practice boundaries that are typically imposed by state law and reserve most decision-making to physicians unless decisions are expressly delegated. Scope-of-practice boundaries are a major factor and – depending on one’s perspective, a major barrier- to full realization of emerging models of medication management such as Comprehensive Medication Management (CMM) or Medication Therapy Management (MTM).

Federal health agencies have pioneered models of care in which substantial authority is delegated to pharmacists. These models include pharmacist-led primary care, a model adopted by the federal government’s Indian Health Service in the 1970s. The IHS model delegates some prescribing authority to pharmacists, and continues in practice to this day.24 Pharmacist-led primary care is also utilized within the Veterans Health Service.25
Collaborative Drug Therapy Management (CDTM)
Collaborative Drug Therapy Management (CDTM) is rooted in collaborative practice agreements. Collaborative practice agreements are regulated under state laws (or through federal agency guidelines, in the case of federal health services), and allow physicians to delegate various medication-related tasks to pharmacists, including authority to prescribe and to adjust prescribed dosages, typically on a practice site-specific or condition-specific basis.

After pharmacist authority to prescribe was curtailed by the Food, Drug & Cosmetic Acts of the 1930s-1950s, California began limited experimentation with pharmacist prescribing in the 1980s. Over 38 states now authorize some form of collaborative practice agreement.26

Collaborative Drug Therapy Management is carried out through formal collaborative practice agreements, but the CDTM concept is more expansive than a simple delegation of tasks from the physician to the pharmacist. As defined by pharmacy organizations, CDTM is collaboration in which the pharmacist becomes a team member with the physician and physician-led staff. Within formal, defined agreements the pharmacist may be permitted to conduct patient assessments, order lab tests, administer drugs, and select, initiate, monitor, continue and adjust entire drug regimens.27
References

2. Ibid.
3. Related medication management concepts – such as medication reconciliation, clinical pharmacy and collaborative drug therapy management (CDTM) – are explained in more detail in Appendix I.
7. These included multiple chronic conditions, multiple Part D drug prescriptions, and annual per patient drug spending of $4,000, a threshold that was later reduced to $3,000.
8. A mail option was also provided for and later dropped.
12. Ibid.
16. For examples, see the recent systematic review on medication adherence interventions commissioned by the Agency for Healthcare Research and Quality.16
19 Remarks of Marie Smith, Pharm D, Professor, University of Connecticut School of Pharmacy, at NEHI Roundtable on Hospital Readmissions and Patient Medication Adherence, American College of Cardiology, Washington D.C., July 27, 2012.
21 See Community Care of North Carolina at https://www.communitycarenc.org/population-management/pharmacy/.
25 Ibid.
27 Ibid.