Get the Medications Right:
A Blueprint for Change

Optimize medication use through patient-centered, team-based care leveraging health information technology, precision medicine and value-based payment models

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GTMRx Institute™

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ACKNOWLEDGEMENTS

Make a habit of two things: to help; or at least to do no harm.
— Hippocrates

Where did modern medication use veer from this discipline? We hold in our hands an overabundance of options to heal. It requires prudence to use them deliberately, which is wise, because their power can unleash great harm as well.

Our journey to optimized medication use that helps, without harm, requires a roadmap. We are grateful to the numerous willing guides who helped us plot the route. First and foremost, the GTMRx Board of Directors set a high standard for all, contributing financial support and ongoing, active engagement. These incredible leaders have made the GTMRx mantra their own; we are sincerely grateful for their strategic guidance and investment in the organization.
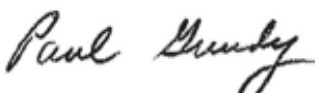
Early in the process, Susan Dentzer, senior policy fellow at the Duke-Robert J. Margolis, MD, Center for Health Policy, committed her support as moderator for our Executive Roundtable. A longtime voice in health care policy and leadership, her intellect and instincts were invaluable in this effort.

We were likewise fortunate to gain the early support of Carolyn Clancy, MD. In her role as deputy undersecretary for discovery, education & affiliate networks, Veterans Health Administration, Dr. Clancy contributed informed leadership and an enlightened voice in support of team-based care that relies on medication experts for improved outcomes.

The appropriate setting and parameters for discussion and deliberation are essential to produce fruitful results. We are grateful to Anand Parkeh, MD, chief medical advisor for the Bipartisan Policy Center, for his partnership and support. His experience in tackling thorny health policy issues, as well as his steadfast commitment to prevention and the collaborative process, were critical.

We are also indebted to our GTMRx workgroups, who devoted months of deliberation, research and thoughtful discussion to the process. That body of work was the basis for the Executive Roundtable, which convened 50 national thought leaders and invited guests. To these we are also grateful, as their guidance, feedback, and candid insight greatly influenced the shape of this blueprint.

As shepherds of the effort to get the medications right, we feel the weight each day to move closer to a system in which every individual's medication needs are carefully considered and wisely administered. We are fortunate to awaken daily to the knowledge that more than 900 GTMRx members not only have our backs, but also share this ambitious goal. You share our struggles and deserve the laurels when we've accomplished our task.

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EXECUTIVE SUMMARY

On Feb. 6, 2020, the GTMRx Institute hosted its first public event with the Bipartisan Policy Center (BPC), called *"Get the Medications Right: Innovations in Team-Based Care."*

Afterward, more than 50 national thought leaders convened for a six-hour Executive Roundtable discussion, moderated by Susan Dentzer, MA, senior policy fellow, Duke-Robert J. Margolis, MD, Center for Health Policy.

The GTMRx Institute used the BPC morning session, the Executive Roundtable discussions and six months of work from the Institute's four workgroups to inform this Blueprint for Change.

The Blueprint creates a roadmap for the Institute's work as we move forward over the next 12 to 24 months to engage physicians, clinical pharmacists and other team members who share a complete commitment to medication optimization. We will accomplish this by providing tools, data, practice standards and implementation resources to advance their ability to optimize medication use in their own settings.

All this is designed to ensure all Americans have access to a personalized, patient-centered, systematic and coordinated approach to medication use—one that will vastly improve outcomes and reduce overall health care costs.

Almost 75% of patients leave their physician's office with a prescription[1], and nearly one-third of adults in the U.S. take five or more medications.[2] Comprehensive medication management (CMM) addresses medication therapy problems, thereby improving medication-related outcomes.

Failure to ensure appropriate use of medications comes with a tremendous human toll. Avoidable illness and death resulting from non-optimized medication therapy led to an estimated 275,000 *avoidable* deaths in 2016. The cost: $528.4 billion.[3] That's 16% of the annual $3.2 trillion in U.S. health care expenditures.

We can change that with a collective call for medication management reform.

Our ability to optimize medication use is within our reach, but we must first align systems of care to integrate comprehensive medication management. We must engage and support patients to ensure they are willing and able to take those medications that are indicated, effective and safe. And we must support and pay for a patient-centered, team-based medication use process called CMM.

We know that appropriate diagnosis, bringing clinical information to the point-of-care through health information technology, and access to advanced and complementary diagnostics are essential ingredients to target correct therapies. We also know success requires team-based, patient-centered care models that recognize appropriately skilled clinical pharmacists—medication experts working in collaborative practice with physicians and other providers.

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1   https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2016_namcs_web_tables.pdf
2   https://psnet.ahrq.gov/primer/medication-errors-and-adverse-drug-events
3   Watanabe, JH, McInnis, T, and Hirsch, JD. "Cost of Prescription Drug–Related Morbidity and Mortality."
    Annals of Pharmacotherapy, 2018; 52(9), 829–837..org/10.1177/1060028018765159.

What We Learned

Optimal patient care requires optimal medication use

Optimal patient care cannot happen without a systematic approach to medication use. Medication-related problems are a top preventable cause of serious adverse health events and hospital readmissions.[4] Because of suboptimal therapy, patients are not reaching their treatment goals. However, being on the right medications at the right time indirectly says you will discontinue unnecessary medications.

The way we manage and evaluate medication use matters. We must move to a more rational, team-based, systematic approach to medication therapy management that effectively and efficiently connects the *right* medications to the right patient with the right dosage at the right time, taken as intended in order to reach clinical goals of therapy.

BOTTOM LINE: Medication management reform is essential to ensure appropriate use of medications and gene therapies. The evidence is clear: Practice-level integration of medication optimization efforts improves patient care, leading to better outcomes, decreased health system costs and improved overall access to care.

Achieving medication optimization requires a more rational, patient-centered, team-based and integrated approach called comprehensive medication management

We cannot expect to succeed if we address medication therapy problems (inadequate therapy, unnecessary therapy, dose too high, adverse reaction and non-adherence[5]) through discrete and non-aligned activities. Change requires an evidence-based pharmaceutical care process called comprehensive medication management (CMM).

BOTTOM LINE: Transformation cannot be piecemeal (e.g., adherence program only). No matter how promising individual elements of comprehensive medication management are, their impact is minimal unless all team members understand their role, are engaged and CMM is integrated into the practice.

The evidence supports comprehensive medication management

Practices around the country demonstrate the value-proposition for CMM each day. The financial return on investment (ROI) of team-based medication management services has been well documented "to average around 3:1 to 5:1 and can be as high as 12:1, resulting in a reduction in the direct mean medical cost of between $1200 and $1872 per patient per year for each of the first 5 years for those patients with chronic diseases such as diabetes, cardiovascular health issues, asthma and depression."[6] The evidence of its effectiveness continues to grow. It has been shown to improve the health of populations, enhance the experience of care for individuals, reduce the per capita cost of health care and improve physician satisfaction.

BOTTOM LINE: CMM works well when an integrated team functions cohesively. It fulfills all four elements of the Quadruple Aim: improve clinical quality, cost savings, patient outcomes and physician satisfaction.

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4   OIG Report on Preventable Serious Adverse Events in Hospitalized Medicare Patients. https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf
5   Comprehensive Medication Management in Team-Based Care. American College of Clinical Pharmacy. https://www.accp.com/docs/positions/misc/CMM%20Brief.pdf
6   Cipolle RJ, Strand L, and Morley P. Pharmaceutical Care Practice: The Patient Centered Approach to Medication Management. Third Edition. New York, NY: McGraw-Hill Medical; 2012.

Optimal medication use requires better data

Medication optimization relies on having the *right* data at the right time at the point-of-care. That data must be *actionable.* It must be *useful* to the care team. Only then will the care team be equipped to provide CMM services to patients who need it. Lack of availability and access to clinical information at the point-of-care greatly limits community-based interdisciplinary teams from efficiently providing and performing all elements of CMM.

BOTTOM LINE: By liberating data and overcoming barriers to information access through technology, all members of the patient care team have full access to all relevant clinical and health care data necessary to provide a patient-centered approach to medication management through CMM services—at the point-of-care.

Data must be actionable

Providers and patients must have secure and timely access to the information necessary to

- identify patients who have not achieved clinical goals of therapy,

- identify all drug therapy problems, and

- collaboratively develop a care plan.

This information must be available at the point-of-care in a usable format. For example, pharmacogenomics (PGx) results that are today added to the EHR as non-discrete data (e.g., PDFs) must be fully integrated. This will enable more useful clinical decision support and the ability to query data in the service of CMM.

BOTTOM LINE: Medication optimization relies on comprehensive and validated data. Current health information technology systems do not capture the appropriate data needed to comprehensively manage a patient's medication regimen or evaluate whether clinical goals of therapy have been met.

Optimal medication use may require advanced diagnostics

Precision medicine enabled by advanced diagnostics enhances the provider's knowledge of an individual's response to a specific drug. Problems such as incorrect dosing and adverse drug events can be avoided with use of advanced and complementary diagnostics to target correct therapies informing the medication plan created during the CMM process.

BOTTOM LINE: Education about the use and benefits of companion and complementary diagnostic testing (to include pharmacogenomic testing) will enable the care team to optimize medication use. There is an immediate need to better understand availability and application of PGx tools and results.

New payment models will be necessary for broad access to CMM

The movement to payment for value rather than volume necessitates new ways of managing and paying for care. As with most practice-level solutions, financial incentives will drive much of the expansion and scaling needed for broad adoption and access. Payment systems are starting to evolve, but fundamentally, they are grounded in fee-for-service (FFS) models.

BOTTOM LINE: As CMM is scaled up, it will require a move away from FFS to value-based models. For value-based models to succeed, they will need CMM. However, changes in how we pay for CMM must start now, even within the current FFS payment models.

Health insurance plan sponsors save more than money from medication optimization

Inherent within plan sponsorship is the fiduciary responsibility to assure that plan assets are used appropriately. Assuring the right medication is used at the right dosage, as intended, the first time significantly reduces liability risks for fully insured and self-insured plan sponsors.

BOTTOM LINE: CMM is a valuable liability protection tool for sponsors of health care insurance.

Medication optimization provides patients with more than health improvement

As patients take on greater amounts of cost share and first-dollar payments for their health care claims, avoiding ineffective medications has become a key financial priority.

BOTTOM LINE: CMM is a valuable financial conservation tool for health care consumers, enabling them to answer, "Is this the right medication for me?"

Inability to meet desired clinical outcomes is an important trigger for identifying patients who can benefit the most from comprehensive medication management

BOTTOM LINE: A risk stratification process should be used to identify those in a patient population who would most benefit from CMM. The level of need varies by patient population.

Medication optimization leadership requires buy-in and an organizational supporting culture

Engagement and buy-in from key stakeholders—those who pay for care, those who provide care and those who receive care—as well as a supporting culture that embraces change management, the interpersonal team approach, and inclusion of the patient as an equal team member are needed components to drive progress in medication optimization.

BOTTOM LINE: Strong practices that support a culture focused on medication optimization through CMM will improve patient outcomes.

Action Changes Things: Steps in Moving Forward

What Needs to Be Done Now?

✓ Practice and Care Delivery Transformation

- Identify evidence to promote the value of optimized medication use for payors, consumers and providers.

- Develop tools to engage and educate key stakeholders (patient advocacy organizations, professional groups, physicians, caregivers, care teams, consumers, pharmacists, and employers) to gain support for a standardized definition and process for CMM.

- Further develop the essential structures and language of value-based agreements within CMM services.

- Offer guidance and use cases to key stakeholders on contract standards and the consistent practice of CMM in clinical care.

- Identify leadership and champions to ensure more rapid practice transformation nationwide.

✓ Precision Medicine Enablement via Advanced Diagnostics

- Fully integrate PGx services into the pharmaceutical care process to support useful clinical decision making through increased availability of data.

- Ensure providers and payors have secure and timely access to the information necessary to identify patients who have not achieved clinical goals of therapy.

- Optimize testing usefulness and interpretation by strengthening the relationship between the FDA and laboratories that provide PGx testing.

- Promote precision medicine literacy among providers and patients in the context of its application to the clinical care role in optimizing medication use.

- Enable evidence-based processes and strategies that support precision medicine as a tool used in the CMM process and enable effective standardization, awareness and interpretation.

✓ Payment and Policy Solutions

- Identify foundational elements of policy solutions necessary to overcome barriers to the adoption of CMM and optimization of medication and gene therapies.

- Identify successful use cases for utilization in advocacy and coalition building.

- Identify payment solutions and policy and payment strategies that reward the value of CMM services in terms of cost, quality and patient outcomes.

- Design an approach to educate and engage policymakers about CMM.

✓ Health IT to Support Optimized Medication Use

- Work with regulators, practice organizations and industry to establish standards and best practices that drive standardization and interoperability.

- Develop guidance for health IT requirements to support the successful integration of CMM services.

- Aggregate and integrate new data to help support optimized medication use through AI (e.g., social determinants of health, PGx, clinical analytics, genomic risks, population health).

- Promote utilization of AI-enabled risk stratification tools to support population health management to aid health systems, payors and prescribers in patient identification for CMM services.

- Further develop and share the Health IT/ AI Maturity Matrix & Leadership IT Checklist.

FOREWORD | CMM: IT'S TIME TO PAY ATTENTION

LIZ FOWLER, *executive vice president of programs for The Commonwealth Fund; former special assistant to President Barack Obama on health care and economic policy at the National Economic Council. Adapted from keynote remarks to the Feb. 6, 2020 Bipartisan Policy Center and GTMRx event, "Get the Medications Right: Innovations in Team-Based Care."*

By ensuring appropriate use of medications, including gene therapies and personalized medicine, we have the potential to address many of the issues that policymakers have been grappling with for decades. And today, we have a Blueprint for realizing that potential.

Think about all the time we've spent on drug pricing and all the energy we've put into trying to control spending on medications in this country. Many of us have been looking for policies and approaches to deliver the *right* therapy to the right patient at the right time.

Comprehensive medication management is a solution that's been right under our noses. Speaking for myself, I thought that public policy had already weighed in on medication therapy management. As a congressional staffer, I worked on the Medicare Drug Bill in 2003, and medication therapy management was required for all Part D plans. And then the Affordable Care Act extended the requirement to all Part D beneficiaries.

That represented a tremendous advancement, but it was just a first step. As I started digging into the research and reading all the material and all the studies to prepare for this event, it became apparent there was a *lot* more work to do. And I became a believer.

Ten years later

It's not that policymakers hadn't been thinking about these issues all along. The ACA led to the creation of several new models of primary care. The Medicare Comprehensive Primary Care Initiative, for instance, improved care coordination and reduced emergency department visits. But it didn't have a significant impact on spending—or on the physician experience.

And CMMI—the Center for Medicare and Medicaid Innovation—has made great strides, testing more

than 40 new payment models, but only two models have been expanded across Medicare.

Cost containment: A scalpel or a scythe?

There's a growing call for cost containment, and it's becoming more difficult to ignore. We're all paying attention now—and rightly so—to the coronavirus. But regardless of what the new normal looks like, Congress *will* be forced to step in to address Medicare spending. And we all know that when that happens, there will be across-the-board cuts that don't discriminate between high-quality and low-quality providers.

Those of us in Washington health policy circles are watching the horizon, and we know the debate over health costs is coming. We have a limited window to identify solutions that improve patient care, reduce costs and improve outcomes. Improving job satisfaction among physicians should also be a priority.

Enter comprehensive medication management.

So where do we begin?

Structural and attitudinal barriers inhibit the adoption of a systematic approach to appropriate medication use across the health care continuum. Yes, our payment systems are starting to evolve as we explore new innovations in value-based care, but the fundamentals of our system remain outdated—built on a fee-for-service chassis. As a result, it often discourages coordination across providers. It doesn't reimburse for certain services or certain providers. I don't need to enumerate the barriers to those of you who study these issues and know them better than I do.

So where do we begin? We need to demonstrate that the savings are achievable. That's what carries weight with policymakers.

Is comprehensive medication management the solution to our broken health care system? By itself, no. Practicing medicine is complex. Managing medications is complex. But I am convinced that comprehensive medication management should be an important part of the solution—and it's one that hasn't received enough attention.

It's time to pay attention. This Blueprint is an important start. ■

INTRODUCTION

Katherine Herring Capps, Co-Founder, Executive Director, GTMRx Institute

Mapping the path toward medication optimization

"When people are on the right medicines, they reach their health goals. When they reach their health goals, the reason that we're saving money is because they're not ending up in the hospital. They feel good. They go to work. It's a great story, and employers want their employees to be healthy. They want their employees to be able to go to work and do their work. And if they're going to pay less in health care and have more productive employees, I mean, how is that not a win?"

— Dan Rehrauer, Pharm.D., senior manager, Medication Therapy Management Program, HealthPartners[7]

Why here? Why now?

Advances in biologics, drug development and diagnostics continue to exceed expectations, but their promise has yet to be fulfilled. Innovations at the bench are not reaching the bedside in an efficient or timely manner.

As research speeds forward, patients still suffer due to the sub-optimal use of medications. Medication-related problems are a top preventable cause of serious adverse health events and avoidable hospital readmissions.[8]

Illness and death resulting from non-optimized medication thera-py led to an estimated 275,000 *avoidable* deaths and cost $528.4 billion in 2016.[9] That represents 16% of the annual $3.2 trillion in U.S. health care expenditures. That's a conservative figure that excludes indirect costs such as transportation and caregiving; it does not factor in costs related to lost productivity and disability. There is overwhelming evidence that this points to significant waste in the system.

The academic literature and the lived experience of patients, physicians and other providers conclusively demonstrate the enormity of the problem.

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7   From the "Get the Medications Right: Innovations in Team-Based Care" event co-hosted by the Bipartisan Policy Center and the GTMRx Institute on Feb. 6, 2020.

8   OIG Report on Preventable Serious Adverse Events in Hospitalized Medicare Patients. oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

9   Watanabe, JH, McInnis, T, and Hirsch, JD. "Cost of Prescription Drug–Related Morbidity and Mortality." *Annals of Pharmacotherapy,* 2018; 52(9), 829–837.. org/10.1177/1060028018765159.

Yet Another Reason to Get the Medications Right

By Susan Dentzer, Senior Policy Fellow, Duke-Robert J. Margolis, MD, Center for Health Policy

Add to the long list of reasons to "get the medications right" the COVID-19 pandemic. It's clear that the fight against the SARS-CoV-2 virus will include an arsenal of thera-pies to combat the virus and its devastating effects on the body. This reality affords a clear rationale for comprehensive medica-tion management, perhaps as never before to the same degree.

As of this writing, the U.S. Food and Drug Administration has issued emergency use authorizations (EUAs) for one new antivi-ral drug—remdesivir—and for Fresenius Propoven, a sedative to treat patients on ventilators. (An EUA for the use of hydroxy-chloroquine and chloroquine was issued temporarily, then revoked amid mounting evidence of lack of their effectiveness in treating COVID-19). FDA also has allowed antibody-containing convalescent plasma to be administered to those with life-threat-ening COVID-19 infections. Other therapies and vaccines are in development and under-going clinical trials.

What's more, as the virus wreaks its havoc on the body, many patients with COVID-19 need treatment with antithrombotic, anti-coagulant or antiplatelet agents to combat potentially deadly inflammation and throm-bosis. Many of those who are most affected have multiple conditions that require an array of medications, including ACE and ARB inhibitors, statins and NSAIDs.

How are all these therapies being managed for today's COVID-19 patients? Are they be-ing managed? And how will an even greater

Medication optimization through CMM

What does it mean to optimize medications? It means ensuring appropriate use of medications. It means moving to a more rational, team-based, systematic approach to medication therapy management that effectively and efficiently connects the right medications to the right patient with the optimal dose at the right time in order to reach clinical goals of therapy.

Now, imagine a medication use process that achieves the goal of medication optimization and addresses the growing physician shortage while achieving better care, lower costs, improved access and greater provider and patient satisfaction.[11] That is the promise and opportunity we see in broad adoption and access (for those who need it) to CMM services.

Specifically, CMM is

> *The standard of care that ensures each patient's medications (whether they are prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements) are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended.*[12]

A team-based process includes a medication expert

"I can tell you in the spirit of health care being a team sport, we couldn't serve the nation's 9.2 million veterans who are enrolled in our system as well as we do without a fully robust team, including a pharmacist. Getting the medication right is important, and it is doable."

—Carolyn Clancy, MD, deputy undersecretary for discovery, education & affiliate networks, Veterans Health Administration, Bipartisan Policy Center remarks, Feb. 6, 2020

10   "What is the Comprehensive Medication Management Process?" GTMRX Institute, gtmr.org/what-is-the-comprehensive-medication-management-process/
11   "The Outcomes of Implementing and Integrating Comprehensive Medication Management in team-based care: A Review of the Evidence on Quality, Access and Costs, June 2020, www.gtmr.org
12   McInnis T, Webb E, and Strand L. *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes,* Patient Centered Primary Care Collaborative, June 2012.

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continued

range of treatments be managed in the future? Debates over the appropriate use and effectiveness of COVID-19 therapies will continue to grow as more products come on the market. The risk of drug-drug interactions will be high, and in some cases, a patient's genetic makeup may render certain treatments ineffective, or even deadly.

Now is the time

All these factors create a compelling mandate for comprehensive medication management in the context of COVID-19, its aftermath, and the multiple other conditions affecting patients. Consider the implications across the four key domains of the GTMRx Institute's efforts: Practice and Care Delivery Transformation; Health IT and AI; Payment and Policy; and Precision Medicine. Each area will have a clear COVID-19 mission in the months, and possibly years, ahead.

Practice and care delivery transformation

Practice and care delivery transformation arguably has the heaviest immediate lift as cases of COVID-19 continue to mount. In many parts of the country, inpatient management of medication must be tracked by teams that are already exhausted and overstretched.

Given COVID-19's lingering effects, including strokes and neurological deficits, the need for outpatient medication management will be substantial. This need arises at a time when the spread of infection and cancellation of much in-person care has reduced direct care access for many patients. In some respects, these developments will only increase the challenges of executing on CMM. But on the other hand, the opportunities have increased as well, particularly with respect to more virtual forms of health care such as telehealth. Imagine how a clinician conducting a follow-up visit with a recovering COVID-19 patient over Zoom could now have a pharmacist on the care team easily and seamlessly weigh in.

Health IT

Similarly, health IT also has a robust role to play in CMM during the pandemic. Especially in the short-term, interoperability of EHRs will be critical as

COVID-19 patients potentially move from one care site to another, including care via telehealth.

There have already been calls to speed up implementation of interoperability rules finalized by The Centers for Medicare & Medicaid Services and the Office of the National Coordinator for Health IT—and, in particular, to hasten the rapid adoption of standard application programing interfaces (API) for EHRs, which will allow for faster and more scalable access to health information. Such measures will advance the cause of medication optimization now, during the pandemic, and well into the future.

New payment models

The health care system needs to adopt new payment models to support CMM, appropriate use of telehealth, and team-based care. This goal has become more urgent amid the pandemic, and it will remain so as the health care system begins the long road back to financial recovery.

Opportunities also abound for precision medicine and advanced diagnostics to be part of the COVID-19 response, given everything from the variability of patients' responses to the virus to the potential emergence of new genetic variants of SARS-CoV-2 in the future.

Avoiding unnecessary deaths

With the United States approaching nearly 3 million documented SARS-CoV-2 infections as of this writing, and more than 130,000 COVID-19 deaths, curbing the spread and successfully treating patients is the nation's most immediate challenge. But reducing illness and death from non-optimized medication use—especially amid the pandemic—is not far behind.

COVID-19 has both revealed the failings of our current approach to health care delivery and spotlighted the tremendous opportunities for improvement. The disease is forcing all stakeholders—including payers, health systems, regulators, health IT vendors, and others—to adopt innovative approaches to diagnosis, treatment, and management of populations. The nation can't afford to waste this opportunity to make comprehensive medication management a permanent cornerstone of our health care. ■

CMM is a coordinated team endeavor that improves patient care by utilizing the skills and expertise of *everyone* on the care team—including the clinical pharmacist who works in collaborative practice with the physician. It replaces the current trial-and-error approach to medication, leveraging technology and advanced and complementary diagnostics through a *process* designed to achieve optimized medication use. Integrating CMM services into practice may require development of a collaborative practice agreement (CPA) between one or more physicians outlining the scope and services of a clinical pharmacist.

"In providing collaborative drug therapy management (CDTM) on interprofessional care teams, clinical pharmacists apply specific drug therapy knowledge, skills, and experience to complement the care provided by collaborating professionals."[13]

Informed by our beliefs, a call for medication reform

Since the launch of the GTMRx Institute in April 2019, we have grown to more than 900 members from 49 states, to include the District of Columbia. Our diverse views make us stronger and able to do the hard work required for interprofessional problem solving. Barriers faced by the health care system due to lack of data liquidity and clear diagnostic guidance become more real when the entire team, to include the patient, is working together to get the medications right.

"Our patients assume that there's seamless flow of information and a real game plan, when I think it's fair to say that's not the case."

> —Carolyn Clancy, MD, deputy undersecretary for discovery, education & affiliate networks, Veterans Health Administration, Bipartisan Policy Center remarks, Feb. 6, 2020

Medication reform requires support, action and commitment.

GTMRx leadership, workgroups and actively engaged members are working together to find solutions. We are focused on four key domains, the Institute's pillars of change. Member-led workgroups have been focused on change needed in four key domains. The Institute's pillars of change include:
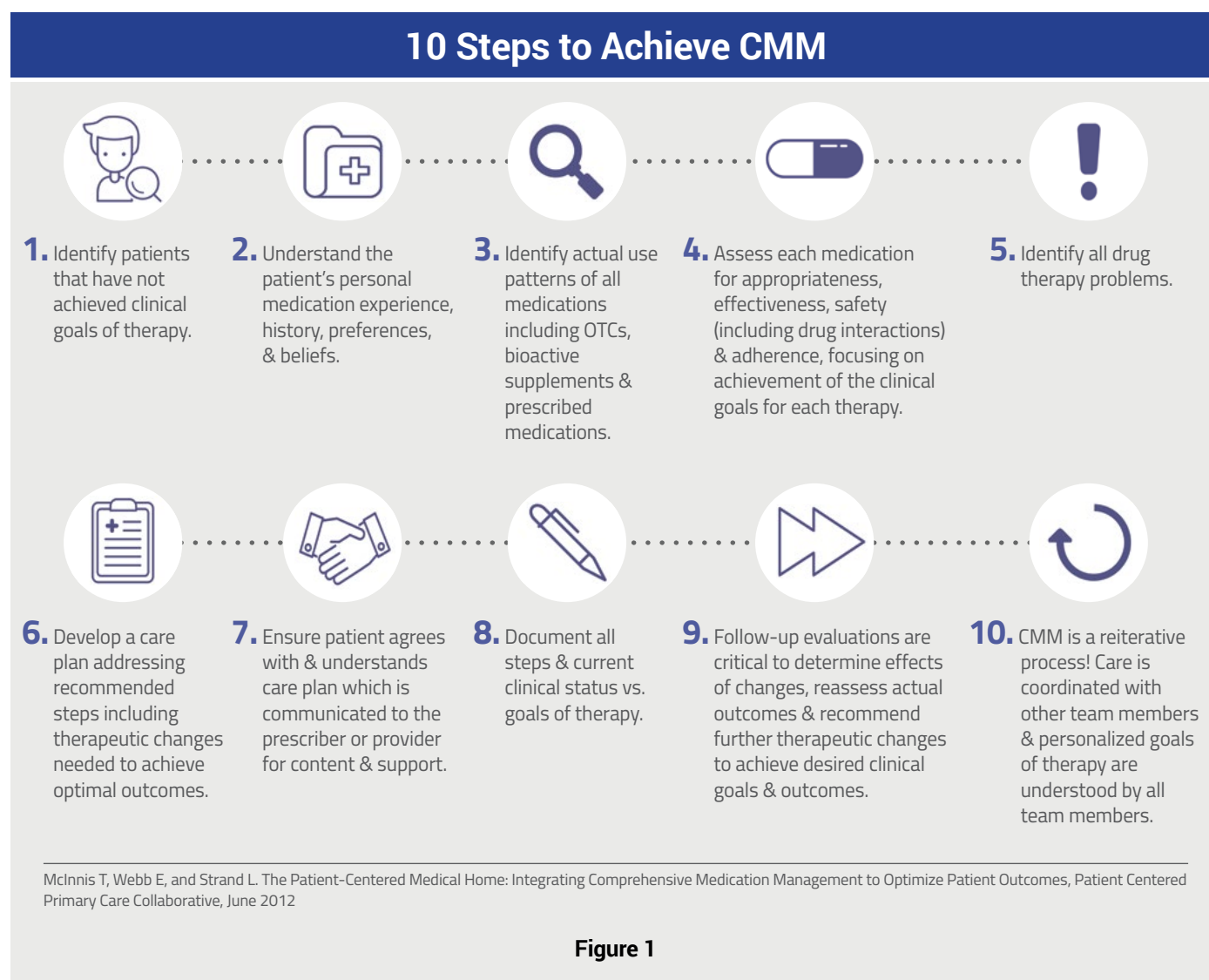
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13 "Comprehensive Management in Team-Based Care", ACCP, https://www.accp.com/docs/positions/misc/CMM%20Brief.pdf

- Practice and Care Delivery Transformation

- Health IT to Support Optimized Medication Use

- Payment and Policy Solutions

- Precision Medicine Enablement via Advanced Diagnostics

Thought leadership from across the country informed this Blueprint for Change, offering keen focus and a roadmap to guide our work in the near term so we can advance our vision of enhancing life by ensuring appropriate use of medications and gene therapies.

All that we do is predicated on the GTMRx Institute's beliefs:

- A personalized, patient-centered, systematic and coordinated approach to medication use will vastly improve outcomes and reduce overall health care costs.

- We must align systems of care to integrate comprehensive medication management, engaging patients to ensure that they are willing and able to take those medications that are indicated, effective and safe, to optimize their outcomes.

10 Steps to Achieve CMM

1. Identify patients that have not achieved clinical goals of therapy.

2. Understand the patient's personal medication experience, history, preferences, & beliefs.

3. Identify actual use patterns of all medications including OTCs, bioactive supplements & prescribed medications.

4. Assess each medication for appropriateness, effectiveness, safety (including drug interactions) & adherence, focusing on achievement of the clinical goals for each therapy.

5. Identify all drug therapy problems.

6. Develop a care plan addressing recommended steps including therapeutic changes needed to achieve optimal outcomes.

7. Ensure patient agrees with & understands care plan which is communicated to the prescriber or provider for content & support.

8. Document all steps & current clinical status vs. goals of therapy.

9. Follow-up evaluations are critical to determine effects of changes, reassess actual outcomes & recommend further therapeutic changes to achieve desired clinical goals & outcomes.

10. CMM is a reiterative process! Care is coordinated with other team members & personalized goals of therapy are understood by all team members.

McInnis T, Webb E, and Strand L. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes, Patient Centered Primary Care Collaborative, June 2012

Figure 1

- We need immediate delivery system, payment and policy transformation to streamline clinical trials and reduce costs of bringing drugs to market while enabling successful, broad-scale adoption of integrated, comprehensive medication management services.

- Appropriate diagnosis and access to advanced diagnostics with companion/complementary pharmacogenomic (PGx) testing is essential to target correct therapy.

- Success requires team-based, patient-centered care models that recognize appropriately skilled clinical pharmacists as medication experts who work in collaborative practice with physicians and other providers.

Blueprint for Change

We believe that optimizing medication use is the decade's most urgent—and promising—opportunity to save lives and save money. By releasing this Blueprint for Change, the GTMRx Institute offers a roadmap to advance acceptance and recognition by providers and payors (which includes employers as plan sponsors) of the importance and utility of implementing, promoting and paying for programs designed to ensure appropriate use of medications and gene therapies.

This roadmap offers key considerations around leveraging technology to transform practice, using diagnostics to target the correct therapies, creating interprofessional teams centered around the patient, and integrating medication experts as essential members of the care team. And, it outlines work to be done in crafting payment and policy solutions necessary to enable these activities.

It is our hope that this multi-stakeholder guidance will further engage physicians, clinical pharmacists and other team members to join our movement.

Finally, we will use this guide to educate and inform patient groups, Congress, CMS and payors (to include national integrated delivery systems) about the imperative to add "appropriate use of medications and gene therapies" to today's discussions heretofore limited to policy solutions around affordability and access.

This report begins a journey to offering industry guidance, tools, practice standards and research-based implementation resources to advance the delivery system's ability to optimize medication use across all care settings. It also serves as a call for medication management reform.

We invite you to join us. ■

PRACTICE AND CARE DELIVERY TRANSFORMATION WORKGROUP

Optimizing medication use: CMM adoption across the care continuum

"When we talk about something that is a terrific idea, the data are compelling, and it's obvious everybody ought to be doing it—and people aren't doing it—we've got to ask ourselves why and what it would take to get there." **—Workgroup member**

Optimal patient care cannot happen without a systematic approach to medication use. Pharmaceuticals are the most common medical intervention, and their potential for benefit *and* harm is enormous.[14] The way we manage and evaluate their use matters.

Ensuring a rational approach to medication use across the delivery system, however, requires significant structural changes. Patient-centered, team-based care models, supported by health information technology, must be adopted at the practice and health system levels. Appropriate diagnosis and access to advanced diagnostics with companion/complementary pharmacogenomics (PGx) testing should be considered vital to target correct therapy. Policy and payment solutions must be in place to encourage, shape and support these transformative efforts.

Recognizing that delivery system transformation must occur if we are to get the medications right, the GTMRx Practice and Care Delivery Transformation Workgroup (referred to as the Workgroup) is taking on the challenge to provide guidance and recommendations that will enable broad practice adoption of a patient-centered, systematic approach to medication optimization across the continuum of care.

That process begins by establishing the value proposition, creating a pathway and implementation roadmap that will align systems of care to adopt and integrate comprehensive medication management (CMM) services and engaging patients to ensure they are willing and able to take medications that are indicated, effective and safe, as a means to optimize outcomes. That demands focused strategies and tactics. We need:

- **Strategies** to accelerate the care delivery team and practice transformation efforts that ensure personalized and appropriate use of medications. These strategies also acknowledge that success requires team-based, patient-centered care models that recognize appropriately skilled clinical pharmacists as medication experts working in collaborative practice with physicians and other providers.

  The financial return on investment (ROI) of team-based medication management services has been well documented, as articulated by Cipolle, et al., "to average around 3:1 to 5:1 and can be as high as 12:1, resulting in a reduction in the direct mean medical cost of between $1200 and $1872 per patient per year for each of the first 5 years for those patients with chronic diseases such as diabetes, cardiovascular health issues, asthma and depression."[15] The challenge is to bring physicians, nurses and other providers on board *and* ensure they understand each team member's role in getting the medications right. A related challenge is to ensure the interprofessional team turns to pharmacists when necessary. CMM is a vital tool for optimizing medications for high-risk patient groups, especially those not meeting their treatment goals.

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14   Benjamin RM. "Medication adherence: helping patients take their medicines as directed." *Public Health Rep.* 2012;127(1):2−3. doi:10.1177/003335491212700102 (citing The Institute of Medicine, *National Academy of Sciences. Informing the future: Critical issues in health.* 2007).

15   Cipolle RJ, Strand L, and Morley P. Pharmaceutical Care Practice: The Patient Centered Approach to Medication Management. Third Edition. New York, NY: McGraw-Hill Medical; 2012.

- **Tactics** that advance the care team's ability to identify, evaluate and understand barriers to optimized medication use, including

    o   medication experts working in collaborative practice,

    o   point-of-care clinical data access,

    o   appropriate diagnostics,

    o   practice standards,

    o   implementation resources, and

    o   evaluation tools.

We will be successful once patients can engage with an integrated care team, confident their medications are optimized so that they are appropriate, safe, effective and customized to meet their unique needs (genetic, personal, social, cultural) within an aligned and constantly "learning" health care delivery system.

Because of the depth and breadth of the challenge, the Workgroup recognized three distinct but intertwined areas for focus and change: *system transformation*, *care delivery* and *practice integration*.

What does it mean to optimize medication use?

The cost of non-optimized medication use—to the health care system and individual patients—has been well document-ed. But what does it mean to optimize medication use? The Workgroup defined it as ***the sum of an optimal medication regimen and the optimal use of that medication regimen.*** To achieve this, a process of care must be adopted to identify, manage, mitigate and assure that a wide range of medication therapy problems are resolved to achieve complete medication optimization (see Figure 2).

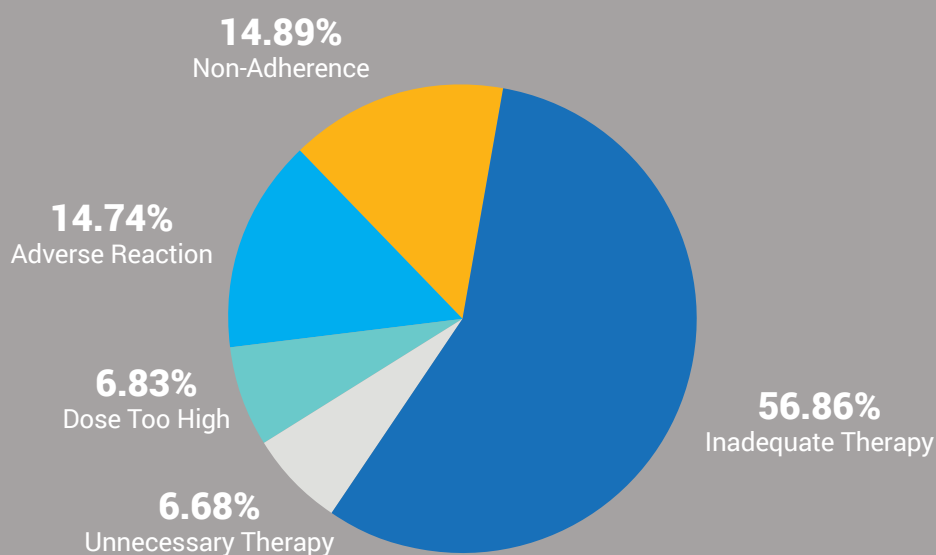Is _this_ the right medication for _this_ person? (It is more than non-adherence)

- 14.89% Non-Adherence
- 14.74% Adverse Reaction
- 6.83% Dose Too High
- 6.68% Unnecessary Therapy
- 56.86% Inadequate Therapy

Figure 2. Medication therapy problems.

Consider this:

> More than **4 billion prescriptions** are filled each year.[16] Nearly **1/3 of adults take five or more medications.**[17] And Medicare Part D beneficiaries have an average of **three to four prescribing providers.**[18] What's more, **80% of the way physicians treat and prevent disease is through medications.**[19] Given the wide range of medication therapy problems and the frequency of medication use today, there has never been a more important time to focus on the need for medication optimization.

Ambulatory care presents its own challenges. Current medication use systems in these environments are inadequate and fragmented. The value too often is placed on a product focusing on the lowest net cost. This translates to a lack of patient-centeredness by rewarding *product* delivery rather than *care* delivery.

The time allotment for typical patient-visit activities is also a challenge. A primary care physician's key area of focus—resolving difficult diagnostic dilemmas while building a healing relationship of trust—leaves little time for managing the sheer volume and variation of medications. Managing medication therapy problems, without additional expertise on the team, is a process set up for failure. And as the primary care physician shortage grows and patient panels grow larger, the situation will only worsen. A team-based approach is necessary, but it is nowhere near sufficient. *Merely having a team doesn't drive results.* However, strong practices that support a culture focused on medication optimization through CMM incorporate all these key elements to achieve improved patient outcomes.

A system-level transformation is required to address medication therapy problems in a more comprehensive and integrated fashion. But today, most systems lack the structure to consistently deliver quality pharmaceutical care, especially outside the acute care setting. The Workgroup identified three primary barriers to successful integration:

- **IT systems and access to clinical information at the point-of-care,** crucial to perform CMM functions appropriately;

- **Team-based care structures and culture** that supports and nurtures a standardized approach to medication optimization that includes utilization of quality CMM; and

- **Leadership and champions** in health care systems and among payors and employers. This leadership must recognize the importance of delivering pharmaceutical care services, including CMM, that optimize medication use.

Transformation cannot be piecemeal. No matter how promising individual elements of CMM are, their impact is minimal unless they are *all* integrated into the practice. The evidence is clear: Practice-level integration of medication optimization improves patient care, leading to better outcomes, decreased health system costs and improved overall access to care.[20,21,22]

Integrating CMM also enhances the clinician experience, improving work-life balance and decreasing burnout—a very real threat to primary care physician retention and development of a new cadre of these providers.[23] When pharmacists are part of the primary care team, they serve as medication experts providing CMM for high-risk and vulnerable patient populations and reducing the need for these patients to be seen for medication-related follow up. This frees physicians and other team members to focus on other care needs.

16   Schumock GT, et al. *American Journal of Health-System Pharmacy,* July 2018, 75 (14) 1023-1038.
17   https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2016_namcs_web_tables.pdf
18   CMS Chronic Condition Data Warehouse Medicare Part D Prescription Drug Utilization 2008-2017.
19   McInnis, Terry, et al., editors. *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes.* 2nd ed., Patient-Centered Primary Care Collaborative. PCPCC Medication Management Task Force collaborative document.
20   Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. "US pharmacists' effect as team members on patient care: systematic review and meta-analyses." *Med Care* 2010 Oct;48(10):923-933.
21   Perez A, Doloresco F, Hoffman JM, et al. "Economic Evaluations of Clinical Pharmacy Services: 2001–2005." *Pharmacotherapy* 2008; 28: 285e–323e.
22   Blum, K. "'Shark Tank' VA Pharm Finalists Help PRIMARY CAREs Focus on Acute Care." *Pharmacy Practice News.* 2016.
23   Funk KA, Pestka DL, Roth McClurg MT, Carroll JK, Sorensen TD. "Primary Care Providers Believe That Comprehensive Medication Management Improves Their Work-Life." *J Am Board Fam Med.* 2019 Jul-Aug; 32(4):462-473.
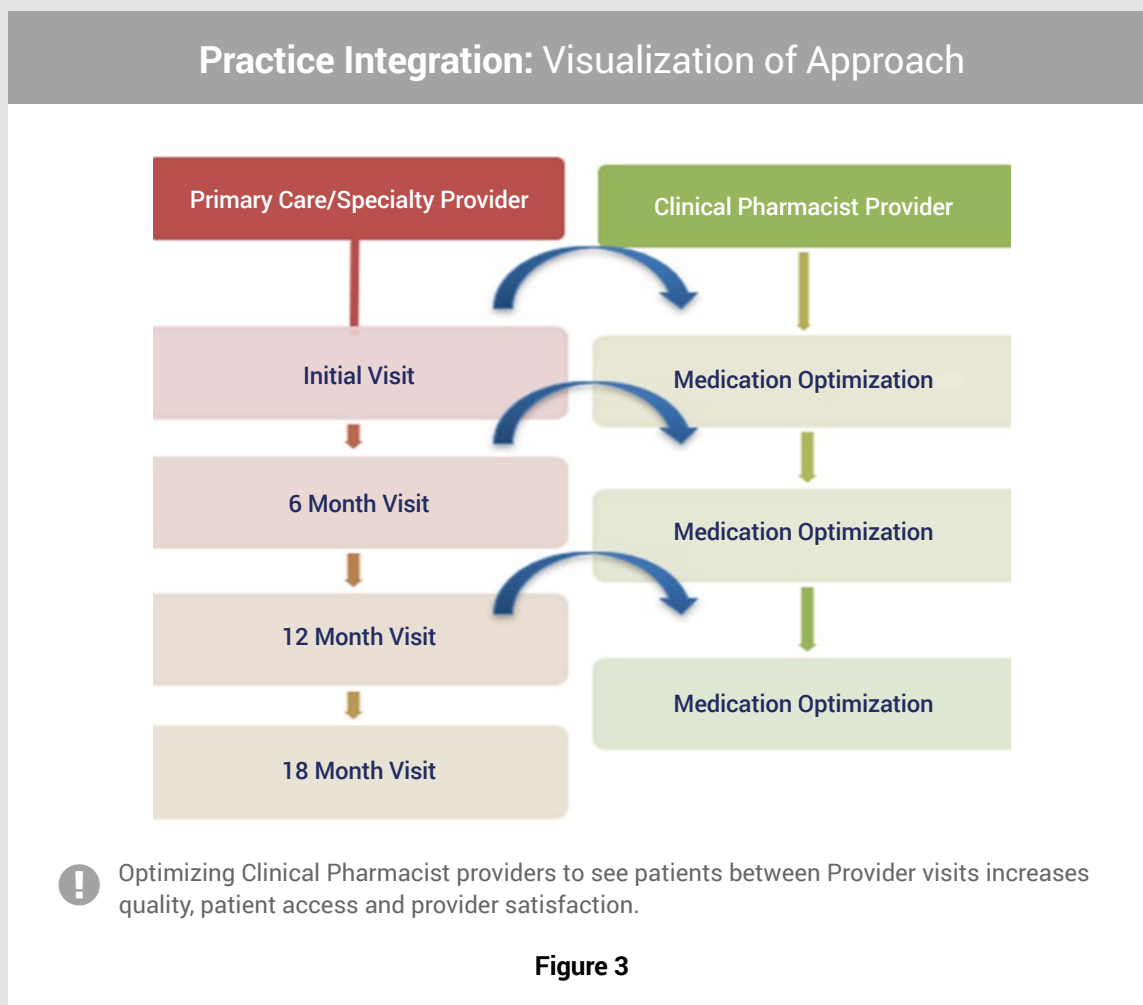
Team-based care that includes a medication expert

Medication optimization is a team endeavor. The team includes individuals from different professions and the patient who effectively collaborate with each other to solve problems too complex to be managed by a single provider.[24] *Who* is on a particular patient team varies, based on the needs of the patient.

A medication expert acting as a dedicated member of the team helps ensure medication optimization is achieved over time in partnership with the patient as an active and engaged team member. The clinical pharmacist plays that crucial role in providing CMM and is essential to practice success.

We know it works: As one Workgroup member put it, *"We're looking at decreased readmission rates. We're looking at improvement in overall health outcomes. We don't need another five-year study to prove that; the data is there."*

A patient can be referred to the clinical pharmacist in various ways, but once the patient is referred, the clinical pharmacist optimizes medication through CMM. The primary care provider may not see that patient for six months, but they know the patient's medications are optimized. During that time, the primary care provider can focus on other, higher-need patients.

Practice Integration: Visualization of Approach

Primary Care/Specialty Provider — Clinical Pharmacist Provider

Initial Visit — Medication Optimization

6 Month Visit — Medication Optimization

12 Month Visit — Medication Optimization

18 Month Visit

Optimizing Clinical Pharmacist providers to see patients between Provider visits increases quality, patient access and provider satisfaction.

Figure 3

24   OM (Institute of Medicine). 2011. *Allied health workforce and services: Workshop summary.* Washington, DC: The National Academies Press.

Envisioning the future

Workgroup members envisioned how the future could look, compared to current practice:

Today	Envisioning the Future
Each team member works in a silo. Physicians are overwhelmed and burned out. Compounding the problem is inconsistency in team member roles, especially relative to medication management accountabilities. Frequently, there's no clear point person when it comes to the patient's medication regimen or medication list. Often, the medication list available to a primary care physician is inaccurate.	A full complement of interprofessional team members works collaboratively, supported by health information technology and diagnostics. Each team member has access to the patient's clinical data at the point-of-care, and members provide complementary knowledge and skills for a comprehensive, coordinated approach to medication use. All professionals are working at the top of their license, and each team member has a clearly defined role and understands the role of the other team members.
Patients must navigate a broken system with little guidance and inconsistent access to a comprehensive medication management (CMM) service.	Care transitions are coordinated across the continuum, with an emphasis on evaluation of medication use to ensure clinical goals of therapy are being met across transitions. Medications are monitored with appropriate measures at appropriate intervals. Adverse effects are identified and resolved. Access and affordability issues are considered. All patients that need CMM, especially those at high risk of medication errors, have access to it across settings. Interprofessional roles are clear, so the whole team knows who is responsible for medication management as patients transition across settings.
Lack of availability and access to clinical information at the point-of-care greatly limits community-based interdisciplinary teams from efficiently providing and performing all elements of CMM services. For instance, pharmacies often have information only about the medications they dispense, contributing to inaccurate medication lists. Primary care practices and specialists often have information only about medications they prescribe, contributing to medication misuse or overuse.	By liberating data and overcoming barriers to information access through technology, all members of the patient care team have full access to all relevant clinical and health care data necessary to provide a patient-centered approach to medication management through CMM services—at the point-of-care.
Health systems and payors don't recognize the economic and human toll of poor medication outcomes. That toll includes lives lost—not only hospital visits, ER visits and long-term care admissions, but also medication that makes you sicker, that is wrong or is not taken as intended.[25] Value-based agreements don't consider CMM services as a value driver for programs designed for those with chronic diseases (requiring multiple medications) or as a solution to management of the overall drug benefit and global health care spend. Patients and employers do not recognize the value of medication optimization as a means to decrease wasteful spending, increase care quality, enhance quality of life or decrease total cost of care.	Business models recognize and reward medication-related outcomes rather than product delivery, transforming the current product-centric approach into a patient-centered one. Patients and employers recognize the value of medication optimization, including CMM, driving demand within a value-based framework. This, in turn, drives additional needed system and practice transformation. Providers, payors and patients understand the elements necessary for a more rational approach to medication use and the need to integrate efforts to adopt it.
The role and function of the pharmacist on the health care team varies from practice to practice.	CMM is standardized, with widespread implementation of evidence-based medication optimization practices.

25   Watanabe JH, McInnis T, Hirsch JD. *Ann Pharmacother.* 2018 Sep;52(9):829-837.

Barriers to success

What stands between where we are today and that bright tomorrow?

While the goal of medication optimization is clear, the path for ensuring it in the most high-risk patients is not yet in focus. The Workgroup identified more than two dozen barriers to success; most fall into three overarching challenge areas:

- **Lack of a consistent standard:** The literature on CMM integration into team-based practices varies. Standards are lacking for consistent implementation of the common elements for CMM integration: organizational support, care team engagement, care delivery process and program evaluation to ensure consistent quality of care.[26]

- **Lack of a common language:** The absence of an established definition for CMM leads to inconsistent integration of CMM into team-based practices. It also makes it difficult for employer plan sponsors and health plans to pay for these services, to understand what CMM is (and is not) and the role of the pharmacist on the interprofessional team. Perceived lack of alignment and inconsistent ways of describing the clinical pharmacist's impact on team leadership inhibits development of a business case and effective CMM expansion.

- **Lack of resources:** Resource constraints limit the ability of practices to add CMM services or invest in staff to perform these services. Current reimbursement models do not support pharmacist-delivered CMM services. Other financial barriers include the costs associated with development, implementation and optimization of health IT to comply with frequently changing requirements and to ensure point-of-care access to clinical information.

Areas for further work: What's next?

The Workgroup identified several interrelated areas where change and resources are needed to facilitate system transformation, impact care delivery and ensure practice transformation:

For practices and care teams	• Offer guidance to shape and inform consistent practice integration of medication optimization with CMM for physicians to ensure a consistent and standardized approach to practice. • Clearly identify and offer guidance on the composition of the care team, roles, responsibilities and accountabilities in the provision of a systematic approach to medication optimization. This approach is designed to decrease waste and ensure access to medications that are safe, effective and appropriate with the use of CMM in high-risk patient populations. • Further develop and disseminate a web-based, interactive, evidence-based resource that allows care team members to build collaborative practice agreements based on best practices. • Develop guidance to promote and ensure that relevant health information flows efficiently to all team members at the point-of-care. • Formally educate practices on medication optimization, offering guidance and encouraging support for adoption of CMM. • Develop a clear vision and execute it with agility. Incorporating CMM requires setting a vision for the practice while being nimble enough to change and nurturing the team dynamic over time. • Recognize that the best teams are co-located and have the ability to document care within the same medical record.

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26   Pestka DL, Frail CK, Sorge LA, Funk KA, Roth McClurg MT, Sorensen TD. "The practice management components needed to support comprehensive medication management in primary care clinics." *J Am Coll Clin Pharm.* 2020;3(2):438-447. doi:10.1002/jac5.1181.

| **For contracting** | • Offer definitions and guidance to inform contract standards and common definitions between those who buy care (consumers and employers as plan sponsors) and those who contract for care (health plans, consumers, government). |

• Further develop and disseminate resources outlining the essential structures and language to incorporate CMM services within value-based agreements. This includes dissemination of the value-based glossary developed by the Workgroup.

• Perform a systematic review of literature around CMM practice integration to identify impact on cost, quality and provider satisfaction—including examples in public, private and commercial sectors. The goal is to ensure consistent, effective and sustainable integration of CMM into practice and to inform contract and network requirements.

• Identify partners, develop tools, guidance and a dissemination plan (practice leaders, physicians/their agents, consultants, care teams and payors) to increase awareness of, build demand for, and ensure adoption and use of successful strategies and standardized implementation processes for CMM integration.

For health systems and/or IT vendors

• Develop health IT infrastructure and access to support medication optimization, including broad expansion of CMM. This means making the assets across the continuum of care available to all members of the health care team as needed—not just at certain points along the journey.

• Develop business models for medication-use systems that reward medication-related outcomes—from product-centered to patient-centered.

For GTMRx and other advocates

• On an ongoing basis, develop use cases on the successful journey toward practice transformation and full implementation. Identify practice sites and health systems that are getting it right so they can be replicated, rather than forcing organizations to reinvent the wheel.

• Create guidance, best practices and resources to support GTMRx efforts to educate and support care teams on medication optimization and encourage providers to adopt and integrate CMM processes into practice.

• Work with professional organizations to ensure more rapid practice transformation nationwide.

• Create public and private sector demand for medication optimization, including the use of CMM, as a component of value-based models. Currently, CMM is not called out as a separate line item in value-based agreements. In tandem with creating demand, stakeholders will need to determine the structure of CMM in value-based contracts.

For all stakeholders

• **Develop resources** to communicate the extent—and underlying causes—of the economic and human toll of non-optimized medication use. At the same time, develop resources to communicate the evidence that medication optimization achieved through high-quality CMM can reverse these trends.

• Identify evidence and develop use cases to promote the value of optimized medication use to payors, consumers and providers to ensure consistent and widespread adoption of a team-based, patient-centered, systematic approach.

• Develop guidance tools for consumers, payors and providers so they understand the role of the clinical pharmacist on the team. This should clearly define—from the point of view of each stakeholder—the value of an appropriately skilled pharmacist, in collaborative practice with physicians, as a medication expert.

- Develop tools to engage patient advocacy and professional groups to move toward a full understanding of the economic and human toll resulting from non-optimized medication use.

- Educate consumers and employers about what to expect from the care team, including the clinical pharmacist, as we build demand for a systematic approach to medication use.

Moving forward

The ensuing discussion among all the participants touched on a range of issues for the Workgroup to consider as it moves forward.

While medication optimization is an important goal for all patients, it's important to define which patients need access to CMM services. There was discussion that all patients who need the service should have access to the opportunity to optimize outcomes of medications they are taking and/or cease taking medications that offer no value. Recognizing that the first step in the CMM process is identifying individuals that have not achieved clinical goals of therapy allows practices to triage those who need the service most. It will be vital to showcase the value—*specifically how CMM impacts appropriateness of medication use, quality and cost.*

Integrated teams vs. handoffs: Facilitating the steady and coordinated integration of the team vs. a simple handoff is essential. Medication optimization is everyone's business; ideally, a community of clinicians, with defined roles and functions, can more readily and effectively care for the patient. This requires deliberate and ongoing communication among team members. Offering a realistic outline of what this process looks like and putting it into practice will be key. Implementation science has been used to define this process.[27] A patient-centered approach to medication use is far more complicated than a handoff; it represents the steady integration of the team.

Data collection as a metric for success: Data drives practice. All recognized that access at the point-of-care to clinical information and the right information was vital.

Getting there from here: A recurring theme was how to move from theory to practice—rapidly. There is a great deal of research to support the value of CMM, and payment vehicles are emerging that will allow for broader adoption. We need a step-wise process to engage public and private sector payors immediately.

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27   The Patient Care Process for Delivering Comprehensive Medication Management (CMM): Optimizing Medication Use in Patient-Centered, Team-Based Care Settings. CMM in Primary Care Research Team. July 2018. Available at http://www.accp.com/cmm_care_process

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Communicating to Stakeholders: *What's in it for me?*

So how do you roll this out to a fragmented health system and get uptake and buy-in?

■ **CLINICAL PHARMACISTS**
Encourage clinical pharmacy colleagues across the board to adopt common language, definitions and standards of practice around CMM services.

■ **EHR VENDORS**
Speak to EHR vendors in a way that fosters consensus so they'll work to overcome built-in workflow barriers. The number of clicks to write a prescription, discontinue a medicine or reconcile a medication list consumes too much time, making it an unsustainable activity.

■ **PATIENTS**
They must first understand the "why," in human and financial terms. "Why would I take my personal time and sit down with a pharmacist, a nurse or whomever is asking very personal questions about whether I can physically, emotionally and financially take a medication?" one participant asked.

■ **PHYSICIANS**
Find the CMM success cases that apply to different types of practice (primary care and specialists) and outline the business case to include patient outcomes and financial rewards. Define operationally how it will work for solo or small group physicians.
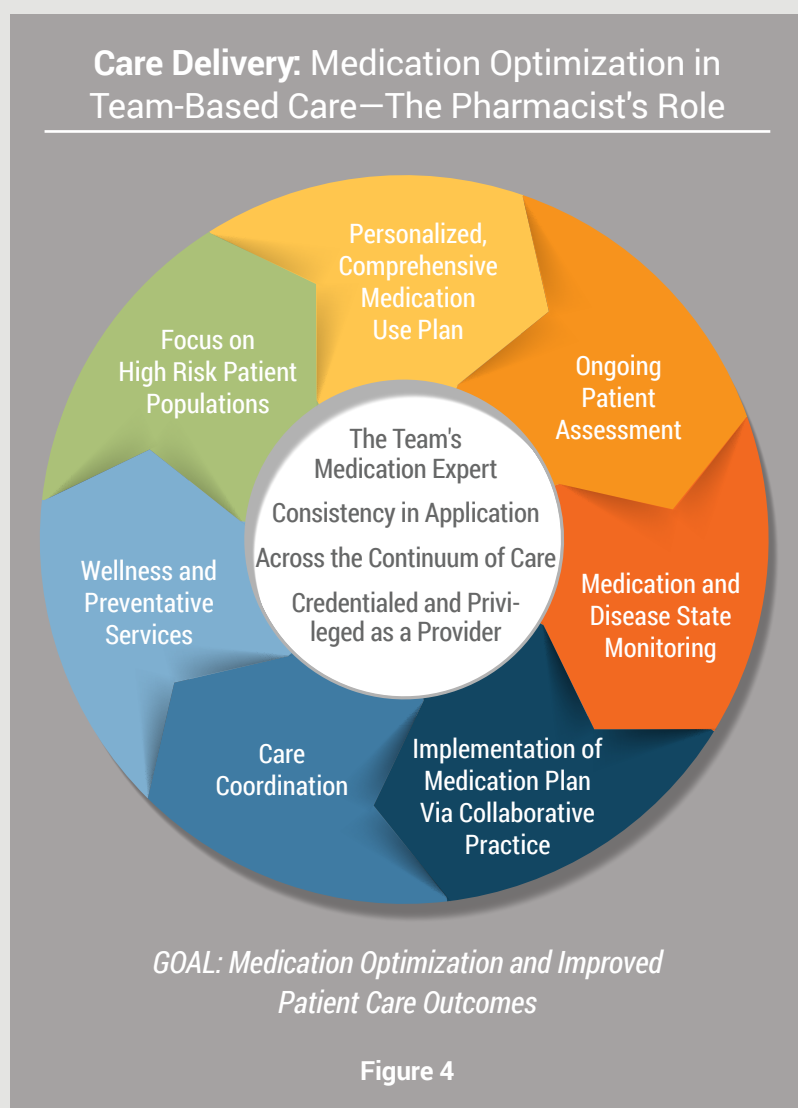
■ **EMPLOYERS (AS PLAN SPONSORS)**
Answer the bottom-line questions, like "how do I utilize these services to decrease waste and increase quality in my pharmacy benefit structure, or as I look at total cost of care?" Or, "is this something that my health plan can do for me, and if so, what should I ask them to do to ensure that the level of service is being delivered?"

Tailored engagement and education: Identify what to ask for. The focus of education will be different depending on the stakeholder. Use examples, including CMM use cases, to highlight the benefits pertinent to each stakeholder. As one participant put it, "We're looking at communicating in different ways to different stakeholders, all of which have got to change what they're currently doing, and change is not something people want."

All stakeholders should be brought into the conversation *early* and be substantively engaged—not after "what needs to be done" has already been decided. Medication optimization takes an integrated team approach and support from all stakeholders in order to be successful. GTMRx recognizes the challenges in achieving the goal of medication optimization. The Workgroup continues its focus on minimizing barriers and encouraging adoption of CMM for high-risk patients as key initiatives.

Achieving the goals associated with CMM, combined with team-based patient care, has the potential to significantly improve the lives of patients and decrease health care costs. The mandate before us to ensure that medication use is optimal, safe and effective for all people all the time should be what we strive to achieve as an interprofessional team through the important efforts of GTMRx. Our patients are counting on us.

Care Delivery: Medication Optimization in Team-Based Care—The Pharmacist's Role

The Team's Medication Expert
Consistency in Application Across the Continuum of Care
Credentialed and Privileged as a Provider

- Personalized, Comprehensive Medication Use Plan
- Ongoing Patient Assessment
- Medication and Disease State Monitoring
- Implementation of Medication Plan Via Collaborative Practice
- Care Coordination
- Wellness and Preventative Services
- Focus on High Risk Patient Populations

GOAL: Medication Optimization and Improved Patient Care Outcomes

Figure 4

What Needs to Be Done Now?

✔ **Practice and Care Delivery Transformation**

- Identify evidence to promote the value of optimized medication use for payors, consumers and providers.

- Develop tools to engage and educate key stakeholders (patient advocacy organizations, professional groups, physicians, caregivers, care teams, consumers, pharmacists and employers) to gain support for a standardized definition and process for CMM.

- Further develop the essential structures and language of value-based agreements within CMM services.

- Offer guidance and use cases to key stakeholders on contract standards and the consistent practice of CMM in clinical care.

- Identify leadership and champions to ensure more rapid practice transformation nationwide.

PAYMENT AND POLICY SOLUTIONS WORKGROUP

Optimizing medication use: Demonstrating value

"There's ambiguity in payment structures, and there's ambiguity in the regulatory language that can prevent key members on the team from providing care that's truly effective and efficient for the team-based care model. Regulatory ambiguity can also limit scope of practice, which impairs the efficiency of the team-based care model. So, our work is really trying to drive guidance so that we advance CMM implementation, advance optimizing medications and gene therapy to produce better outcomes, by actually being able to better define what it is." **—Workgroup member**

We know what the problem is: Medication-related problems represent the top preventable cause of serious adverse health events and avoidable hospital readmissions.[28] Because of suboptimal therapy, patients are not reaching their treatment goals.

We also know what is possible: Ensuring access to and affordability of medications will lead to improved outcomes and reductions in the overall cost of care. Achieving that goal demands a systematic approach to medication use—one that requires practice transformation and change in how care is delivered.

Such change requires policy and payment strategies that reward the value of CMM services in terms of both cost and quality. The policies and payment structures of yesterday's volume-based system are inadequate for a value-based system of care that includes CMM approaches. CMM differs from medication therapy management (MTM)—an administrative benefit under Medicare Part D—as an ongoing, coordinated, holistic approach compared to MTM's minimal one-time intervention.

The movement to payment for *value* from *volume* necessitates new ways of managing and paying for care. As with most practice-level solutions, financial incentives will drive much of the expansion and scaling needed for broad adoption and access. To optimize medication use, the GTMRx Institute believes the most value can be achieved through the provision of CMM services. The Institute also believes that payment reform should start now, even within current fee-for-service payment models.

Expanding the value framework to enable the adoption of a systematic approach to medication use that optimizes clinical outcomes will require payment and policy solutions that:

1. Articulate the value CMM brings to the health care system and how that value should be measured by key stakeholders and organizations to facilitate system-wide adoption of CMM;

2. Evaluate policy and payment barriers to the adoption of CMM and the use optimization of medication and gene therapies;

3. Identify foundational elements of policy solutions necessary to overcome those barriers and optimize the use of medication and gene therapies;

4. Identify payment structure solutions necessary to overcome barriers to adoption of CMM and optimize the use of those therapies; and

5. Design an approach to educate and engage decision makers about these solutions.

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28   OIG Report on Preventable Serious Adverse Events in Hospitalized Medicare Patients. oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

Why does this matter?

The value proposition for CMM is demonstrated each day in practices around the country with growing evidence of its effectiveness. CMM advances all elements of the Quadruple Aim: improve the health of populations, enhance the experience of care for individuals, reduce the per capita cost of health care and improve physician satisfaction. Consider that:

- Almost 75% of physician office and hospital outpatient clinic visits involve medication therapy.[29] CMM addresses medication therapy problems to improve medication-related outcomes.

- Medication optimization through CMM promotes patient engagement in developing the patient-centered care plan.[30]

- Optimizing medication use (including but not limited to reducing nonadherence) can decrease downstream health spending.[31]

- CMM enhances physician work-life, reducing burnout and improving engagement among providers.[32] As an accountable member of the primary care team, the clinical pharmacist can alleviate the workload of managing patients' chronic conditions and helping people achieve their therapeutic goals. This frees physicians and other members of the team to provide care that aligns with their expertise and delivers enhanced team efficiency.

Envisioning the future

The challenge going forward is not simply to demonstrate that programs work but to support a new payment methodology that will support and expand access to CMM-level services. This is particularly important to organizations that are rewarded through value-based contracting arrangements and payment models.

The current system lacks a defined payment structure to reward programs designed to optimize medications through CMM services provided by a medication expert. Future payment models must recognize the importance of managing total costs of care and the benefit offered through CMM in integrated team-based models. But without payment models that support rapid growth, movement toward full system-wide adoption of team-based CMM services varies, as seen in stages of practice adoption (Figure 5).
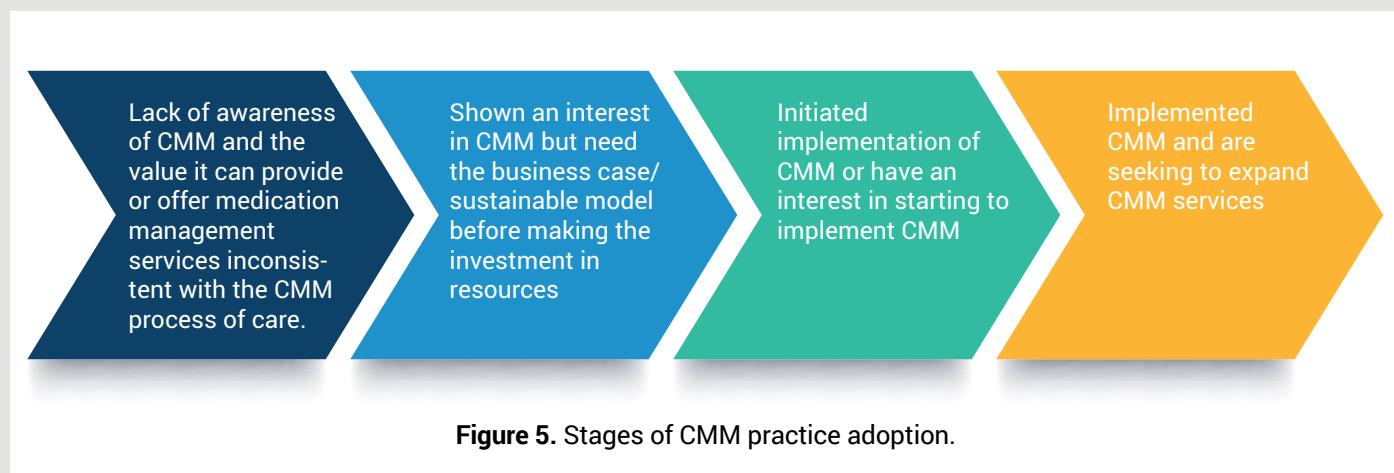

Figure 5. Stages of CMM practice adoption.

Clear, consistent and standardized payment policies are needed to support practice transformation efforts focused on driving value that will create long-term sustainable programs. Evidence shows that integrated team-based models of care can improve outcomes and efficiency. The Institute also believes that payment reform should start now, even within current fee-for-service payment models.

29   Centers for Disease Control and Prevention. "Therapeutic drug use." https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm. Accessed May 28, 2017.
30   "The Patient Care Process for Delivering Comprehensive Medication Management (CMM): Optimizing Medication Use in Patient-Centered, Team-Based Care Settings." CMM in Primary Care Research Team. July 2018. Available at https://www.accp.com/docs/positions/misc/CMM_Care_Process.pdf
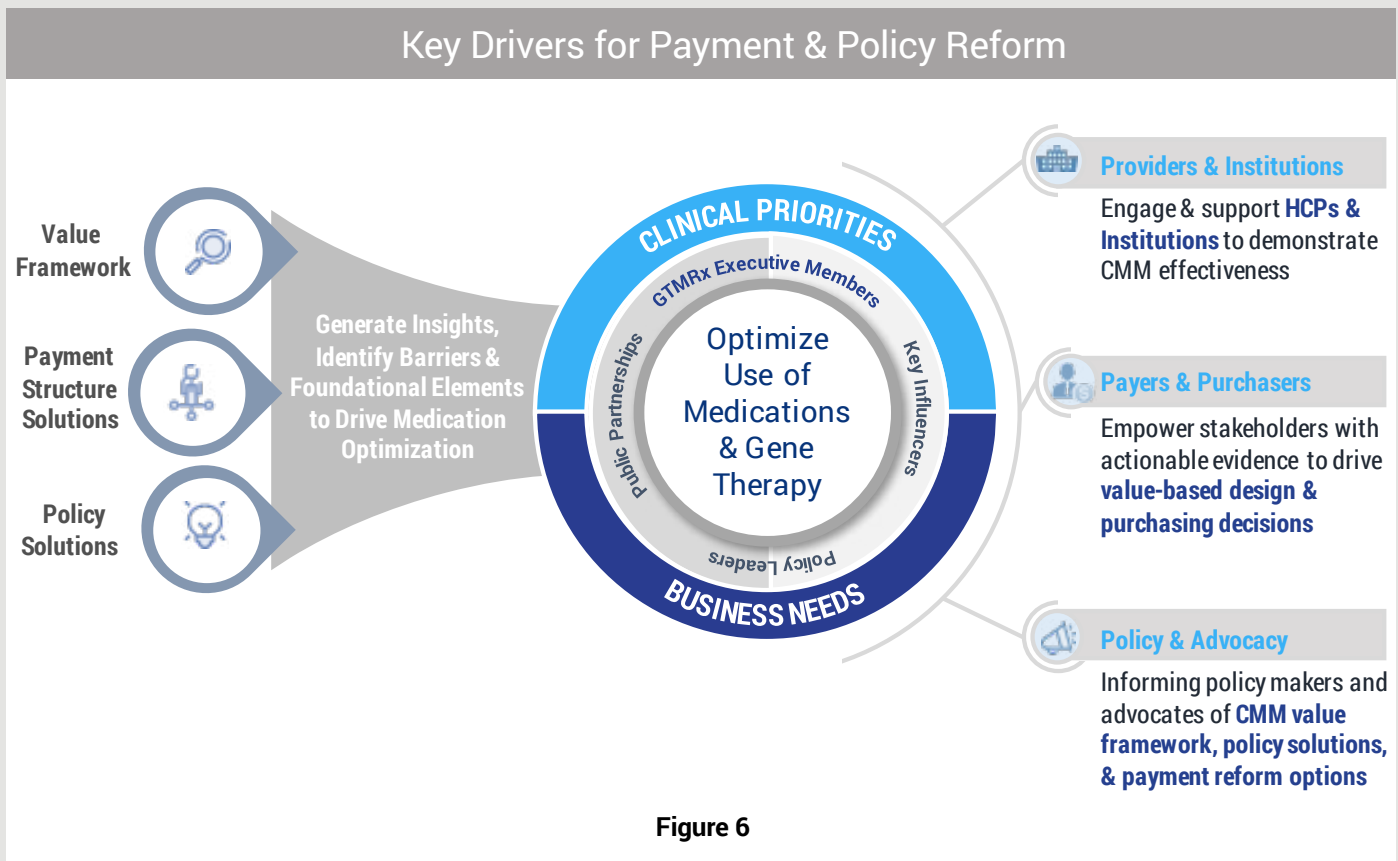31   Jonathan H. Watanabe, Pharm.D., MS, PhD, Terry McInnis, MD, MPH, Jan D. Hirsch, PhD. "Cost of Prescription Drug–Related Morbidity and Mortality." *Ann Pharmacother.*2018 Sep;52(9):829-837.
32   Kylee A. Funk, et al. "Primary Care Providers Believe That Comprehensive Medication Management Improves Their Work-Life." *J Am Board Fam Med* 2019;32:462– 473.

Key Drivers for Change

Engagement and buy-in from key stakeholders, as well as supporting culture and change management, are needed to drive progress in medication and gene therapy optimization.

To accomplish this, we must create a value framework and identify policy and payment structure solutions that will further practice and system transformation. Engaging a diverse group of stakeholders, including key influencers, policy leaders and public partners, will generate insights and identify barriers as well as foundational elements to drive medication optimization. These insights and key elements will be used to offer meaningful guidance and recommendations to effect change, taking into consideration clinical priorities and business needs for advancing practice and care delivery.

Key Drivers for Payment & Policy Reform

Value Framework

Payment Structure Solutions

Policy Solutions

Generate Insights, Identify Barriers & Foundational Elements to Drive Medication Optimization

CLINICAL PRIORITIES

GTMRx Executive Members

Public Partnerships

Key Influencers

Optimize Use of Medications & Gene Therapy

Policy Leaders

BUSINESS NEEDS

Providers & Institutions
Engage & support **HCPs & Institutions** to demonstrate CMM effectiveness

Payers & Purchasers
Empower stakeholders with actionable evidence to drive **value-based design & purchasing decisions**

Policy & Advocacy
Informing policy makers and advocates of **CMM value framework, policy solutions, & payment reform options**

Figure 6

Areas of further work: The Framework and beyond

The GTMRx Payment and Policy Solutions Workgroup (Workgroup) recognizes the importance of an initial framework. This framework should be evergreen, and guidance needs to incorporate evolving evidence and use cases. To advance the integration of CMM into policy and payment initiatives, the Workgroup will

- **Create the value framework.** To create this framework, the Workgroup will assess and articulate the value CMM brings to the health care system and suggest how that value should be measured by each *stakeholder,* each *organizational type* and each *payor type* (public, private and employers as plan sponsors) to facilitate system-wide adoption of CMM.

Key components creating the value framework:

- o **Identifying evidence, promising payment frameworks, use case examples and tools** for advocacy considering the value of optimized medication use across target audiences: consumers, providers, public and private sector payors.

- **Providing guidelines and proof points for advocacy and showcasing** the ways in which the CMM process leads to appropriate use, decreased waste and optimized outcomes. Robust evidence will be sought to build a business case for all levels of care and a variety of stakeholders (those who pay for care, those who provide care, those who receive care), when that evidence is available. Evidence will be packaged and retooled into the appropriate forms for advocacy to ensure that it provides

    - Guidance and advocacy tools to demonstrate CMM's effectiveness and advance its integration into payment and policy initiatives, and

    - Resources for practices and systems of care based on "where they are," fitting the transitional stage they are in now in the evolution from fee-for-service to value-based payment.

  - **Offering guidance to inform contract standards** and common definitions between those who buy care (consumers, and employers as plan sponsors) and those who contract for care (health plans, consumers, government).

- **Identify and evaluate barriers to adoption.** The Workgroup, in consultation with other GTMRx workgroups, will *identify barriers and determine the foundational elements* that must be present to ensure program outcomes that matter. This will inform a plan to overcome policy and payment barriers by each stakeholder group, each organization type and each payor type.

  For instance, how should CMS structure a payment methodology for CMM-level services to reward what matters? How should an employer as plan sponsor, interested in this level of service (generally the commercial side), structure payment and/or expense to justify programs to its CFO? How should an integrated delivery system evaluate risk, rewards and benefits of these programs?

- **Determine key policy elements.** Identify foundational elements of policy solutions necessary to overcome those barriers to adoption of CMM and optimize the use of medication and gene therapies.

  - **Identify successful use cases** (commercial, public, private) for use in advocacy and coalition building in support of and to advance the mission and vision of GTMRx.

  - **Specifically define characteristics and foundational elements** that will inform a policy platform intended to overcome barriers to broad and sustainable adoption of team-based care activities that are designed to optimize the use of medication and gene therapies.

- **Identify payment solutions.** Identify replicable and scalable payment structure solutions (and their component parts) that have been successful and those that have failed, in order to advance successful advocacy efforts and encourage testing, piloting and adoption.

- **Design an approach to educate and engage policymakers** about these solutions. Identify partners and develop tools, guidance and a dissemination plan.

  - Engage and support providers and institutions to offer a pathway to demonstrate CMM effectiveness, cost-saving opportunities for those at risk and opportunities to enhance quality of care and patient satisfaction.

  - Empower payors and purchasers with actionable evidence and payment approaches to inform and drive value-based benefit design and decrease waste (avoidable hospitalizations, medical visits, additional medications).

  - Inform policymakers and advocates of the CMM value framework, policy solutions and payment reform options for programs designed to save lives and save money through a patient-centered, team-based approach.

Call to Action

The GTMRx Payment and Policy Solutions Workgroup strives to formulate and inform key policy and payment strategies to enable introduction and adoption of a systematic approach to medication use that optimizes clinical outcomes. Reductions in overall cost of care and improved outcomes will be realized by assuring access and affordability of innovative medications—for the right patients.

Achieving this goal requires

- activities to collect, evaluate and promote widespread understanding among providers/systems, payors and patients;

- information sharing; and

- adoption of contemporary payment reform strategies and methods now occurring in U.S. health care (quality, safety, outcomes, value) and their logical alignment with (and essential application to) providing CMM services across all care settings.

The Workgroup recognizes there is a delicate balance between putting the foundational principles of a value framework in place while allowing flexibility for broader appeal and feasible implementation. The journey to sustainable payment and policy solutions is an evolutionary process and solutions, in order to be effective, must be tailored to address the needs of each of the audiences (those who pay for care, those who deliver care and those who receive care) to motivate change. What is essential is the ability to explain CMM in a way that's meaningful, digestible and actionable for each particular audience. The goal is to encourage, support and motivate stakeholders to implement programs that optimize medication use and result in better patient outcomes, saving lives and saving money.

What Needs to Be Done Now?

Payment and Policy Solutions

- Identify foundational elements of policy solutions necessary to overcome barriers to the adoption of CMM and optimization of medication and gene therapies.

- Identify successful use cases for utilization in advocacy and coalition building.

- Identify payment solutions and policy and payment strategies that reward the value of CMM services in terms of cost, quality and patient outcomes.

- Design an approach to educate and engage policy-makers about CMM.

Value-based models: MACRA provides incentive for providers to adopt CMM

Practices do not have to start from scratch; they can build on existing value-based structures. MACRA (Medicare Access and CHIP Reauthorization Act of 2015) can provide resources to pay for extended members of the team.

MACRA replaced the Sustainable Growth Rate formula with the Quality Payment Program (QPP). QPP has two primary tracks. MIPS (Merit-based Incentive Payment System) provides performance-based adjustments to Medicare payments. Advanced APM (Advanced Alternative Payment Model) requires networks to assume financial risk for their patients. (Think ACOs, Oncology Care Model, etc.)

Both MIPS and APMs use value-based payment models to give providers financial incentives to improve patient care while controlling costs. This includes embracing team-based care and integrating clinical pharmacists into that team.

By integrating CMM into advanced primary care medical home models, the care team can optimize each patient's medication use, resulting in increased quality and payment for the medical practice. Optimized medication leads to increased quality, which results in increased payments for the medical practice.[33]

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33   Payment Methods in Outpatient Team-Based Clinical Pharmacy Practice, Part 2: MACRA for Pharmacists ACCP, 2018

HEALTH IT TO SUPPORT OPTIMIZED MEDICATION USE WORKGROUP
Optimizing medication use: Turning data into actionable information

"We don't need more information; we need information at the point-of-care available to us as a care team, in a useful, actionable way." —**Workgroup member**

Medication optimization relies on having the right data, at the right time, at the point-of-care. That data must be *actionable.* It must be *useful* to the care team. Only then will the care team be equipped to provide comprehensive medication management (CMM) services to patients who need it.

The GTMRx Health IT and AI to Support Optimized Medication Use Workgroup (Workgroup) is addressing this challenge— specifically, the need to ensure that technology supports the transfer of data to the point-of-care. It is focused on making that data accessible to all team members to enable medication optimization. Its goal: Provide leadership, practice guidance and recommendations that will overcome barriers to the use of technology—technology that enables broad practice adoption of a systematic approach to medication use (specifically CMM) across the continuum of care.

Access to point-of-care clinical information enabled by technology (e.g., diagnostic results, clinical notes, patient status) allows care teams to fulfil important activities in the CMM process. In particular, access helps teams to identify patients who have not achieved clinical goals of therapy (or who are experiencing medication therapy problems) and evaluate actual use patterns of all medications (e.g., OTC, supplements, prescribed drugs and biologics). Access also allows care teams to utilize the information needed to properly assess each medication for appropriateness, focusing on the achievement of the clinical goals for each therapy.

The Workgroup has identified key activities for broad market adoption of technology solutions—activities that will advance and enhance the delivery of comprehensive medication management services. The group is focusing on the following key areas:

1. **Supporting data standards:** Support the adoption and expansion of both private and public sector initiatives to ensure adoption of data standards required to ensure widespread CMM practice integration.

2. **Engaging government:** Be a visible resource to support government initiatives that advance data interoperability, CMM practice standards and regulatory requirements for reimbursement that are consistent with the CMM framework, aligning priorities with the GTMRx Policy and Payment Workgroup.

3. **Facilitating use of advanced algorithms:** Describe and delineate elements necessary for advanced algorithms. Ensure that advancements in pharmacogenomics, AI and related intelligence models and systems are rapidly and judiciously incorporated into IT systems and practice standards.

4. **Showcasing use of health information technology within the CMM framework:** Ensure the consistent visibility, adoption and advancement of the data, health IT and AI systems necessary to advance adoption of the CMM framework.

Why does this matter? In a word, *Sylvester*

To put this in context, the Workgroup shared the story of a patient, Sylvester. He has several health conditions, including hypertension, diabetes and COPD. He takes 14 unique medications in 19 daily doses via three different administration methods. Because Sylvester was receiving conflicting medication advice from his various providers, he and his caregivers were confused and conflicted. He had no one looking at him holistically as a patient, a caregiver who considered all the medications he was taking while tracking his ability to reach the various clinical goals of therapy. His medication use was not being managed in a patient-centered way; he did not have access to a medication expert integrated into the care team and working in collaborative practice with his physician and other team members.

The lesson from Sylvester—and so many other patients—is this: We don't need more data; we need medication-related information organized and actionable at the point-of-care, available to the care team as a basis to develop an effective medication plan. Today, medication-related data and information are not well organized.

When considering the goal (to optimize medication use), health IT and AI come into play as enablers of the process. But to make this process efficient and effective, use of these tools must also:

- Ensure efficient use of resources by helping improve identification and risk stratification of patients who would benefit the most from an integrated CMM strategy;

- Connect the care team more efficiently to the clinical information necessary to provide optimal care;

- Gather medication-related information to quickly evaluate indication, effectiveness, safety and convenience, allowing a care-team member to more efficiently evaluate medication with the patient's input; and

- Allow the process of optimizing medications to be streamlined.

Envisioning the future

The Workgroup offered a vision of what the future could look like if health IT and AI are effectively used to support CMM services.

- **Health IT would be the facilitator for aggregating and integrating real-time data from external sources.** Health IT would integrate the digital therapeutic health information that a patient is gathering alongside the pharmacogenomic data that clinicians currently receive as a separate, cumbersome report. These types of information would come together in an EHR, in a usable fashion.

- **Health IT would collate data to support medication-related clinical decisions.** The EHR would group medications by diagnosis or the reason the patient was taking them. A clinician could easily discern the reason a medication was stopped. Was it ineffective? Did it cause an adverse reaction? Was it no longer covered by the patient's plan? Was it affordable? A medication-related dashboard could support anyone on the care team, allowing them to make simple, streamlined decisions about a patient's medication therapy. This dashboard could include objective data that helps clinicians decide if a patient needs a higher level statin, or if the blood pressure medicine should be increased, or whether pharmacogenomic data is needed to assess safety or efficacy of the medications.

- **Integrated data from EHRs, pharmacies, health plans and other reliable sources would provide the foundation for deployment of comprehensive risk models.** Risk stratification tools allow care providers to easily identify the patients who are at risk. Health systems, pharmacies, payors and prescribers could all proactively reach out and invite these patients to participate in CMM services.

- **Purpose-built software would drive consistency and demonstrate the value of CMM practice.** Software supports the practice management systems developed around CMM workflows and thought processes, driving consistency of the CMM service. Software ensures capture of compliance and regulatory reporting requirements unique to CMM services. Health IT allows us to collate and identify medication-therapy problems in a systematic way that can be gathered and analyzed across systems. Participation in CMM services—identification and resolution of medication therapy problems—can be correlated with broader changes in health status or health care utilization patterns, thus demonstrating contribution and value to the health care system. Ideally, we could show similar outcomes and similar practice fidelity across the nation.

But getting to that future from the status quo is a heavy lift. It can be done, of course, but we must scale some substantial hurdles.

Barriers to success

Numerous barriers stand in the way of using health IT and AI as tools to enable the delivery of CMM services that will ultimately optimize medication use. The Workgroup identified five key barriers that must be overcome.

- **Lack of access to timely information:** The medication expert on the team and other team members providing care to patients often lack access to the best or most timely information to support optimal clinical decisions regarding drug therapy. There are many reasons, including:

- Siloed care delivery models that lead to incomplete information residing in multiple locations, because that information is owned and/or managed by different parties;

- Insufficient adoption of clinical data standards to drive interoperability, liberating the data and allowing it to flow to the point-of-care, wherever that care is provided;

- Sequestration of information, particularly among the largest players—i.e., the largest owners of data;

- Lack of structured methodology to store and transfer patient information that is available to all authorized parties in real time; and

- Balancing all the above with assurances of patient privacy.

- **Lack of integrated data:** Absence of a full view of the patient's medical information at the point-of-care constrains our ability to demonstrate CMM's contribution toward efficiency, outcomes and affordability in health care.

- **Exponential growth in the volume and complexity of data** is exacerbating challenges present with siloed information, increasing the difficulty in developing useful tools for CMM. This increasingly will restrict the development of more advanced risk-assessment algorithms to support CMM practice.

- **Diagnostic results and therapeutic monitoring activities missing.** Current health IT systems are largely unable to handle rapidly evolving advances in pharmacogenomics, AI, therapeutic drug monitoring and other diagnostics that aid in medication selection.

  - EHR systems do not support integration and clinical translation of pharmacogenomics to help prescribers understand the applicability of pharmacogenomics in everyday medicine.

  - Many prescribers and health care providers lack trust and confidence in risk stratification and AI models; those models can help identify patients who would benefit most from CMM and other high-touch interventions.

- **Integrating care-management processes.** Care management processes are not currently designed to support CMM care delivery and measurement of related outcomes.

  - Regulatory reporting requirements for CMM services are not supported in the most widely used health records.

  - EHR systems do not support medication-centric workflows used by CMM pharmacists; these medication-centric workflows include categorization of medication-therapy problems, interventions and resolution codes.

  - Pharmacist/CMM pharmacy-centric platforms are not interoperable with EHR systems widely used by other members of the health care team.

How do practices assess where they are today, and where they should be tomorrow?

The Workgroup recognized that adopting technology to support the delivery of CMM services requires a certain level of readiness, sophistication and technological maturity. This can be plotted on a maturity matrix and is supported by a set of leadership accountabilities found on the leadership checklist developed by the Workgroup. The group developed key tools to assist with this process, designed to offer guidance to the market as practices consider how to operationalize CMM services enabled by health IT.

Thinking about what comes next

A robust discussion followed the presentation, much of it focused on not burdening practices and providers. Three key themes emerged.

First, be deliberate and don't overwhelm with tools that do not integrate into workflow: Move deliberately, cautioned one participant. The higher the risk, the slower the pace of adoption needs to be. For example, having the population-management tools to identify high-risk patients takes time and bandwidth. Practitioners—physicians, pharmacists and other care team members—may already be at capacity, one participant warned. We need to be mindful when implementing health IT tools, not to introduce more time into the workflow generating additional resource allocations. "People think that IT solutions solve a lot of problems, but they create as many problems as they solve sometimes."

One way to avoid this is to build foundational components of AI and health IT, including standardizing the care processes. Interoperability *demands* standardization, warned another participant.

Moving at a deliberate pace and putting in place a solid foundation are doubly important for smaller practices. Several participants expressed concern about the capacity of smaller practices to implement the health IT solutions needed for CMM. Discussion turned to one possible solution: creating centralized utilities for smaller practices.

The Workgroup noted that standardization—and cloud-based software—makes it easier to exchange and use data for practices of all sizes.

Second, ensure AI accuracy: So far, AI isn't accurate enough for health care. But that's changing. As one participant said, "We're beginning to get that secret sauce in the middle of the neural network that we don't understand." Until then, organizations need to approach AI with care. One of the participants offered a stark reminder why accurate modeling requires accurate data: The Department of Justice investigated one national payor over risk models that appeared to be biased against people of color. But, one participant noted, the problem wasn't the model. It was the data.

Third, physicians *must* have a say: When it comes to leveraging health IT and AI to support optimized medication, those who deliver care must have a seat at the table—especially in terms of clinical risk modeling. Little discussion was needed on this point: Everyone appeared to agree.

Areas of further work: Narrowing the focus and moving forward

Overall, the discussion revealed that leveraging health IT and AI for medication optimization touches every aspect of clinical care. It also revealed that many issues and concerns remain to be resolved. While acknowledging that numerous changes need to be made, the Workgroup will focus its work in 2020 on five priorities:

1. Work with regulators, practice organizations and the industry to establish standards and best practices to drive standardization and interoperability. (The Office of the National Coordinator for Health Information Technology has already been providing guidance around the future state of interoperability.)

2. Develop guidance for health IT requirements to support the successful integration of CMM services, specifically around peer-to-peer documents.

3. Aggregate and integrate new data to help support optimized medication use through AI (e.g., social determinants of health, pharmacogenomics, clinical analytics, genomic risks, population health).

4. Promote utilization of AI-enabled risk stratification tools to support population health management to aid health systems, payors and prescribers in patient identification for CMM services.

5. Further develop, field test and share the Health IT and AI Maturity Matrix and the Health IT and CMM Practice Management Leadership Checklist.

What Needs to Be Done Now?

Health IT to Support Optimized Medication Use

- Work with regulators, practice organizations and industry to establish standards and best practices that drive standardization and interoperability.

- Develop guidance for health IT requirements to support the successful integration of CMM services.

- Aggregate and integrate new data to help support optimized medication use through AI (e.g., social determinants of health, PGx, clinical analytics, genomic risks, population health).

- Promote utilization of AI-enabled risk stratification tools to support population health management to aid health systems, payors and prescribers in patient identification for CMM services.

- Further develop and share the Health IT/AI Maturity Matrix & Leadership IT Checklist.

Maturity matrix: Moving toward the future

The Workgroup created a visualization to show how practices can use health IT to support CMM. Specifically, it illustrates where information collection and use of technology tools may be today, and where they must evolve to support optimal medication use.

This illuminates the "Health IT Capabilities and Functionalities for CMM Practice Maturity Matrix" (Appendix III.b) and considers several use cases with Delta, a hypothetical patient, and how she might encounter four different responses to her needs depending on where the practice or service is on the maturity matrix.
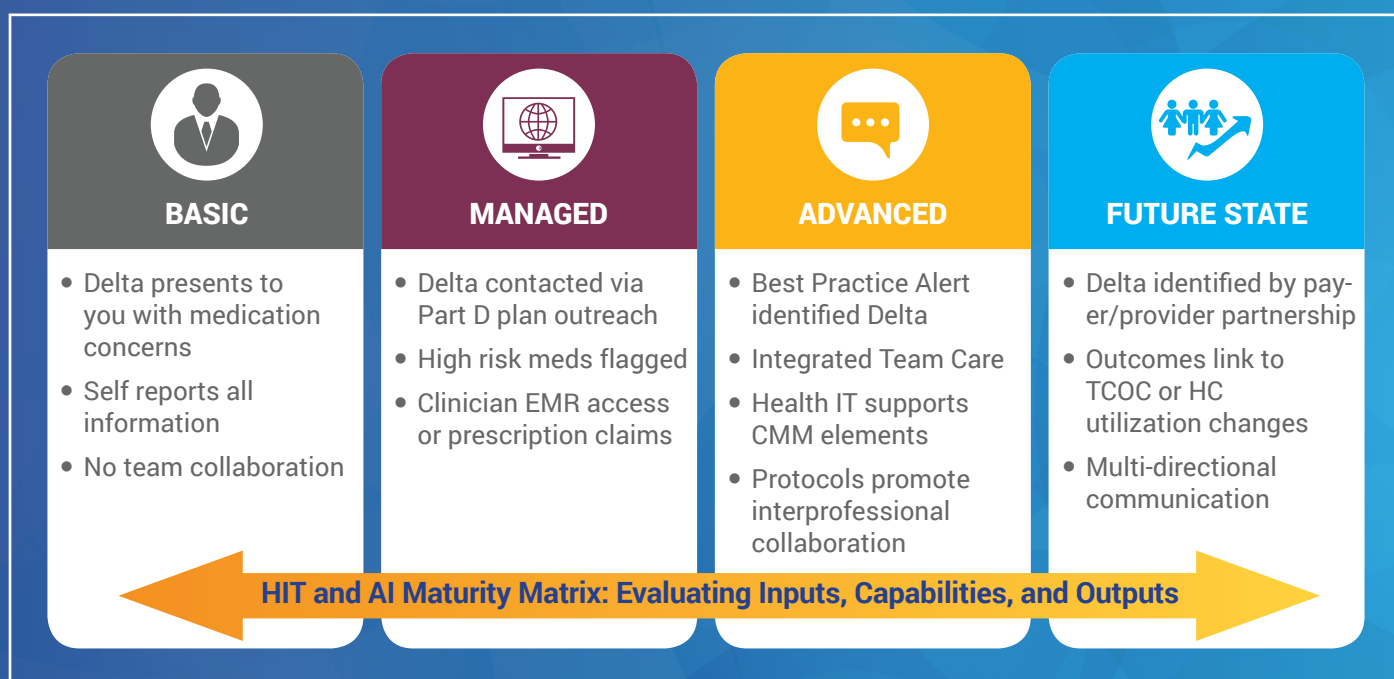
BASIC	MANAGED	ADVANCED	FUTURE STATE
• Delta presents to you with medication concerns • Self reports all information • No team collaboration	• Delta contacted via Part D plan outreach • High risk meds flagged • Clinician EMR access or prescription claims	• Best Practice Alert identified Delta • Integrated Team Care • Health IT supports CMM elements • Protocols promote interprofessional collaboration	• Delta identified by payer/provider partnership • Outcomes link to TCOC or HC utilization changes • Multi-directional communication

HIT and AI Maturity Matrix: Evaluating Inputs, Capabilities, and Outputs

Figure 7. Health IT and AI: Visualization of Approach.

BASIC LEVEL

Delta and her family present either at the pharmacy or the primary care clinic. They have concerns about medications and adverse effects. She is new to the pharmacy/clinic facility, and she self-reports all her information. She has her most recent after-visit summary and a written medication list, so the information is considered reliable. But the facility lacks a complete medication record, and it doesn't know who is on her care team. Delta must identify them. The facility doesn't have access to her medical record to determine actual diagnoses or clinical goals of therapies for prescribed medication.

MANAGED LEVEL

Delta's Medicare Part D plan reaches out to her, encourages her to visit with their pharmacist to review her high-risk medications. She prefers to talk with her clinician first, who refers her to the clinic's pharmacist. Her Part D plan has flagged some of her high-risk medications based on prescription claims. The clinician has EHR access but no access to her prescription claims. Or, in a similar scenario, Delta prefers to meet with her community pharmacist who has all her prescription fill history, but no access to objective lab results or formal diagnoses.

ADVANCED LEVEL

A Best Practice Alert identifies Delta as needing some sort of medication-related intervention. She has an integrated care team, and protocols promote some interprofessional collaboration. Health IT supports CMM elements and team-based care. Health IT tools support the pharmacist protocols to adjust doses, send prescriptions and order labs for some disease states. The pharmacist's note captures medication-therapy-problem-specific data and can be sent electronically to Delta's specialists for intervention.

FUTURE STATE

Delta is identified through a payor and provider partnership, combining multiple variables and data sets for population health risk stratification. Proactive outreach invites her to participate in CMM services. Pharmacogenomics, a facet of many clinical support tools, is used to build relevant objective findings to integrate results into the EHR. CMM-related outcomes can be linked to changes in the total cost of care or changes in high-cost health care utilization. Delta and her daughter have read/write access to the EHR, so they can provide health data from home monitoring.

It is clear that the "Future State" outlined in the maturity matrix, enabled by technology, leads Delta and her providers to an integrated and comprehensive approach to medication use. However, the Workgroup recognized that today, practices around the country are at different levels. To reach the future state, the Workgroup has developed tools to facilitate more rapid advancement.

Leadership Checklist

Recognizing the importance of leadership support and organizational culture in successful adoption, the Health IT and AI Workgroup created a succinct, actionable checklist to ensure organizational and practice leadership readiness. They designed the Health IT and CMM Practice Management Leadership Checklist (Appendix IV) for organizations interested in leveraging health IT. It outlines **five essential areas of practice** as important considerations for those beginning CMM practice, as well as those who have moved to a more advanced state of CMM implementation. The checklist outlines **key characteristics** that should be present and/or anticipated as the system or practice embarks on the delivery of health IT-enabled CMM practice.

As Figure 8 illustrates, leveraging health IT to enable CMM requires the presence of

- organizational support,
- a care delivery process supporting CMM capabilities,
- effective care team engagement,
- an evaluation process for CMM services, and
- ensuring consistent and quality of care.

Figure 8. Visualization of Approach: Leadership HIT & CMM Practice Management Checklist.

Source: Pestka DL, Frail CK, Sorge LA, Funk KA, Roth McClurg MT, Sorensen TD.

Organizational Support
- Availability of space and IT resources
- Billing and revenue IT resources

Care Delivery Process
- Identification of at-risk patients & workflow operations
- Optimizing care documentation

Care Team Engagement
- Optimizing IT utilization of collaborative practice agreements
- IT support for interprofessional collaboration

Evaluating CMM Services
- Measuring CMM specific data elements and coding
- Ability to report CMM data and outcomes

Ensuring Consistent & Quality Care
- Practitioner-specific training to electronic medical record
- IT support for quality assurance processes

PRECISION MEDICINE ENABLEMENT VIA ADVANCED DIAGNOSTICS WORKGROUP

Optimizing medication use: Leverage the power of genomics to improve patient care

"We really need to make sure that we have an elevated level of awareness with regard to these precision medicine technologies so that we are supporting the team at the point-of-care. It's an immense amount of information, and we need to ask how we can support providers so they can assimilate all of this into their practice." —**Workgroup member**

Advances in diagnostics—including pharmacogenomics (PGx) and the understanding of the individual variability of drug response—are rapidly changing our approach to medication therapy and treatment of disease. The current trial-and-error method will soon give way to personalized, more *precise* medication use. However, these emerging diagnostics, aided by an explosion of scientific discovery, have yet to find a pathway to rapid deployment in the market or at the point-of-care.

Why does this matter?

Ensuring Americans receive the most benefit from advances in pharmacology is a critical component of improving the national health care system. But appropriate diagnosis and access to next-generation clinical testing is essential to target correct therapy.

Companion and complementary diagnostics are tools to target more appropriate use of medications. Rapidly getting these tools to the point-of-care, interpreting the results and developing a care plan (with therapeutic changes needed to achieve optimal outcomes through medication use) are all enhanced through use of a systematic, team-based approach. This is often enabled by tests that evaluate the body's absorption, distribution, metabolism and elimination of medications, as well as the biotransformation of medications that affect the way they are metabolized.

Current outcomes offer rationale for a new approach:

- **Medications that make you sicker,** are wrong or are not taken as intended undermine quality, safety and effectiveness.[34]

- **Inadequate therapy** (dose too low, alternative drug needed, wrong drug, contraindications, etc.) accounts for more than half of the medication use/treatment failure problems encountered.[35]

- **Adverse drug events** account for nearly 700,000 emergency department visits and 100,000 hospitalizations a year.[36]

Pharmacogenomics testing is an important tool to help the care team solve these problems. Effectively used as a diagnostic companion in support of CMM services, it has the potential to reduce the overall cost of care, adverse drug reactions, failed trials, effects of disease on the body and the length or type of a treatment regimen.

But we face another challenge: **communicating the value of PGx testing while challenging the status quo.**

PGx is complex, making it a complicated story to tell. It's also an everchanging story, because new insights continue to emerge. For instance, in oncology, new genetic mutations are being discovered, and questions abound around the clinical impact of individual mutations. How do we tell a story about the value and appropriate use of diagnostic tools that keep evolving?

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34   Watanabe, JH, McInnis, T, and Hirsch, JD. "Cost of Prescription Drug–Related Morbidity and Mortality." Annals of Pharmacotherapy, 2018; 52(9), 829–837.. org/10.1177/1060028018765159.

35   Comprehensive Medication Management in Team-Based Care. American College of Clinical Pharmacy. www.accp.com/docs/positions/misc/CMM%20Brief.pdf

36   Medication Errors. June 2017, psnet.ahrq.gov/primers/primer/23/medication-errors. AHRQ Patient Safety Network.

With caution and humility, according to the Precision Medicine Enablement via Advanced Diagnostics Workgroup, which offered this warning: "Every system is perfectly designed to yield the exact results it produces."

Envisioning the future

Building on these challenges, the Workgroup identified examples of how the status quo fails—calling the current state "imprecision medicine." It then articulated what successful use of pharmacogenomic testing within team-based, patient-centered treatment offers today and what it can offer tomorrow.

Today, the absence of an FDA framework for phenotype interpretation and/or annotation inhibits a clinician's ability to make informed decisions at the point-of-care. PGx results provided by labs include phenotype information, but no medication reference. *Ideally, in the future,* FDA will provide clear rules for including genetic insights, annotation and phenotype recommendations in a single document and/or process. PGx reports will provide both genetic information and medication insights.

Along those same lines, the current lack of broad-scale, federally accepted and standardized interpretations of pharmacogenomic lab findings limits the care team's ability to leverage this clinical knowledge for actionable medication management at the point-of-care. Moving forward, we need standard-setting organizations to provide guidance and evidence-based insight in order to achieve optimal outcomes.

In this ideal future, we'll have a systematic approach to medications. Physicians and pharmacists will ensure medications are individually assessed to determine whether each is appropriate for the patient, effective for the condition, safe (given the comorbidities and other medications being taken) and able to be taken by the patient as intended.[37] All this will be supported by advanced diagnostics such as PGx. This systematic approach will become a regular component of patient-centered primary care for patients with chronic conditions.

Accomplishing this, of course, requires liberating the data to allow widespread availability of information to support discrete results and clinical decision support at the point-of-care. *In the future,* providers, payors and patients will have secure and timely access to the information necessary to identify those patients who have not achieved clinical goals of therapy, identify all drug therapy problems and collaboratively develop a care plan (including therapeutic changes needed to achieve optimal outcomes for patients), *regardless of the financial or contractual relationship between parties.*

This information not only needs to be available at the point-of-care; it must be in a usable format. PGx results that are *today* added into the EHR as non-discrete data (e.g., PDFs) will *one day* be fully integrated to enable more useful clinical decision support and ability to query data in the service of CMM. Only then will we be able to reap the full benefits of genomic and personalized medicine.

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37   McInnis T, Webb E, and Strand L. *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes,* Patient Centered Primary Care Collaborative, June 2012.

Important Insights & Considerations

Pharmacogenomic (PGx) analysis provides important clinical insights into genetic variances that may affect how a patient's body interacts with medications. Gene variances when translated into protein variances are reported as "phenotypes," which affect how a patient's body metabolizes, transports or responds to medications. In many instances, a variance in a phenotype forms the basis of prescribing decisions—for example targeted therapies. However, other factors beyond genomics may also influence how a body interacts with medications.

Considering a patient's genetically-derived phenotype alone is insufficient for clinicians to adequately assess drug response. Other factors, such as disease state or the concomitant administration of other drugs leading to multi-drug interactions, should also be considered as phenoconversion can occur. One to four phenoconversion is a temporary phenotype shift (e.g., normal metabolizer to poor metabolizer), which can significantly affect drug response.[a,b] For example, phenoconversion to a poor metabolizer as a result of a drug interaction could increase a patient's risk for adverse drug reactions (if a directly active drug is administered) or pharmacotherapy failure (with prodrugs such as most opioids and clopidogrel).[a,b,e] Additionally, disease states with chronic inflammation (e.g., cancer, Type 2 diabetes), cause phenoconversion and affect drug response as well.[c,d]

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a   Shah RR, Smith RL. Addressing phenoconversion: the Achilles' heel of personalized medicine. Br J Clin Pharmacol. 2015;79(2):222-240.

b   Malki MA, Pearson ER. Drug-drug-gene interactions and adverse drug reactions. Pharmacogenomics J. 2019.

c   Gravel S, Chiasson JL, Turgeon J, Grangeon A, Michaud V. Modulation of CYP450 activities in patients with type 2 diabetes. Clin Pharmacol Ther. 2019.

d   Shah RR, Smith RL. Inflammation-induced phenoconversion of polymorphic drug metabolizing enzymes: hypothesis with implications for personalized medicine. Drug Metab Dispos. 2015;43(3):400-410.

e   Deodhar M, Dow P, Al Rihani SB, Turgeon J, Michaud V. An illustrative case of phenoconversion due to multi-drug interaction. Clin case Reports J. 2020; 1(3):1-6.

How does this work? Relationships and drivers

How will PGx, properly executed, work in the clinical setting? It begins with the interprofessional care team.

To fully consider the variables that affect a patient's medications, all the key players must be part of that patient's interprofessional care team. Who is considered "key" will vary by patient. Patients require a clinical pharmacist and may also require a genetic counselor or medical geneticist on the care team.

Pairing PGx with CMM makes sense, but it is critical to consider the following external factors influencing *and* potentially holding us back from implementing that process. (See Figure 9.)

- **Patient access to precision medicine technologies:** Patients—and their clinicians—who feel they need these technologies lack access, largely due to reimbursement challenges, not just for the testing, but also for the interpretation.

- **Provider education:** We must improve provider awareness of precision medicine technologies and support providers for efficient and effective clinical decision support at the point-of-care. How do we support them so they can assimilate all of this into their practice and workflow?

- **Patient education:** Patients need general genomic literacy to understand these technologies and what they may mean to their clinical care. This should be accompanied by a shared decision-making process with the clinical team.

- **IT and interoperability:** There are numerous issues related to health IT. One of the most important is the ability to bring data into the EHR in a discrete and actionable format. Providers can't query non-discrete data, use it for research or use it with clinical decision-support tools. Discrete data allows providers to functionally use genomic medicine information to help patients at both the individual and population levels.

- **Clinical practice and interpretation:** This area is constantly evolving, with many moving parts. New regulations are being released and more companion and complementary diagnostics are emerging. We need to be aware of these and how they interplay with medications, and we must take care that we're pairing these appropriately. We need to have reference labs that can partner with our health systems. And health systems need to be able to interface with external vendors (e.g., labs) and bring data into the EHR.

Figure 9
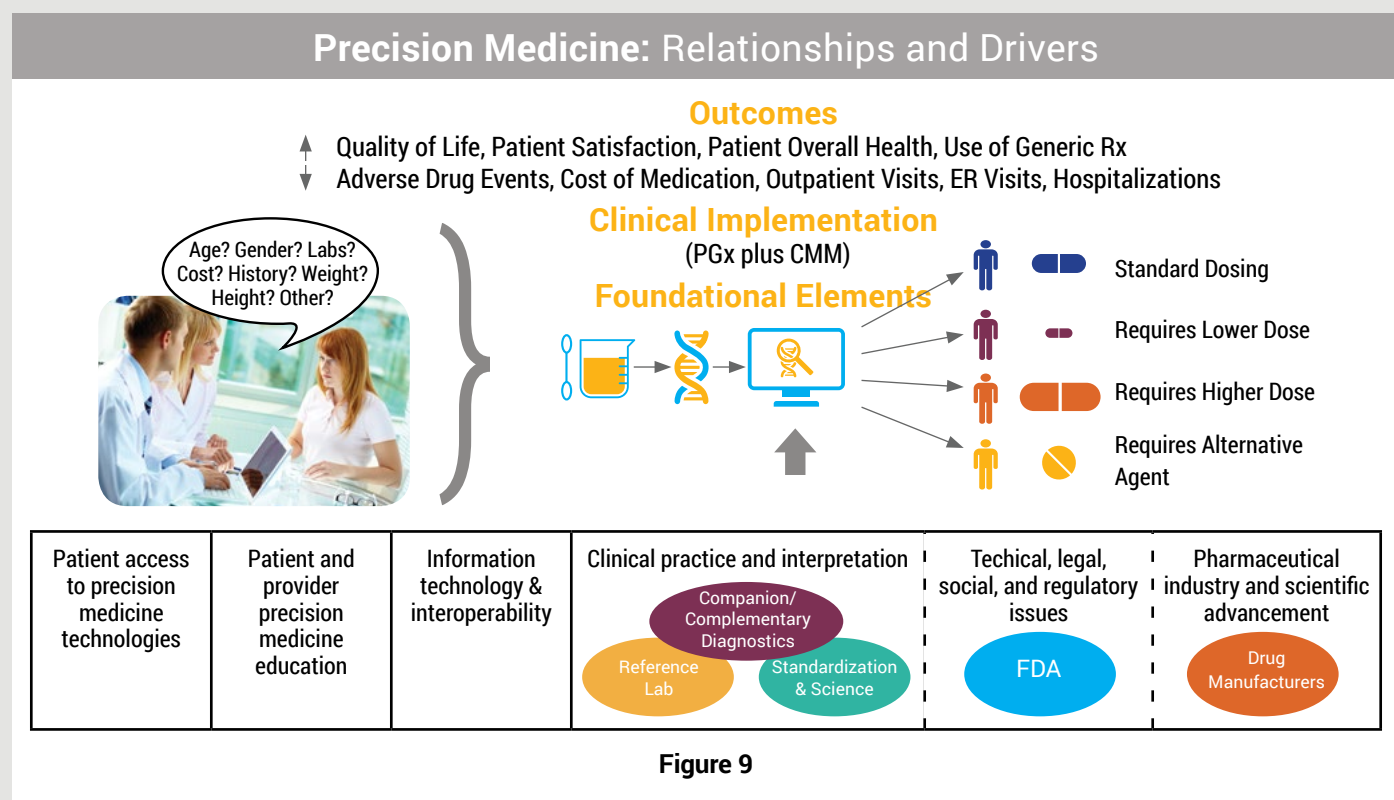
- **Ethical, legal, social, racial and regulatory issues:** Genetic information is powerful, and it must be used responsibly. Each action must take into consideration ethical, legal, racial and social implications.

- **Pharmaceutical industry and scientific advancement:** Because of the speed of scientific advancements in the pharmaceutical industry, the clinical community needs to develop creative ways to track and disseminate information about new therapies.

Moving forward: Barriers to success

We know that a personalized, patient-centered, systematic and coordinated approach to medication use will vastly improve outcomes and reduce overall cost of care. We also know that appropriate diagnosis along with access to advanced diagnostics with companion/complementary and pharmacogenomic testing, is essential to target correct therapy.

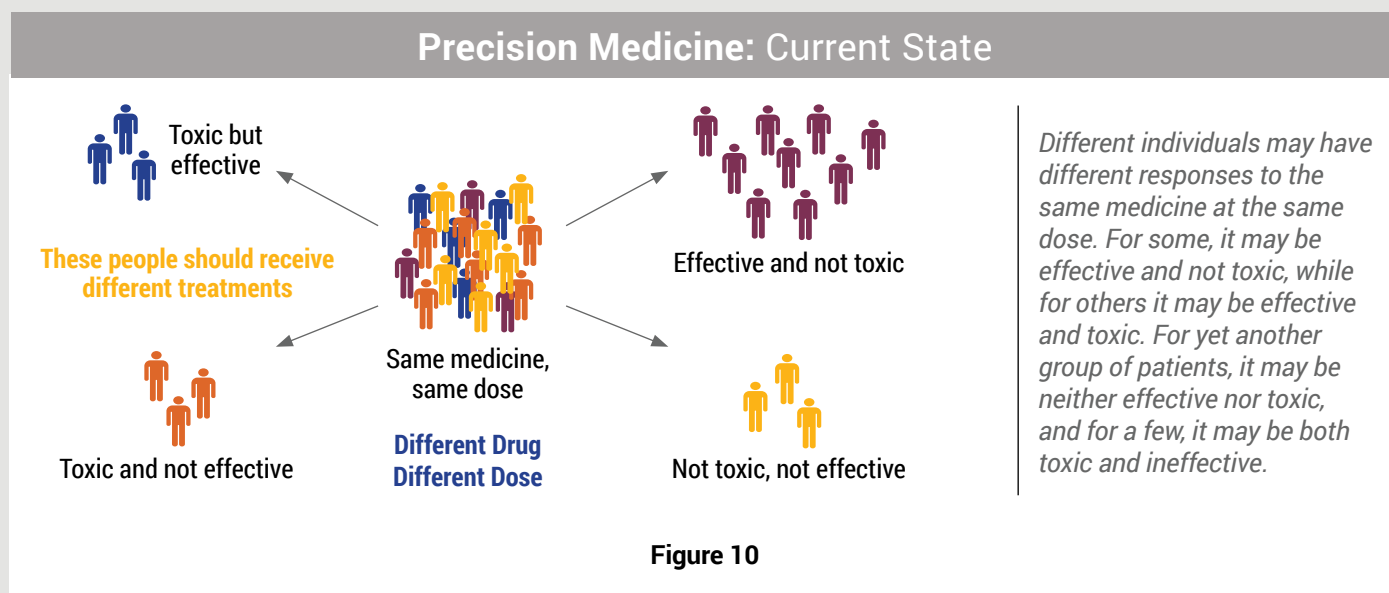But moving from the status quo to eventual success will be a heavy lift. Barriers include:

Guideline recommendations: On the clinical side, existing guideline-recommended testing (e.g., hereditary cancer, companion diagnostics prior to prescribing, etc.) is not being used to inform care decisions. Although clinical tools are *available* to enable pharmacogenomics, we need more support to augment the guideline-development process and adoption at the point-of-care.

Awareness of scope of problem: Emerging pharmacogenomics (PGx) diagnostics lack a pathway to rapid deployment in the marketplace. One reason is that the market still fails to grasp the scope and scale of adverse clinical and financial outcomes linked to medication that is not used appropriately. Another reason is lack of understanding of use and application of these tools through a team-based process at the point-of-care.

Health plans slow to move: Both market and clinical barriers contribute to a lack of access. For example, insurance coverage for pharmacogenomics remains limited. In addition, when considering a systematic approach to medication use, combined with CMM, there are not enough appropriately trained clinical pharmacists to provide pharmacogenomic and CMM services at the point-of-care. And as reimbursement stands now, pharmacists are not paid consistently for cognitive services.

Areas of further work: Advancing a more targeted approach to medication use

Regulation: Strengthen the relationship of the FDA with laboratories that provide PGx testing to optimize the testing's usefulness to patients and providers. Define clinical needs, roles and responsibilities of providers to offer guidance on how health care practitioners fit into a regulatory framework. We need to know how to use this data; we need to know what the expectations are so that we can promote responsible use of genomics in medical care. In addition, FDA device and drug divisions need to work together to advance precision medicine.

Precision Medicine: Current State

Toxic but effective

These people should receive different treatments

Same medicine, same dose

Different Drug Different Dose

Toxic and not effective

Effective and not toxic

Not toxic, not effective

Different individuals may have different responses to the same medicine at the same dose. For some, it may be effective and not toxic, while for others it may be effective and toxic. For yet another group of patients, it may be neither effective nor toxic, and for a few, it may be both toxic and ineffective.

Figure 10

Thinking about what comes next

A robust discussion after the presentation touched on an array of issues, including these three:

Health plan inconsistency: Right now, the inconsistency among health plans on how to manage pharmacogenomic tests presents a challenge, participants said There's no standard tool or process. On top of that, there are inconsistencies in terms of how testing is submitted, coded and priced. Authorizations are inconsistent. "It would be great to have a common cross-plan standard around what are the components in the test, how is it coded and then allow the labs to compete on price."

Working with the FDA: In other contexts, the FDA has identified flexible regulatory approaches for certain classes of products. Clinicians need to help the FDA understand what data they need at the point of care. As one participant put it: "To do that, we have to have a conversation with FDA, as a clinician, and say 'This is the data that I need to be able to treat my patient. This is how I need you to let me access that information.'"

Provider adoption and use: There's been an explosion of scientific knowledge, but how do we interpret and use it clinically within care teams? The growing evidence/implementation gap must be addressed, but old paradigms can't fix new realities.

Health IT and AI: Develop tools that enable the practice of precision medicine and advanced diagnostics. For instance, offer guidance and an outline for standard operating processes for the integration of PGx testing into CMM. Informatics is the backbone of precision medicine. Without it, we can't integrate precision medicine and clinical care. Neither can we do it without interoperability.

Marketplace strategy: Promote precision medicine literacy among providers, patients, policy makers and payors. Integrate this so that everyone is aware of precision medicine and its role in care—and that providers are applying it in an appropriate way for patients.

Education and public awareness: Standardize a process for precision medicine care and support providers in its delivery and adoption. For example, identify a process to raise awareness and educate clinical providers around competitive inhibition and the importance of *when* a medication is taken.

Evidence-based process: Leverage and encourage evidence-based processes and strategies that support precision medicine data and enable effective understanding, awareness and interpretation. The amount of data will grow dramatically—new biomarkers, new drugs coming to market, more real-world data, etc. We must build a workforce that knows how to use it.

What Needs to Be Done Now?

Precision Medicine Enablement via Advanced Diagnostics

- Full integration of PGx services into the pharmaceutical care process to support useful clinical decision making through increased availability of data.

- Ensure providers and payors have secure and timely access to the information necessary to identify patients who have not achieved clinical goals of therapy.

- Optimize testing usefulness and interpretation by strengthening the relationship between the FDA and laboratories that provide PGx testing.

- Promote precision medicine literacy among providers and patients in the context of its application to the clinical care role in optimizing medication use.

- Enable evidence-based processes and strategies that support precision medicine as a tool used in the CMM process and enable effective standardization, awareness and interpretation.

PATIENTS
Optimizing medication use: Including the patient perspective

"The implementation of Comprehensive Medication Management (CMM) will improve quality of life and save lives of people with chronic conditions, while lowering total health care costs and adding value for people covered by public and private health plans. Making sure that patients and clinical pharmacists are a part of the medication care team will assure that CMM will be successful."

—Elizabeth Helms, president and CEO, California Chronic Care Coalition

For comprehensive medication management to be sustainable, the patient must be recognized as a full member of the integrated team and have a role in the development of their own medication plan.

"Patients are the biggest stakeholders. Because their lives are on the line, they have the most to lose and gain. They need to understand and have confidence that their medications will work together and cause them no harm in order to build trust," says Elizabeth Helms, president & CEO, California Chronic Care Coalition (CCCC).

The CCCC represents more than 30 leading consumer health and patient-advocacy organizations, as well as physician and provider groups, representing Californians living with chronic conditions. It promotes the collaborative work of policy makers, industry leaders, providers, patients and consumers to improve the health of all Americans with chronic conditions.

The human toll

As others have already pointed out, non-optimized medication therapy was responsible for 275,000 *avoidable* deaths in 2016.[38] Non-optimization includes—but is not limited to—the use of unnecessary and ineffective medication, subtherapeutic and excessive dosage, inadequate monitoring, medication interactions, poor adherence and the inability of the patient to afford the medication. Although every prescriber of medications is expected to consider these variables, many barriers prevent this from happening.

Fragmentation of data (the inability to access clinical information across health systems) and the limited time allotted for medical visits makes optimal medication prescribing virtually impossible, particularly for high-risk patients with complex medication requirements or multiple chronic diseases.

The health care system does not encourage teamwork for a variety of reasons including the "fee-for-service" payment system, narrow scope of practice limitations, health care "silos," payor practices, electronic interoperability capabilities, etc.

The solution is to support team-based approaches to care. To be truly effective, we must include the patient as a full member of the team.

The patient as member of the team

The patient should be recognized as a full member of the integrated team and be part of the decision-making process of the development of his/her own medication plan. The worst-case scenario would be if a team developed a care plan *without* active patient participation and then presented it to the patient as a *fait accompli.* But that's exactly what's happening now in most care settings, Helms says.

Individual providers do not have adequate time to explain medications to patients, she says. "Patients need time and knowledge to digest all the elements of a medication plan. How can one 'eat an elephant?' It is easier to do so in bits and

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38   Watanabe, JH, McInnis, T, and Hirsch, JD. "Cost of Prescription Drug–Related Morbidity and Mortality." *Annals of Pharmacotherapy,* 2018; 52(9), 829–837.

pieces rather than be presented with the entire elephant and be expected to eat it whole. That would be a prescription for confusion and non-adherence and the antithesis of the goals of CMM."

As a full member of the team, patients will be engaged to learn and better understand the "whys and wherefores" of each element of their individualized plan and able to provide input and feedback to the team at every step in the process. "They will be better able to buy into the plan, which increases adherence and health outcomes."

Patients must be *informed* team members; this demands education and engagement. Providers, health plans, professional education schools and organizations, continuing education provider publications, patient advocacy organizations and policy makers all have a role to play.

Changing the status quo

The integrated team approach to medications is a departure from current practice but offers the hope to patients that they will get the medications they need, when they need them and at an affordable cost. More people in this country need to understand the importance of CMM and the impact it could have on their health care and lives.

"We are proud to work with GTMRx to undertake this education and policy campaign to move closer to personal precision health care," Helms said.

EMPLOYER PLAN SPONSORS
Optimizing medication use: Decreasing waste and holding partners accountable

"We're trying to change the status quo and transform pharmacy benefits."

—Cheryl Larson, CEO of the Midwest Business Group on Health (MBGH)

Having led health care innovation for decades, employers are actively shaping health care's new era of value-based care—with strategies to address the financial and health costs of suboptimal medication use as the highest priority. The Midwest Business Group on Health (MBGH) has been among the most active employer coalitions driving policies and initiatives to take a more comprehensive approach to medication management.

As CEO of MBGH—the Chicago-based 501(c)(3) coalition of mid-size, large and jumbo self-funded public and private employers—Cheryl Larson offered the perspective of what's at stake to optimize medication use through the lens of companies such as Caterpillar, Boeing and Sargento Foods. All are self-insured, but, Larson said, "regardless of how you're paying for health care in our world, the employer as the purchaser is the real payor."

Healthy employees, less waste

"What do employers want? They want healthy people—employees and family members. They want a productive workforce. They also want the right drug, right patient, right price and right site of care," she said. "I don't need to go to a hospital outpatient room and pay eight times more for an infusion than if I went to another location."

Employers want to eliminate waste, she said: "Waste, misuse and low-value care in the health care system. Waste in the pharmacy benefit. If we got rid of the 30-plus percent waste in our health care system today, we could pay for this. We can pay for so many wonderful things, while decreasing member costs and experiencing positive impacts to the employer's bottom line."

But as it stands now, waste continues to drive up costs. Employers, especially smaller ones, bear the brunt. Large and jumbo companies are getting their needs met in terms of contracts and pricing, but too often, mid-size-to-small employers (250 to 5,000 lives) pay much more than they need to.

Target: Specialty drugs

MBGH has identified pharmacy—specialty drugs in particular—as a major challenge for employers. The issue isn't only cost or even that they're being developed for an increasing number of conditions. It's waste, from inappropriate prescribing by physicians to non-adherence by patients to intermediaries (e.g., pharmacy benefit managers, or PBMs) adding to the already high cost.

Transforming pharmacy benefits management

To transform pharmacy benefits, employers must revisit how they are working with PBMs. Larson estimates that large PBMs can increase employer costs from 10% to 30% or even 40%. "We're working with employers to optimize their PBM contracts and get rid of all the language in those contracts that prevents them from being innovative; only then can they achieve price transparency, increase flexibility and focus on outcomes at the lowest unit cost."

Other options include managing a custom formulary to ensure drugs on it are based on clinical efficacy and not rebates, which usually only benefit the PBM. That's one of the biggest problems in the marketplace today. Employers can then pull other levers to carve out specialty pharmacy and mail order, and then contract directly with the retail pharmacy. All this gives employers more direct control, thus saving money.

Turning to the pharmacist

There are many ways that clinical pharmacists work with employers to offer value-added services through programs that focus on specific chronic conditions. The MBGH has a 15-year history with its pharmacist-led diabetes management programs, in which several members participate. The program started as part of the Ten City Challenge and was modeled on the successful Asheville, N.C., project. Participating employees meet regularly with a pharmacist trained in diabetes education and monitoring. The value-based initiative waives copays and provides free diabetes supplies for patients who participate. "We saw real impact," Larson said. Employers averaged $1,200 to $1,500 savings annually per patient.

A fiduciary responsibility

Employers have good reason to move in a new direction: Self-funded employers are fiduciary for their plan beneficiaries—employees and family members. "They are responsible for offering the best benefits at the best price. Paying for waste, misuse and low-value care and treatment is not in alignment with these priorities."

However, Larson points out that employers must be clear with what they want. "I think we're at a tipping point from a policy and legislation perspective," she said. Employers are powerful influencers in driving system change, and they can assert that influence to address misaligned incentives and help transform the system. But they must understand what they are buying and be clear about their contractual expectations.

They can't do it alone. "Collaboration matters. Collaboration like you see through the GTMRx Institute right now—a team-based approach—matters."

PROVIDER AND HEALTH SYSTEM
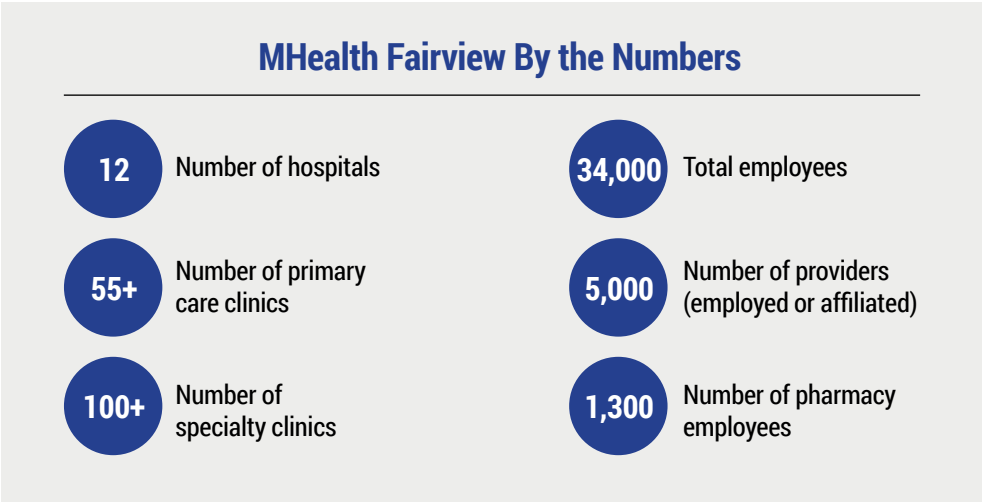## Optimizing medication use: Standardizing the care process

"We need to really come together to share results and be able to continue this movement and get the medications right."

—Amanda Brummel, Pharm.D., BCACP, vice president of clinical pharmacy services at Minneapolis-based MHealth Fairview

Decades of real-world evidence shows that providing team-based care that leverages the expertise of a medication expert across the care journey accomplishes the Quadruple Aim—achieving higher outcomes at a lower cost while improving the patient experience and the care team's job satisfaction.

For more than 20 years, the team at Minnesota-based MHealth Fairview has been refining a model to deliver comprehensive medication management (CMM) services in ambulatory care clinics. Their experience is instructive for primary care and specialty practices alike on how a patient-centered, integrated approach to medication management can be implemented.

Amanda Brummel leads Fairview's CMM program, launched 21 years ago, which includes 45 pharmacists in 54 different locations, including 13 specialty sites. "The practice model and comprehensive medication management services do not change based on what practice specialty or location," she explains.

MHealth Fairview By the Numbers

12 Number of hospitals	**34,000** Total employees
55+ Number of primary care clinics	**5,000** Number of providers (employed or affiliated)
100+ Number of specialty clinics	**1,300** Number of pharmacy employees

Brummel knows that to support a philosophy of pharmaceutical care practice—and do it right—it must be patient-centered and integrated across the care delivery system. "MHealth Fairview has comprehensive pharmacy services, and we like to ensure we are able to holistically offer services our patients need. I like to say we have every flavor of pharmacy—from our own PBM, retail and specialty pharmacy, home infusion, compounding and CMM. You name it, we have it."

Standardizing a care process: Consistency is key

Over the years, Brummel has made fidelity of CMM practice across sites a top priority. She recounts what one physician told her: "I don't care if they're up in our rural clinics or if they're in our most metro clinic, the care that's being provided to patients must be the same. I don't want one pharmacist doing one thing and another pharmacist doing another thing. We have to have consistency and fidelity across our practices."

Such fidelity can be difficult to achieve, she told the participants. "I think it has been a challenge for our profession at times," she said. "We have worked really hard within our practices to make sure we're providing the same care no matter what pharmacist is providing it."

Fee-for-service world creates limitations

MHealth Fairview operates primarily in a fee-for-service world, but about half of the patients who benefit from CMM services are in some sort of at-risk contract. "This has allowed us to kind of take more of a population-health approach and be able to work with our health plans in a different way in order to provide these services.

"We have strategies to look at the risk levels of our populations and help our care teams identify those patients who we should be seeing and which care team member is best to be involved in each patient's care," she said.

A body of evidence

"CMM *does* work," she said. MHealth Fairview has amassed data to show how CMM meets all four elements of the Quadruple Aim: Improve clinical quality, cost savings, patient experience and medical provider experience.

For example, she and her colleagues have published evidence that shows improved care quality due to A1C reduction, better adherence and reduced admissions. "We have work that we published showing a 33% reduction in readmissions." [39,40,41]

The result is lower costs, and employer plan sponsors have seen a return on their investments—sometimes as high as 12:1. It is essential to look at the *total* cost of care, she said. Pharmacy costs generally increase because of its enhanced role in patient care, but the total cost of care drops. It is the decrease in emergency room and inpatient visits that drive the majority of the cost reduction. "If we silo these cost centers, it does not show the whole picture of how CMM can have an impact on total costs."

Provider satisfaction has improved. "We've done a lot of work to look at how this improves our providers' well-being and reduces provider burnout."

Providers appreciate the help. A 2019 survey found 88% of MHealth Fairview providers strongly agreed that they would recommend CMM to their patients, and 87% of them strongly agreed they were confident in the recommendations the pharmacist was making.

Patients were even more satisfied—with 95% giving the clinical pharmacists a top box score of a nine or 10.

Beyond Fairview

Organizations across the country like MHealth Fairview are making strides,[42] but the next step, Brummel said, is for systems across the country to come to the table to advance CMM. "We need to really come together to share results and be able to continue this movement and get the medications right."

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HEALTH PLAN

Optimizing medication use: An integrated approach to lowering the total cost of care

"Health plans should pay for comprehensive medication management services, hold people accountable to the fidelity of practice, and really work to build the provider base that we need."
— **Daniel Rehrauer, Pharm.D., senior manager, Medication Therapy Management Program, HealthPartners**

HealthPartners is the largest consumer-governed nonprofit health care organization in the nation. Headquartered in Minnesota, it provides health insurance to 1.8 million members, provides care to 1.2 million patients and it operates its own research institute.

"Acting as a nonprofit allows us to do some things that I think gives us some advantages and is one reason we have been forward thinking in our approach to comprehensive medication management," Rehrauer explained.

"Our goal, of course, is for our members and patients to achieve the best possible health outcomes for the lowest possible cost, with the best possible experience." Accomplishing that requires an integrated approach to managing medications.

"We are integrated in our care delivery model, and we are all about total cost of care. We're about the total cost because costs in health care are so interdependent," he said. "If we do a great job controlling drug spend but accomplish the low spend by keeping utilization lower than it should be, we end up with people who are sicker than they need to be and drive up the cost on the medical side. We're not doing any justice to the people who are purchasing insurance from us when our focus is not on the big picture."

Offering comprehensive medication management (CMM) allows for a more rational approach to medication use; it's one way HealthPartners is addressing the system's commitment to integrated care.

Centrality of the care team

HealthPartners wants to connect its plan members with providers they already know, so it offers CMM services through a network of contracted pharmacists. Today, it has more than 300 pharmacists at more than 450 locations in their coverage area. This contrasts to many traditional medication therapy management programs, which provide care centrally. "Those programs are fragmented, not associated and/or connected with the physicians, with the nurses, with the care coordinators. Everything that we're doing focuses on making those vital connections."

Supporting and integrating the care team delivering pharmacist-driven CMM services is key to HealthPartners' integrated medication therapy management program.

Demonstrating success

One stunning success was a pilot in a dual-eligible Medicare-Medicaid population—"incredibly high-need patients," he said. Among those who participated in the CMM program, hospital readmission rates dropped from 16% (already low for that population) to 6%.

Overall, looking at total cost of care, Partners' CMM demonstrated nearly $1,300 of savings per member per year in its commercial population.

Right patient, right time: Targeting those who need it.

From HealthPartners' perspective, all systems of care, to include payors, should offer CMM services to individuals who need it and should have a process in place to identify those who have not achieved the clinical goals of therapy. A risk stratification process should be put in place to identify those in the patient population who would benefit from the service; the level of need varies by patient population.

HealthPartners is targeting about 1% of its commercial population for CMM, about 10% to 15% of the Medicaid population. That rises to about 20% to 25% in the Medicare population. "If we go even further and look at our dual eligible special-needs population, we can get up into the 35% to 40% range," Rehrauer said.

Making the business case

Rehrauer said that providing team-based CMM services to health plan members "does not add significant costs to our bottom line."

HealthPartners offers the CMM benefit across its entire book of business. "We do not restrict access to the programs based on number of medications or conditions. We're doing nothing to 'manage' this benefit." The point isn't to restrict access but broaden it, he said. "We are trying to engage more members in the program and physicians to refer to the program because we know that people love it, it improves their health, and it reduces the total cost of care."

Plans need to lead the way

Health plans are slow to follow HealthPartners' example. Rehrauer often hears concerns about how much it's going to cost or who will provide the service.

Health plans need to be proactive. It will pay for itself, but they need to lead the way.

"This is something that we as a health plan have focused on. Yes, we've had to go out and help build a provider network. We have health systems that we insure, and we've gone to them and said, 'You need to start offering this service. You can help build it by hiring pharmacists and offering the benefit to your employees, and you can pay yourselves to do this.'"

Health plans must build networks, he said. But he cautions that success requires a *defined and standardized* CMM service: "Pay for comprehensive medication management services, hold people accountable for fidelity of practice and really work to build the provider base that we need."

APPENDICIES

Appendix I: Establishing the value proposition through evidence

CMM has demonstrated improvement in patient clinical outcomes, including control of hypertension, diabetes, hyperlipidemia and HIV.[43,44,45,46,47,48,49,50,51] It has also resulted in fewer hospital and emergency department visits.[52,53,54]

CMM has demonstrated a positive impact related to cost avoidance and has demonstrated a positive return on investment ranging from an average of 3:1 to 5:1, and up to 12:1.[55,56,57,58,59,60,61,62]

Primary care physicians view the pharmacist as value-added, providing a unique skill set specific to medication optimization and allowing them to have more time to spend on patient care tasks. They find the pharmacist to be a collaborative partner in caring for the patient.[63,64,65]

Patients find CMM and the role of the pharmacist to be of value.[66,67] Specifically, CMM can improve their overall health and well-being, enhance medication adherence, help them reach and maintain their therapy goals, minimize medication adverse effects and improve their understanding of medications.[68,69,70]

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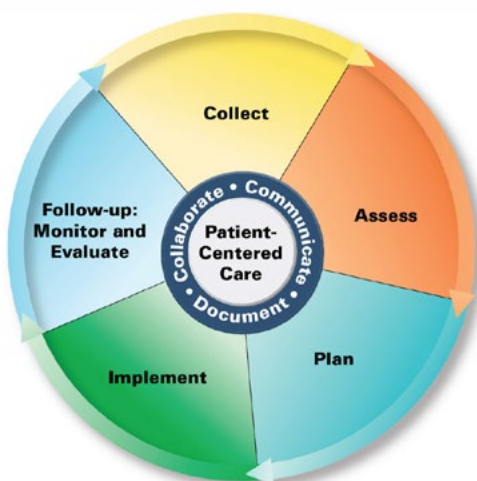70   Ramalho, op. cit.

MEDICATION OPTIMIZATION

Medication optimization is a patient-centered, team-based approach to improve patient outcomes. ACCP supports the goal of achieving medication optimization for all patients across the care continuum.

accp
American College of Clinical Pharmacy®

IMPACT

Medication optimization is integral to achieving all components of the Quadruple Aim:

- Improving population health
- Enhancing the patient experience
- Reducing costs
- Improving work life for health care clinicians

OPTIMAL REGIMEN → PATIENT CARE TEAM COMMUNICATION ← OPTIMAL USE

→ MEDICATION OPTIMIZATION

→ ACHIEVE PATIENT-CENTERED AND THERAPEUTIC GOALS

→ CONTRIBUTE TO ACHIEVING QUADRUPLE AIM

JCPP Pharmacists' Patient Care Process

jcpp.net/patient-care-process

PROCESS

Medication optimization results from a consistent patient care process, such as that endorsed by the Joint Commission of Pharmacy Practitioners (JCPP). It is achieved by optimizing the patient's medication regimen and optimizing medication use.

Optimizing the medication regimen requires the health care team to:

- evaluate response to current medications
- identify areas for improvement
- develop a care plan to achieve treatment goals

Optimizing medication use requires the health care team to ensure that the patient:

- understands and agrees with the care plan
- has access to the medications
- participates in follow-up evaluations

IMPLEMENTATION

Comprehensive medication management (CMM) is a holistic, consistent approach to the patient care process that optimizes medication-related outcomes.* Based on the findings of the CMM in Primary Care Study, ACCP encourages implementation of CMM in all patient care settings.

*accp.com/CMM_Care_Process

For more information on CMM, visit optimizingmeds.org.

DISSEMINATION

ACCP advocates dissemination of the results of the CMM in Primary Care Study and ongoing research related to medication optimization. As a founding member of the Get the Medications Right Institute (gtmr.org), ACCP promotes medication optimization and CMM practices that ensure appropriate personalized use of medications and gene therapies. This approach emphasizes to all stakeholders how a systematic, collaborative, and evidence-based decision-making process can achieve medication optimization.

Appendix III.a:
Health IT Capabilities and Functionalities for CMM Practice Maturity Matrix Glossary

GLOSSARY: Health IT/AI Capabilities and Functionalities Supporting CMM Practice Maturity Matrix Key Considerations, Intent for Utilization, Beliefs, and Principles

Understanding the beliefs and principles behind the Health IT/AI Maturity Matrix

- There are many ways to effectively and optimally incorporate health information technology and artificial intelligence into a CMM practice.

- We intentionally excluded specific software or IT platform names. We excluded the idea of regulations or certifications around health IT/AI incorporation.

- The creators of this health IT/AI Maturity Matrix suggest that health IT and AI can be leveraged at various degrees in each of these categories.

- We acknowledge there is no minimum threshold of health IT/AI needed to adhere to the CMM practice model. However, a comprehensive medication management (CMM) practice that more fully leverages health IT and AI will likely produce better clinical outcomes with greater efficiency and lower cost.

- We recognize that more information is not always better, but the right information and utilization of that information is imperative. We must continually seek to define the right information.

Key Considerations and Instructions for Use

Practice leaders will use this maturity matrix to seek opportunities to advance on this continuum to reach larger patient populations, become more effective and efficient, and implement population health stratification tools. Right patient, right care, right time.

Three categories were identified where utilization of health IT/AI can further advance a CMM practice toward the Quadruple Aim.

1. Inputs: Help inform programs of patients who will benefit from CMM services and aid the clinical pharmacist in effective and accurate clinical decision making.

2. Capabilities: Aid the clinical pharmacist in efficient and consistent delivery of the CMM patient care process.

3. Outputs: Streamline communications, collate CMM practice outcomes and promote efficiency and regulatory compliance in billing and revenue capture.

Four levels of maturity were stratified across a continuum. Briefly summarized:

1. Reactive or Manual: Patient, pharmacist, or prescriber reactive engagement to identified medication therapy problems generally at the point-of-care. Processes are largely manual. Limited access to data or platforms to inform clinical decisions, streamline communications or simplify revenue capture.

2. Managed: Limited opportunities to proactively identify medication therapy problems, some information technology to support identification, documentation and communication processes

3. Advanced: Proactive data feed of clinical data and alerts, population health strategy for CMM engagement, well developed health IT tools for documentation, bi-directional communication, revenue capture and CMM-related program outcomes.

4. Future State: Widespread adoption of interoperability standards across multiple payer and care team provider platforms that optimize accuracy, efficiency and collaboration supporting patient care within the CMM practice.

Each CMM practice should minimally have each of the core components in the 'Reactive or Manual' column, but practices may be at different levels of maturity in each category.

While not clinically proven, it is hypothesized that advancement along this maturity scale will allow a practice to become more proactive and strategic in new health care payment models.

A 'Reactive or Manual' level of maturity can still be adherent to the CMM practice model; however, the more advanced your practice is on this health IT matrix, the more effective and efficient your CMM practice will be.

Appendix III.b:
Health IT Capabilities and Functionalities for CMM Practice Maturity Matrix

INPUTS: Data that help inform programs of patients who will benefit from CMM services and aid the care team in effective and accurate clinical decision making.

	Reactive or Manual	Managed	Advanced	Future State
Patient Information	Patient self-reported • Demographic and lifestyle information (e.g., exercise habits) • Biometrics (vitals, height, weight) provided verbally or in writing • Communication preferences	RX (GPI, RxNorm, etc.) or medical claim (ICD10, including J codes) information • Insurance/benefit information (eligibility) • Patient self-reported biometrics (vitals, height, weight) from device printout/report	Prescription and medical clinical information • Biometrics (vitals, height, weight) • Lab data (LOINC) • Patient personal device biometrics from USB (vitals, height, weight)	Data standards to ensure interoperability; Integrated EHR, pharmacy and medical claims • SDoH • Population health panels to identify patients not reaching clinical goals • Assessment responses • Patient biometrics from streaming device, wearables
Patient Health Status	Patient self-reported • Current patient diagnosis & conditions • Past medical history	Prescription or medical claim information • Current patient diagnosis & conditions • Medical claims	Prescription and medical clinical information • Active diagnosis & problem list • Past medical history • Objective lab values and assessments (PHQ9, ACT)	Data standards to ensure interoperability; integrated EHR, pharmacy and medical claims • Integration of genomics • Clinical notes • Encounters from other providers/pharmacists
Medication Information	Patient self-reported • Medication list • Allergies	Prescription or medical claim information • Pharmacy claims • Current medication list • Medication history • Current MTP List	Prescription and medical clinical information • Current medication list • Medication history • Current MTP List • MTP history	Data standards to ensure interoperability; integrated EHR & pharmacy claims • Current medication list can be reconciled with pharmacy claims in EHR • Medication history • Current MTP List • MTP history should consist of the most up-to-date information with provider's information and patient's allergy status
Care Team Information	Patient self-reported • Communication preferences	Prescription or medical claim information • Enrollment in case management or CM/DM clinical program	Prescription and medical clinical information • Contact information for patient care team • EHR communication history (letters and information previously sent to the patient)	Data standards to ensure interoperability; integrated EHR, pharmacy and medical claims • Contact information for patient care team outside of your system • EHR and payer communication history

	Reactive or Manual	Managed	Advanced	Future State

Payer Partnerships	None—Prescribers/pharmacists/patients have ability to self-identify and refer into CMM program	PBM or medical claim information
		• CMM candidates identified through platform
		  – May not have ability to self-identify or self-refer into CMM program
			CMM candidates flagged in EHR
			• Ex: ACO group attributed patient
			  – Prescribers/pharmacists/patients have ability to self-identify and refer into CMM program
				Data standards to ensure interoperability; bidirectional ability to engage priority patients in CMM. Integrated EHR, pharmacy and medical claims
				• Payer identified CMM candidates are flagged in the EHR
				• Prescribers/pharmacists/patients have ability to self-identify and refer into CMM program

Risk Stratification or Population Health Tools	None—Prescribers/pharmacists/patients have ability to self-identify and refer into CMM Program	• Risk stratification provided by payer utilizing a confidential proprietary tool (CMM or medical provider is unsure of criteria used to identify CMM candidate and thus has low level of confidence to engage patient)	• Clinical data is used to generate best practice alerts (BPAs) for CMM engagement criteria or demonstrated need for medication related clinical interventions	Data standards to ensure interoperability; integrated EHR, pharmacy and medical claims • Utilization of internally developed or transparent payer provided risk stratification tools • CMM candidates communicated to leadership who develops CMM engagement strategy in the context of population health strategy

CAPABILITIES: Aid the CMM team in efficient and consistent delivery of the CMM Patient Care Process

	Reactive or Manual	Managed	Advanced	Future State
Care Team Communications	• Care team CMM communication via patient, phone call or fax	• Care team CMM communication via payer • CMM care documented on a different platform	Data standards to ensure interoperability • Read/write access of patient's EHR/chart	• Platform integrated bi-directional communication with care team [HIE]
Clinical	• Longitudinal view of CMM care • Current & MTP history using industry standard MTP classification • Medication related information (drug name, strength, form, indication, sig code, etc.)	• Access to medication adherence data • Access to medication claims/med changes • Read access to a patient's EHR/chart • Medication related information (i.e., source)	• Clinical decision support alerts within pharmacist workflow • Disease/medication specific standing orders or protocols • Ability to track a review of systems • Medication related information (i.e., refill history)	Data standards to ensure interoperability • Collaborative practice agreements that enable health IT actionable real-time clinical decision making, lab and medication ordering • Creation of individualized care plans and condition status tracking • Capture medication experience • Manages follow up process and timing • Medication related information (i.e., images, brand name, etc.)
Information Technology Supporting Documentation of CMM Services	• All CMM documentation completed on one or many non-owned platform(s) • Software available to record eCare Plan	• Internally owned CMM documentation system • Note templates to streamline documentation and ensure contract compliance	Pharmacist has ability to link medication therapy problems to condition, med, and plan for resolution • Configurable workflow at the user level that allows for multi-dimensional customization of workflow and specific data elements.	Data standards to ensure interoperability • Medication therapy problems automatically linked to condition, med, and plan for resolution • Note integration with EHR pulls data elements into CMM clinical note.
Practice Management Systems (as defined by ACCP)	Pharmacist responsible for all scheduling, billing, administrative tasks	Administrative assistants or clinical support staff have access to care platform to assist pharmacist in practice management tasks	Tasks of CMM practice management can be communicated, but not completed, across CMM program and the site of medical care (primary care clinic/health system) Example: a note generated to request a patient be scheduled.	Data standards to ensure interoperability • Tasks of CMM practice management are visible and co-owned within the CMM program and the site of medical care (primary care clinic/health system) Example: bi-directional patient scheduling

OUTPUTS: Streamline communication, collate CMM practice outcomes, and promote efficiency and regulatory compliance in billing and revenue capture.

	Reactive or Manual	Managed	Advanced	Future State
Patient Deliverables	Information related to a care plan, medication list, or medication therapy problems are communicated by mail or physical paper printout	Patient has electronic access to their CMM care plan, medication list, and identification/resolution of medication therapy problems	Patient has read/write capability to interact with their CMM care plan, medication list, and identification/resolution of medication therapy problems	CMM care plan is interoperable with the EHR. Patient has read/write capability to interact with their EHR and CMM care plan
Prescriber/ Care Team Deliverables	Information related to CMM care plan, clinical suggestions or medication therapy problems are communicated by telephone or fax	CMM care plan, clinical suggestions, and medication therapy problems are communicated electronically to prescribers and the care team	CMM care plan, clinical suggestions, and medication therapy problems are communicated to prescribers and the care team through limited access to the EHR	CMM care plan, clinical suggestions, and medication therapy problems are interoperable and bi-directional with the EHR. CMM pharmacist has editable access to medication and problem list. CMM pharmacist can transmit appropriate medication and lab orders.
Billing/ Revenue	CMM revenue capture and billing is manually completed by submitting through various electronic platforms by payer	Revenue capture and billing is completed by submitting through a single electronic platform (clearing house) then submitted to various payers. A continuity of care document (CCD) is generated and submitted separately to satisfy regulatory required data elements	Revenue capture and billing is completed by submitting CPT codes and a continuity of care document (CCD) through a single electronic platform (clearing house) then submitted to various payors	Data standards to ensure interoperability; • Revenue capture is seamlessly integrated into EHR/ Documenting platform. Little/no pharmacist involvement • Integration with third party claims processor
Contract Compliance	Compliance audits and data retrieval are completed manually	Compliance audits and data retrieval are completed through ad-hoc report generation	IT reporting structure supports all compliance elements at the time of visit completion or closing of encounter, reporting is unidirectional	IT interoperable structure supports all compliance elements at the time of visit completion or closing of encounter. Audits can be completed primarily without provider involvement
CMM Program Outcomes	• Manual tally sheet, populated into an Excel document	• Clinic-based performance reporting CMM service elements (MTPs identified and resolved, number of unique patients and total encounters) are reported on a population level/ clinic level.	• Clinical outcomes reporting • CMM service elements (MTPs identified and resolved) can be linked to achievement of patient's clinical goals. Patient-level MTP reporting MTP resolutions linked to objective clinical data (ex: BP of A1C at goal).	Data standards to ensure interoperability • CMM service elements (MTPs identified and resolved) can be linked to changes in health care utilization patterns. • Linked to ROI measures • Achievement of performance-based payment goals • Utilizes standardized code nomenclature (SNOMED codes)

Appendix IV:
Leadership Checklist: Information Technology Supports for Comprehensive Medication Management (CMM) Practice Management Systems[69]

Thirteen essential components have been identified to support effective CMM practice. Effective utilization of information technology is key to many of them. There are a multitude of options and complexities in each essential component. However, this guide can serve as a checklist for system administrators to optimize the IT infrastructure to support a CMM practice.

✔	Essential Component	Information Technology Support Examples
Organizational Support		
	Leadership support	Ability to dedicate resources or adapt IT structures to support CMM practice.
	Availability of clinic space	Telephone, network computer, read/write access to electronic medical record (EMR).
	Billing and revenue systems	Pharmacist payer enrollment and credentialing. Pharmacist has personal NPI number. Defined visit types, CPT, and ICD-10 codes. Availability of coding and billing department or granted/created access to payer portals, secure email transmission for PHI.
Care Delivery Processes		
	Method of CMM patient identification	Internal EHR CMM referral method. Defined quality or population health threshold criteria for CMM eligibility. EHR identification 'flag' for CMM eligible patients.
	Scheduling CMM services	Pharmacist schedule built and linked to their NPI number. Creation of CMM pharmacist schedule template. IT cross communication to utilize different departments to support scheduling patients (e.g., call center/appointment scheduling services, 'MyChart' or Televox automated appointment reminders, on-line scheduling).
	Care documentation	Extensive IT opportunities from basic note templates to integrated data elements and coding.
Care Team Engagement		
	Utilization of Collaborative Practice Agreements (CPAs)	CMM pharmacist defined EHR security template to support additional granted scope of practice elements (e.g., sign medication and lab orders without co-signing or pending).
	Interprofessional collaboration	Read/write access to EHR allowing for assignment to patient's care team. Ability to route notes and messages to all members of the care team.
	Engagement of support staff	IT cross communication to utilize different team members to support practice efficiency and contain administrative costs (e.g., medical assistant for rooming patients, triage RN for patient call back, department assistant for mailing patient letters).
Evaluating CMM Services		
	Measuring CMM data	Extensive variety of IT opportunities from basic volumes to integrated data elements and coding on a patient or pharmacist level.
	Reporting CMM data and outcomes	Extensive variety of IT opportunities from basic system level elements to integrated data elements, CMM medication therapy problem coding, attribution to achievement of quality goals.
Ensuring Consistent and Quality Care		
	Practitioner training	Adequate onboarding with EHR/IT training specific to CMM pharmacist.
	Quality assurance processes	Verification of appropriate utilization of all IT processes and metrics.

69   Pestka et al. 'The practice management components needed to support comprehensive medication management in primary care clinics' J Am Coll Clin Pharm. 2019;**(**):1–10. https://doi.org/10.1002/jac5.1181