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Training to advance Comprehensive Medication Management in practice: Acting on the \$528B opportunity

The numbers are staggering: \$528.4 billion a year—16% of the total U.S. health care spend—is wasted on non-optimized medication therapy, according to a 2018 study.^{1,2}

"If you think about that, it's actually more than we're currently spending on drugs themselves," explains one of the paper's authors, Terry McInnis, MD, MPH, CPE, FACOEM, president/ co-founder of the GTMRx Institute and president of Blue Thorn Inc.

Why are we wasting hundreds of billions of dollars every year for direct medical costs tied to nonoptimized medication regimens? The reasons are complex. **Fragmentation.** The average Medicare Part D member has three to four prescribing doctors,³ and nearly 30% of adults in the U.S. take five or more medications.⁴ Access to complete medical records is rare outside of large, integrated health

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Terry McInnis, MD, MPH, President and Co-Founder, Get the Medications Right Institute and Foundation; President & Founder, Blue Thorn Inc. systems. For most Americans, there is no designated physician actively monitoring and managing medications across all prescribers. We lack a systematic, coordinated approach to medication management that can ensure medications are appropriately and effectively used.

A surfeit of choices. There are more than 10,000 prescription medications on the market, with dozens added every year.⁵ Physicians have a depth of medication knowledge in their own area of practice, but can't be expected to maintain the same depth across medication choices used in all specialties.

The changing landscape. We are in the midst of the greatest evolution in health care, a transition from population health-based clinical guidelines to personalized precision

⁵ Ibid.

¹ Cutler DM, Everett W. "Thinking outside the pillbox: medication adherence as a priority for health care reform." N Engl J Med. 2010;362(17):1553-1555

² Watanabe J, et al. "Cost of Prescription Drug-Related Morbidity and Mortality." *Annals of Pharmacotherapy*, March 26, 2018. journals.sagepub.com/eprint/ic2iH-2maTdI5zfN5iUay/full

CMS Chronic Condition Data Warehouse Medicare Part D Prescription Drug Utilization for 2007-2016. www.ccwdata.org/web/guest/ medicare-tables-reports

⁴ Medication Errors. June 2017, http://psnet.ahrq.gov/ primers/primer/23/medication-errors. Accessed 4 Jan. 2018. AHRQ Patient Safety Network

medicine. One person's hypertension, depression, diabetes or cancer does not respond consistently to the same medication therapy as other patients, even when guidelines are strictly followed and patients are 100% compliant. Genome sequencing is revealing new mutations and will allow ever greater precision. Innovative medications are increasingly targeted therapies.

Advances in pharmacogenomics, diagnostics, targeted therapies and even microbiome influences are turning our understanding of drug and genetic therapy from a shotgun approach to—one day—laser certainty.

Lack of reimbursement. Simply put, policy and payment systems don't align with these rapidly evolving scientific and delivery system realities.

Jan Hirsch, BS Pharm, PhD, director and founding dean, Pharmaceutical Sciences, University of California, Irvine—a coauthor of the study agrees about the overall complexity. "It's not just the number of medications. We know people are taking lots of different medications now, but it's also that regimen complexity encompasses the route of administration (e.g., injections or inhalers are more complex for a patient to manage than taking a tablet) and the directions for use and monitoring requirements all contribute to the complexity of the regimen a patient has to manage. Coordinating and complying with the overall regimen can be very complex."

In the study, the coauthors conclude that expansion of comprehensive medication management (CMM) offers an effective and scalable approach to mitigate these avoidable costs and improve patient outcomes.

So what is comprehensive medication management? Why is it essential? Let's start with the first question. Comprehensive medication management is

A systematic approach to medications where **physicians and pharmacists ensure** that 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.⁶

It includes 10 steps, illustrated in Figure 1. (See next page.)

CMM is all about optimizing clinical outcomes. It's important to distinguish between CMM and other forms of medication therapy management (MTM).

Know the difference

CMM is patient-centric, based on optimizing the clinical goals of

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therapy, and was defined by the Patient-Centered Primary Care Collaborative.⁷

Many organizations have taken to calling what they do "comprehensive medication management." They may do two or three components, but no more. That's like having one wing, an engine and a cockpit and calling it an airplane, McInnis says.

Likewise, CMM is fundamentally different from comprehensive medication review (CMR). "The person conducting CMR may know the drugs the patient's taking but may not know—at all—the patient's clinical status. You really cannot make decisions around which drugs are appropriate if you don't know whether the patient's condition is actually controlled," McInnis says.

⁶ McInnis, Terry, et al., eds. *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.

"What we are suggesting is to really put in a systematic approach and include a lot more time on medications themselves and on the combinations of medications," McInnis says.

What will it take to expand the use of CMM? Greater awareness among payers, providers and patients is required, of course. More specifically, it will require education and training. Perhaps the most important aspect is integration of CMM—and the clinical pharmacist—into the clinical care team.

Better science, more complexity

As is often the case, scientific discovery is outpacing our capacity to process it. Researchers have sophisticated new tools and understand more about biomarkers, genes and pharmacogenomics. There are a host of companion and complementary diagnostics available to ensure a personalized approach to medication use to improve outcomes and reduce overall health care costs. This approach combines genetic, environmental "What we are suggesting is to really put in a systematic approach and include a lot more time on medications themselves and on the combinations of medications."

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Figure 1. 10 Steps to Achieve CMM

and social factors to target the right interventions for the right patient.

"As a result, we're going to be much more precise about which drugs will work for you instead of the shotgun approach that many of us as physicians have used throughout our clinical practice," McInnis says.

Having clinical pharmacists work in collaborative practice with physicians and other prescribers, along with other members of the team, makes an enormous amount of sense, McInnis and Hirsch say.

Seeing the big, complex picture

To illustrate the complexity of managing a patient's medication regimen, Hirsch turns to a tool developed originally by Dr. Candis Morello of the University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences.⁸ (See Figure 2, next page.)

At the center is a person with a disease. Surrounding her is an interconnected "web" of related issues, at varying distance from the patient. For a patient with diabetes, the web may include:

- Clinical parameters such as glycemic control;
- Comorbidities such as cardiovascular disease or behavioral health disorders;

- Complications such as neuropathy and foot care; and
- Socioeconomic and behavioral aspects such as finances, cultural beliefs and practices, and medication complexity.

The concept, Hirsch explains, is that if you sit down with a patient today, you need to address the most immediate issues—the ones closest to the patient in the web. But all that can shift, and you need to be able to monitor and respond to how things change over time with the patient. What if access to care changes? What if they develop retinopathy?

"The spider web visual gives you an idea of how fluid and complex it is. And these are all the things that a pharmacist really needs to be taking into account," Hirsch says. "So looking at the spider web model and CMM, both of these are rooted in treating the whole person over time. We're treating their physical, mental, social, spiritual and environmental situations. They all work together."

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CMM is effectively integrative health care, she says. "We're blending a wide range of modalities, both conventional and complementary, and we're delivering this collaboratively by a wide range of health care professionals. It's interprofessional. It's very complex, and that complexity really requires specialized education."

That's an important point: McInnis and Hirsch both stress that the average dispensing pharmacist in the community pharmacy can't simply pick this care model up. Even clinical pharmacists would struggle without the appropriate training.

For CMM to work, they explain, everyone on the care team needs to be trained. CMM brings a new member to the health care team, and that requires training for the entire team, including nurses, physicians and pharmacists.

⁸ Morello CM, Hirsch JD, Lee. Navigating complex patients using an innovative tool: the MTM Spider Web. JAPhA, 2013.

Training the pharmacist

Beyond being a PharmD, what are the characteristics of the clinical pharmacist delivering CMM? "There's some controversy on what they look like." Requirements vary, Hirsch explains.

"I think it's an area that is evolving. We need to offer our PharmD students within our programs a strong science base. They must understand the intricacies of these increasingly complex medications and newer therapies that are based on advanced and rapidly changing science," Hirsch explains.

Coupled with that, PharmD students require in-depth experiences with clinical applications across a broad range of clinical settings. They also need to participate in meaningful interprofessional education, so they are team-ready when they graduate. Finally, training in evaluation methods and tools to continually assess, communicate and improve the quality and efficiency of patient care is essential.

PharmD curricula—in fact, pharmacy programs in general—are based on four foundational science areas: biomedical sciences, pharmaceutical sciences, clinical sciences, and social and behavioral administrative sciences.



Figure 2. CMM—Inside a Pharmacist's Head.

Training is also based on the application of the Pharmacist Patient Care Process and how that integrates with other providers and caregivers. (See Figure 3.)

This process aligns with and supports CMM: The pharmacist collects data, assesses it, plans a course of action, implements, monitors and evaluates. "It's very collaborative; there's communication amongst all the players, and it's all patient-centered, much like the 10-step CMM process," Hirsch explains.

PharmD programs are already closely aligned with CMM; she points out several other examples of alignment with CMM from PharmD program accreditation standards:

- Entrustable professional activities: These are activities that help gain the trust of the health care team and the public.
 "This really relates to what the team can expect from the pharmacist and what the patient can expect from the pharmacist on the care team."
- Interprofessional education: This prepares students to provide patient-centered care as a contributing member of an interprofessional team.

Training beyond the PharmD

In addition to the PharmD training, many graduates continue on to the next educational phase, residency,



Figure 3. Pharmacist's Patient Care Process (PPCP)

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where the new graduate performs as a licensed pharmacist under the supervision of an experienced preceptor. The resident is deeply involved in patient care and practice management for a one- to two-year experience that hones the new pharmacist's clinical skills across a wide variety of patients. This training, or equivalent experience gained in practice, is important for pharmacists to optimally perform CMM.

What about pharmacists who have been in the field and who may not have been trained using this model? Increasingly, Hirsch says, postgraduate clinical continuing education can help pharmacists develop the skills they need to practice CMM. See the sidebar on next page for some example resources for practicing pharmacists.

But the pharmacist isn't the only one who needs training, she says. "We need to be educating everyone on how to implement CMM as a team and within organizations." The variety of different models currently in the field attest to how complicated it can be to adapt processes to an organization, Hirsch says. And patients, caregivers—the public at large—need to understand how CMM works in their best interest, too.

Collaborative Practice Agreements

Central to practicing CMM is setting up collaborative practice agreements (CPAs). These agreements between physicians and other prescribers establish the framework that allows the pharmacist to take on a role as a clinical provider who actively manages the patient's medications—not someone who merely makes recommendations. CPAs—especially broad CPAs—empower clinical pharmacists to identify and address a patient's medication problems quickly and efficiently.

Hirsch has helped set up CPAs for CMM and other medication therapy management programs within a wide variety of settings. She outlined the key steps in the process:

Create: Working with the team, identify the goals of the institution and of the practice team, and develop an understanding of the business case for all. From there, choose the most viable practice model.

Then the providers and the pharmacist have to create the collaborative practice agreement. "There has to be a lot of give and take—discussion of what's going to be in the CPA and what's not going to be in it," Hirsch explains. The CPA must answer essential questions: Who is responsible for what? What are the roles? How do you close the loop and keep everyone informed? "They need to be very, very clearly defined." The CPA model needs to make sense within the context of the team's process and workflow. **Implement:** For a CPA to work effectively, it's essential to provide adequate staffing and training. "I can't stress this enough. It's not just the training of the professionals. It's also the training of the staff that are supporting the professionals and the patients."

Resources for practicing pharmacists

This is not an exhaustive list, but Hirsch offers examples of programs offering post-graduate clinical continuing education featuring CMM elements:

- Patient-Centered Primary Care Collaborative CMM Training <u>Resource Guide</u>
- Continuing Education Programs:
 - ACCP
 - Comprehensive Medication Management in Team-Based Care
 - <u>The Patient Care Process for Delivering Comprehensive</u> <u>Medication Management (CMM)</u>
 - ASHP
 - <u>A3 Collaborative</u>
 - APhA
 - Patient care resources and continuing education modules for CMM elements
- Pharmacy School Programs
 - <u>UNC Eshelman School of Pharmacy list of CE and certificate</u>
 <u>programs</u>
- Advanced Practice Pharmacist training (for applicable states; online and live modes)
 - USC School of Pharmacy Advanced Practice Pharmacist <u>Certificate in Comprehensive Medication Management</u>
- Collaborative learning groups
 - <u>California Right Meds Collaboration</u>
- Board Certified Specialties
 - Board of Pharmacy Specialties (BPS)

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Ensure access to electronic health records and information exchange for all the participants. Start small, focusing on an initial target patient population. Once that's in place, you can expand to other patients. Hirsch recommends beginning with a discrete population, such as a chronic condition treatment group.

Assess outcomes: "Measure and assess meaningful outcomes— including the return on investment.

The program needs to become selfsustaining." Then revise as needed for sustainability and continuous quality improvement.

CMM spells value

Developing a sustainable program is certainly possible; some organizations have been doing it for years. For example, the CMM programs featured in the 2016 report, *Get the medications right*, reported ROIs ranging from 2.8-to-1 to 12-to-1.⁹

There are several reasons to build CMM into an organization's care approach, including that CMM often targets the most complex—and most costly—patients.

Despite the evidence, McInnis frequently fields questions about the cost of CMM—specifically, the cost of adding pharmacists on care teams. Pharmacists, she acknowledges, are expensive. "Physicians can be thought of as fairly expensive. Nurses are fairly expensive. But the question is, what value are you delivering? And when you look at the \$528 billion being spent for non-optimized therapy, there's a lot of dollars there to actually improve care."

CMM is a proven approach to lower overall cost of care. Once you start reducing emergency department visits and hospitalizations, McInnis says, "there begins to be quite a bit of money to pay for CMM services." It's a matter of *overall* value and ROI, not simply cost, she says.

"I guess I'd almost ask the opposite question: Can we afford *not* to have a systematic approach to medications? And why would we look to other care providers when we have pharmacists that are the experts in medications who could come to the table and meet this goal?" GTMR

Our **VISION** is to enhance life by ensuring appropriate and personalized use of medication and gene therapies.



Our **MISSION** is to bring critical stakeholders together, bound by the urgent need to optimize outcomes and reduce costs by *getting the medications right*.

About the GTMRx Institute The GTMRx Institute is a catalyst for change that brings critical stakeholders together, bound by the urgent need to get the medications right. We are physicians, pharmacists, caregivers health IT innovators, drug and diagnostics companies, consumer groups, employers, payers and health systems—aligned to save lives and save money through comprehensive medication management, or CMM. By showcasing evidence and innovation, we motivate practice transformation and push payment and policy reform. Together, we ACT to champion appropriate, effective, safe and precise use of medication and gene therapies. Learn more at gtmr.org.

⁹ Get the medications right: a nationwide snapshot of expert practices-Comprehensive medication management in ambulatory/community pharmacy. Health2 Resources and Blue Thorn Inc. May 2016.

About the Experts



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JAN HIRSCH, PH.D., is director and founding dean of the School of Pharmacy & Pharmaceutical Sciences at the University of California, Irvine. Prior to that, she served as the first chair of the Division of Clinical Pharmacy at the Skaggs School of Pharmacy & Pharmaceutical Sciences at UC San Diego. As a founding faculty member there, she designed required courses in her field and also served as academic director of a new master's degree program in drug development and product management. She launched a clinical faculty practice business unit that provides both clinical pharmacy services to community clients and educational opportunities for students, residents and practicing pharmacists. She served as executive director of Partners in Medication Therapy (PMT), an outreach program of the school providing medication therapy management services in the community.

Her research assessing the value of innovative clinical pharmacist services across therapeutic areas has been recognized by state and federal agencies, professional pharmacy organizations and the interdisciplinary National Academies of Practice. Previously, she started a clinical research department for a large pharmacy benefit management company and global pharmacoeconomics strategy and research departments for two multinational pharmaceutical companies. As president of Blue Thorn Inc. health care consulting, TERRY MCINNIS sets strategy, formally speaking or leading engagements at more than 100 companies. Previously, as business lead for value-based care at LabCorp, McInnis set the strategy and built internal capabilities to execute and partner with providers to align diagnostic analytics and clinical trials with better outcomes and lower costs. Co-author of the article highlighting the \$528 billion U.S. spend on non-optimized drug therapy, she is a nationally recognized expert in medication management and successful drug cost/value strategies.

McInnis's 30 years of experience spans practice, executive, and consulting roles for organizations including CHESS, SSB Solutions, GlaxoSmithKline, Michelin North America and GE Power Systems.

She completed a residency in occupational medicine and her master's in public health at the University of Oklahoma. She is board certified in preventive and occupational medicine, a Fellow of the American College of Occupational and Environmental Medicine, a certified physician executive and a former course advisor to the department of continuing education of Harvard University. She currently serves as a director on the Board of Pharmacy Specialties.



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