GTMRx Institute™

Get the medications right

Issue Brief | June 2019

275,000 lives lost and a $528 billion price tag

Recent headlines and policy efforts have focused on the rising cost of medications. The opioid crisis has called into question medical practice, prompting strict policies about pain management and quantity limits as regulators and health plans react to the toll on human life—both from overdose and, in some cases, lack of adequate pain management.

However, we have failed to tackle the root cause: the lack of a systematic approach to medication management that can assure medications are appropriately and effectively used, making them *cost effective* in reducing overall medical spend and assuring all conditions—including pain—are effectively managed with fewer side effects and dependency.

Everyone in the health care system recognizes pieces of the problem. Now, research quantifies it and offers a path forward.

Avoidable illness and death resulting from non-optimized medication therapy cost $528.4 billion in 2016, according to a peer-reviewed paper in the *Annals of Pharmacotherapy.* That represents 16% of the annual $3.2 trillion the U.S. spends on health care.[1]

Let that sink in: $528.4 billion in *avoidable costs—or waste. In one year.*

We have failed to tackle the root cause: the lack of a systematic approach to medication management that can assure medications are appropriately and effectively used.

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

And it's a conservative estimate, according to the study's authors. It doesn't include indirect expenditures, such as transportation and caregiving costs, nor does it factor in costs stemming from lost productivity or disability.

The study includes another sobering number: 275,000 avoidable deaths tied to non-optimized medication use—more than a quarter million lives lost.

Non-optimized medication therapy covers a lot of ground: Frequently, the patient doesn't receive the most effective therapy, or receives no therapy at all. A prescription may be for the wrong dose or the wrong medication entirely. It may cause an adverse event. Or perhaps the patient doesn't take the medication as directed after it has been deemed to be effective. Regardless of the cause, it's dangerous for the patient and costly for the system.

The data behind the dollars

The researchers created decision-analytic models of various outcomes that could ensue due to a treatment failure or new treatment-caused medical problem, including emergency department visits, hospitalization, long-term care, medical appointments and additional medications. They collected data from an array of sources, including the Centers for Disease Control and Prevention and peer-reviewed journals. In addition to the 275,000 deaths, the cost impact was astounding, to include:

- $174 billion in hospitalization costs
- $37.8 billion in additional provider visits
- $37.2 billion in emergency department visits
- $7.8 billion additional prescriptions

These costs represent additional medical resources needed to resolve problems due to the initial diagnosis and subsequent use of non-optimized prescription drugs.

"This is indeed a very expensive problem for us in the United States—something that we could avoid by just providing better evidence-based care," says Jonathan H. Watanabe, PharmD, MS, PhD, associate professor of clinical pharmacy, University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Science.

It's unsustainable, say the authors. But they offer a solution: comprehensive medication management (CMM). From the study:

> "We propose expansion of comprehensive medication management programs by clinical pharmacists in collaborative practice with physicians and other prescribers as an effective and scalable approach to mitigate these avoidable costs and improve patient outcomes."

But what *is* CMM?

Comprehensive medication management isn't really a new concept; it's been around for roughly a decade and was fashioned from the extensive work in pharmaceutical care.

"What we have found is that having a clinical pharmacist on the team—not at the point of dispensing, but really working collaboratively with the physicians, nurses and other providers working directly with that patient—allows us to jumpstart this process around more effective use of medication."

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"It really means that you have physicians, pharmacists and everybody on the team look at all the patient's medications—and that includes their herbals, vitamins and over-the-counter drugs, not just their prescribed medications. And then we assess these drugs individually to ensure they are appropriate, effective and safe," 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.

It is, fundamentally, a team-based, patient-centered process. "What we have found is that having a clinical pharmacist on the team—not at the point of dispensing, but really working collaboratively with the physicians, nurses and other providers working directly with that patient—allows us to jumpstart this process around more effective use of medication."

The concept emerged from a multi-stakeholder consensus document published by the Patient-Centered Primary Care Collaborative. McInnis was co-leader of the task force that defined it and distinguished it from other forms of medication therapy management as:

> "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."[2,3]

It involves 10 steps[4] that all members of the team should consider (see sidebar below).

"This is patient centered. You have to have a conversation with the patient. This can't be done absent the patient," McInnis says. And then, after completing the process, "at the end of the day, this is reiterated."

And reiterated. It's an ongoing process.

Allowing time for CMM: A call for medication experts to join the team

Pharmacists spend years of study becoming medication experts, and they are already doing this in the inpatient setting. It only makes sense—and it is time—to move them into the clinic, says McInnis. "We're beginning to use their expertise, and they are the natural choice as experts in medications to deliver this level of service and have those face-to-face visits with patients in collaborative practice with physicians."

However, doing this right takes time. McInnis offers a hypothetical patient—one with 10 different medical problems who is taking

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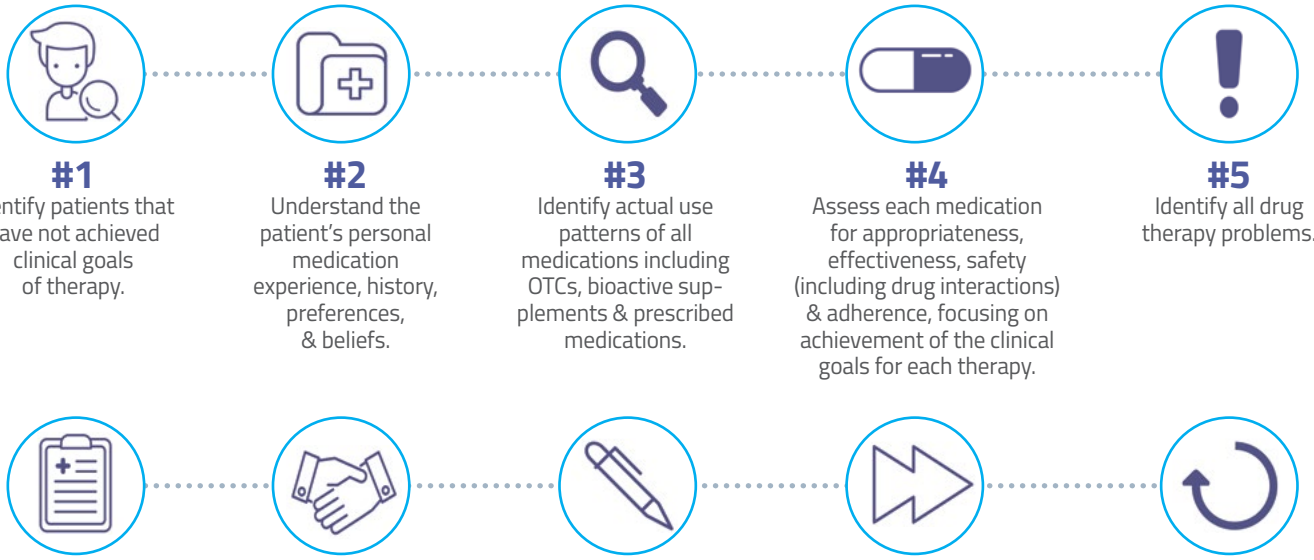
[2] McInnis T, Webb E, and Strand L. *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes,* Patient Centered Primary Care Collaborative, June 2012

[3] *Joint Commission of Pharmacy Practitioners. Pharmacists' Patient Care Process.* May 29, 2014. https://jcpp.net/wp-content/uploads/2016/03/PatientCareProcess-with-supporting-organizations.pdf.

[4] 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

10 Steps to Achieve CMM



15 to 20 medications and is not meeting the clinical goals of therapy in two or three areas. "That's going to be a pretty complicated patient, and that is going to take some time for that initial visit." It could run anywhere from 45 to 90 minutes. One pharmacist-delivered comprehensive medication management model in California addressed patients with an average of 10 medication therapy problems. The CMM process included "check-ins" every two months to ensure optimal care, but it also reduced the need for provider office visits.[5]

Who else but a clinical pharmacist will be able to have these in-depth discussions?

Today, time allotted by physicians to review medications is usually inadequate, especially given the changes in medications and in the population.

A study from the University of California found that approximately 5% of the average 16-minute physician office visit was spent introducing and explaining newly prescribed medications. A mean of 26 seconds was devoted to guideline-recommended components and 23 seconds to discussion of all other aspects of new prescription medications.[6]

That means *less than a minute* was spent on discussing medications that patients could be taking for the rest of their lives. And, Watanabe pointed out, the physicians in the study *knew* they were being recorded for this research.

"These things are complicated. Often, when pharmacists meet with patients it can take 40 minutes to review all their medications—and that's when we've actually worked them up in advance," Watanabe says.[7]

"The problem isn't lack of patient adherence. Non-adherence may contribute to treatment failure, but does not solely translate to poor outcomes."

Jonathan H. Watanabe, Pharm.D., M.S., Ph.D. BCGP, Associate Professor of Clinical Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences University of California, San Diego

The brevity of physician-patient face time is bound to get worse: By 2030, the country will be short an estimated 21,100 to 55,200 primary care physicians. The projected total physician shortfall is between 46,900 and 121,900.[8] This shortage is driven, in large part, by a rapidly aging population—the population most in need of CMM services (see sidebar on next page.)

McInnis points to a closely related issue: multiple providers prescribing multiple medications with little coordination. Primary care clinicians are often—by design or default—the ones who review and reconcile medications. But the majority of the medications in the pipeline will be prescribed by specialists. "Specialists might be very good at the drug they're prescribing, but they may not know anything about the drugs their colleagues in primary care or other specialties are prescribing."

Evidence as a catalyst for change

Watanabe, McInnis and their colleague, Jan D. Hirsch, PhD, had many reasons to conduct this research. Among them:

- **The need for rigor:** Until this paper, the most recent estimate came from a 2009 study. It concluded the cost of non-optimized medication therapy came to $290 billion in 2008 dollars. That 2009 figure, while widely cited, wasn't peer reviewed. "We really wanted to get started with something that would face rigorous analysis," Watanabe says.
- **The need to stop blaming the patient:** Watanabe and his

[5] Butler A, Dehner M, Gates R, et al. *Comprehensive Medication Management Programs: Description, Impacts, and Status in Southern California,* 2015. California Department of Public Health. 23 December 2015. https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CDCB/CDPH%20Document%20Library/CMMWhitePaperCDPH2015Dec23FINALrev.pdf

[6] Tarn DM, Paterniti DA, Kravitz RL, et al. "How much time does it take to prescribe a new medication?." *Patient Educ Couns.* 2008;72(2):311–319. doi:10.1016/j.pec.2008.02.019

[7] Watanabe is the lead researcher of the 2018 study quantifying the cost of non-optimized medication therapy.

[8] *The Complexities of Physician Supply and Demand: Projections* from 2013 to 2025 Final Report Association of American Medical Colleges.

Aging population at particular risk for "medication overload"

Older patients are an increasingly dominant force in health care, Watanabe says. By 2035, there will be 78 million people 65 years and older compared to 76.7 million under the age of 18, according to the U.S. Census Bureau. By 2060, the median age of the U.S. population is expected to be 43, compared to 38 today.

McInnis agrees, and points to a 2019 report from the Lown Institute that articulates just what's at stake if we do not get the medications right. In 2018, 5 million older Americans—one in 10—sought medical attention as a result of a serious reaction to medication. Over the past decade, the rate of emergency room visits for adverse drug events among older Americans nearly doubled.[†]

Medication overload—"the use of medications for which the harm to the patient outweighs the benefit"—will lead to the premature deaths of 150,000 older Americans over the next decade and reduce the quality of life for millions more, according to the report. If this trend continues over the next decade, the authors predict, adverse drug events will result in 74 million outpatient visits, 4.6 million hospitalizations and 150,000 premature deaths among older Americans, costing the health system $62 billion.[‡]

McInnis points out a particularly sobering line from the report: "To put this in context, older adults are hospitalized for adverse drug events at a greater rate than the general population is hospitalized for opioids."

Pair this with the *Annals of Pharmacotherapy* study and other research, and it becomes clear that there's more than one drug epidemic in the country, McInnis says.

"We could begin to stem these problems if indeed we had a systematic approach to medication use. We believe CMM is an effective and scalable approach that can mitigate these avoidable costs and improve patient outcomes in all of these different scenarios, both in the U.S. and throughout the world."

[†] *Medication Overload: America's Other Drug Problem,* Lown Institute April 2019; lowninstitute.org/wp-content/uploads/2019/04/medication-overload-lown-web.pdf

[‡] *Medication Overload: America's Other Drug Problem,* Lown Institute 2019

coauthors wanted to address an issue that has long been misinterpreted in the literature—namely, attributing all the various problems associated with non-optimized therapy to a lack of patient adherence. "The problem isn't lack of patient adherence. Non-adherence may contribute to treatment failure, but does not solely translate to poor outcomes," he says. In some cases, adherence itself can be a bad thing. "Adherence to a non-optimized regimen may contribute to a treatment failure or cause a new medical problem," he explains.

- **Genetics, genomics and biologics:** The cost and complexity of medications has increased substantially over the last decade with advances in genomics and precision medicine. "As costs have escalated and medications have become more complex, what has really taken off in the last few years is increased scrutiny of how we use

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medications," Watanabe says. McInnis adds that roughly 75% of the medications now in the pipeline are specialty drugs with companion or complementary diagnostics, which carry their own high price tag and create a greater imperative to get the medications right.

- **The ACA:** "We've had some seismic shifts in the health care system since 2009, including the Affordable Care Act," Watanabe says. Twenty million more people have access to medical care and prescription drugs, resulting in millions more chances for not only better medical outcomes, but non-optimized medication-related health issues. When Medicare Part D prescription coverage began in 2006, it did not include a mandate for medication reviews for patients in long-term care settings. The ACA changed that, requiring it for all Medicare Part D recipients, but these medication reviews fall far short of the multi-focused, full-scope nature of CMM.

- **The move toward value:** The prescriber community wants improved coordination between pharmacists and other providers to ensure that medication selection provides the highest value for the patient, Watanabe notes. They want to know the medication that best suits the patient holistically, including not only their total disease state and patient profile, but other factors including income and access to the health care system.

- **Data for policy makers:** As health care reform continues to expand, policymakers and others need current estimates of the scope of the problem.

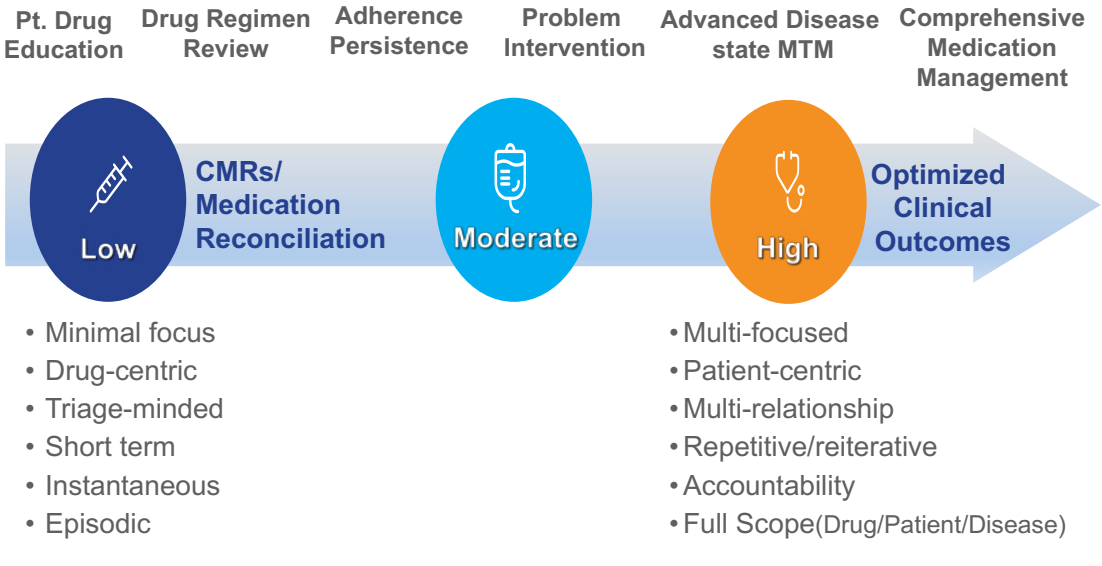
Is our timing right for CMM integration?

"As I argued in our 'Get the Medications Right' report, I believe we're on a path to redefine the role of pharmacy where we actually have clinical pharmacists delivering this level of service in ambulatory collaborative practice settings," McInnis says. That 2016 report, she adds, illustrates how this is already happening beyond the controlled environment of an integrated system like Kaiser or the Department of Veterans Affairs, where CMM is already well underway.[9]

The answer is a resounding "yes," especially in the era of value-based care payments and the shift from

[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. https://gtmr.org/wp-content/uploads/2016/10/GetTheMedicationsRight.v22final-5.20.pdf

Progression of Clinical Pharmacy Service Intensity and Coordinated Medication Management



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population health to precision medicine with advanced diagnostics. In fact, pharmacists are already delivering this level of service in collaborative practice settings, she says. For example, Goodrich Community Pharmacy reported that, with CMM, medication costs remained flat while other costs of care went down. Medication costs often increase in CMM programs, McInnis notes, but they are more than offset by declines in overall cost of care.[10]

Meanwhile, the role of pharmacy is transforming in the context of value-based reimbursement and health care system integration. Watanabe points to CVS Health's acquisition of Aetna. "Now there's the whole move toward doing more that's going to be community-based care and ambulatory-based care."

[10] *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. https://gtmr.org/wp-content/uploads/2016/10/GetTheMedicationsRight.v22final-5.20.pdf

More pharmacies will be pushed to this environment where direct patient care is the expectation, he says. "An in-store primary care clinic with a pharmacist sitting right next door—you've got a setting that's already designed for this kind of activity."

Despite all the successes, CMM can be challenging in a fee-for-service environment. "It can be done, but in general it's important to remember we're moving away from fee-for-service, and that is likely a good thing."

As more systems assume more risk, the case for integrating pharmacists becomes clearer. "Where we are right now is that perfect storm where we are moving away from fee-for-service and instead paying for outcomes," McInnis says.

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She also points to HealthPartners in Minnesota, which reported an 11:1 return on investment for CMM. That spurred the health plan to offer CMM to each beneficiary with a pharmacy benefit. As HealthPartners put more risk on the shoulders of providers, it showed them how pharmacists, as part of their care teams, can reduce costs and improve outcomes.

As the health system moves from volume to value, it is important that we continue to showcase evidence and innovation, offer tools and resources that support practice transformation, and continue to advocate for rational policy and payment reform. "We're at a place where we can put in a systematic approach to medication management," she says. "Now is the time." GTMR

About the Experts

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Jonathan Watanabe is associate professor of clinical pharmacy at the Skaggs School of Pharmacy and Pharmaceutical Sciences at the University of California, San Diego. He is also the lead author of the article highlighting the $528 billion U.S. health spend on non-optimized drug therapy. He practices in post-acute care pharmacy and focuses on outcomes in older adults and residents of extended care facilities. Jonathan trains students, post-docs, and practitioners in multiple disciplines in clinical research and post-acute care.

He is an investigator on the Health Resources and Services Administration-funded San Diego Geriatrics Workforce Enhancement Program Grant. Watanabe serves as the faculty advisor for the Academy of Managed Care Pharmacy student chapter and is a Board Certified Geriatric Pharmacist (BCGP).

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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's 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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