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CLINICAL PHARMACY RESEARCH REPORT

An implementation system for medication optimization: Operationalizing comprehensive medication management delivery in primary care

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The implementation system described in this article is a customizable blueprint for delivery of comprehensive medication management (CMM) and other medication optimization services. This system is the result of merging implementation science expertise with lessons learned from the parent study, the "CMM in Primary Care" grant. This system is comprised of a number of components, including implementation steps and strategies (ie, activities, practical resources such as assessments and informational materials, and learning supports). While these components are integral to any implementation effort, this project describes their unique operationalization for delivery of CMM in a primary care context. Application of this system is illustrated through an example focused on improving the delivery of CMM by pharmacist-led teams in primary care settings.

KEYWORDS

comprehensive medication management, implementation science, implementation system, pharmacy practice

1 | INTRODUCTION

One of the most preventable problems negatively impacting the quality and cost of health care in the United States is the suboptimal use of medications. Based on the most recent estimates, the annual cost of medication misuse leading to morbidity and mortality is actually higher than the cost of prescription spending.[1,2] Pharmacists are uniquely positioned to intervene by providing clinical services and medication optimization interventions, such as comprehensive medication management (CMM), that are designed to maximize the benefits of medications, improve patient care, and reduce cost. Unfortunately, these interventions have not consistently resulted in the desired outcomes, but rather yielded mixed results.[3,4]

The lack of conclusive results is attributed, in part, to implementation variability.[3,4] Delivery of medication optimization interventions, like CMM, appears to be highly variable across pharmacists, patients, and settings. Inconsistent implementation is associated with a number of challenges, including: insufficiently defined interventions and lack of guidance on how to operationalize these interventions in practice; minimal efforts to monitor implementation to ensure that interventions are delivered as intended; and limited use of proactive implementation strategies designed to facilitate successful uptake. Previous research has demonstrated that reducing implementation variability increases the likelihood that an intervention will achieve positive clinical outcomes.[5,6] Identifying approaches to address this challenge are key to realizing the impact and value of medication optimization interventions.

Implementation science, a relatively new field of study, emerged out of the need for evidence-based interventions to produce the same consistent results in real world settings as were obtained under tightly

controlled conditions. This discipline arose from the recognition that simply introducing an intervention into practice was not sufficient to ensure its routine use in clinical and other settings. Implementation science seeks to discover and apply methods to promote and accelerate the routine use of interventions that have the potential to improve the well-being of a population.[7–9] As such, it promotes a systematic, proactive, and data-driven approach to implementation, designed to both drive effectiveness and facilitate replication, sustainability, and scaling of an intervention. While this approach is detailed elsewhere,[10] it is worth noting that implementation science has generated a set of frameworks, strategies, methods, and learnings that are foundational to implementation of any intervention.

Although implementation science has been embraced by other disciplines (eg, mental health, education), it has not yet been fully integrated within pharmacy practice.[11,12] For this integration to be successful, its foundational elements need be customized to the pharmacy context. Implementation science does promote practice principles and steps that are applicable regardless of circumstances (eg, attending to the stage of implementation, building an implementation team); however, operationalizing these principles and steps requires they be adapted to the unique circumstances of a particular implementation effort within a particular context. Tailoring implementation science to medication optimization interventions and health care settings is necessary to maximize its usefulness and impact.

This article describes an effort to operationalize the implementation process for CMM through an ongoing project, the "CMM in Primary Care" study.[13] This study was designed to improve consistent use of CMM in 40 primary care settings with embedded pharmacists. In this project, CMM was defined as "a patient-centered approach to optimizing medication use and improving patient health outcomes that is delivered by a clinical pharmacist working in collaboration with the patient and other health care providers."[14] The commitment to develop and refine an implementation system resulted from the need to promote implementation consistency, while accelerating uptake of CMM. An implementation system can be thought of as a set of connected processes (or steps) and strategies that, when taken together, form an organized approach (ie, a blueprint) to facilitate effective implementation and replication. Implementation strategies have been defined as the methods used to facilitate delivery of an intervention.[15] They include a wide range of techniques, including specific activities (eg, identifying ways of working for implementation teams), practical resources (eg, written instructions, survey assessments), and learning supports (eg, training, coaching), designed to facilitate completion of implementation steps. Table 1 provides a glossary of the implementation science terms that are used in this paper.

The development of this system was initially grounded in one of the implementation science determinant frameworks, the Active Implementation Frameworks (AIFs).[16,17] However, its final operationalization was the result of merging implementation science expertise with lessons learned from the parent study. While some components of this system were identified as key early in the project (eg, orienting participating sites to CMM, creating implementation teams) and, therefore, attended to as part of the parent study, others emerged out of needs that were recognized during the project (eg, assessing the teams' readiness—capacity and motivation—prior to having them implement their initiative).

TABLE 1 Glossary of implementation science terms

Term	Definition
Implementation science principles	The foundational propositions of the implementation science discipline
Implementation stages	A way to organize and differentiate how implementation unfolds over time. Although the stages are often dynamic and non-linear, they provide a heuristic to determine the timing of specific steps and strategies
Implementation strategies	The methods or techniques by which adoption, implementation, and sustainability of an innovation are enhanced. They constitute the "how-to" of changing health care practice and are used to execute on broader implementation steps. They include, but are not limited to, specific activities, learning supports, and practical resources
Implementation steps	Core implementation processes which, when taken together, form an organized approach (ie, a blueprint) to facilitate implementation
Implementation activities	Specific actions and tasks that are completed in support of achieving an implementation step. Implementation activities are one type of implementation strategy
Implementation resources	Informational materials, process tools, and/or assessments used to carry out a specific activity. Implementation resources are one type of implementation strategy
Learning supports	Instructional strategies to facilitate skill and knowledge acquisition, build capacity, and facilitate knowledge transfer for use in practice. Learning supports are one type of implementation strategy
Fidelity	The degree to which an intervention is being delivered or implemented as intended

The intent of this article is 2-fold. First, it details an implementation system, including its steps and associated strategies (ie, specific activities, practical resources, and learning supports). While this system resulted from tailoring the implementation process for delivery of CMM in a primary care context, it was designed as a customizable blueprint for any medication optimization service. Second, the application of this system is illustrated through an example focused on improving quality use of CMM by a pharmacist-led team in a primary care setting. Quality use assumes fidelity of implementation (ie, the intervention core components are being implemented as intended), which translates into consistency of implementation across providers and settings, and enhances the likelihood of achieving positive clinical outcomes. It is important to note that the intent of this system is *to facilitate optimal implementation through quality use of the intervention, regardless of whether the initiative involves initial implementation or efforts to improve an intervention that was previously implemented.* As a result, pharmacists and other health professionals interested in implementing CMM for the first time or improving CMM delivery should be able to use this system. While pharmacy practice research has been primarily focused on demonstrating the effectiveness of medication optimization interventions, this article focuses on operationalizing optimal implementation to facilitate replication, drive clinical impact, and attain scale.

2 | THE IMPLEMENTATION SYSTEM—AN OVERVIEW

The proposed implementation system is illustrated in Figure 1. Use of this system assumes that high-level planning has already occurred. The overarching opportunity or aim underlying the decision to use the system has been identified (eg, increase number of patients at clinical goal), the intervention has been selected (eg, CMM), the intervention is usable in practice (ie, it has been explicitly defined), and initial financial and staffing resources have been allocated. With these considerations in mind, the system's foundational components consist of implementation steps and strategies, including associated activities, relevant resources, and learning supports. These components should be included in any implementation blueprint regardless of intervention or context, with the *steps* serving as a useful guide through the implementation process. These steps, which are applicable to any implementation effort, can be depicted temporally along implementation stages. Implementation stages lay out a useful way to think about how implementation unfolds over time. Although the stages are often dynamic and non-linear, they provide a heuristic to determine the timing of specific steps and strategies. The literature provides diverse classifications of implementation stages.[17–19] However, they can be simplified into three main stages: pre-implementation or preparation, implementation, and stabilization. Briefly, pre-implementation includes the following steps: getting started, building an implementation team, assessing your implementation readiness, assessing your foundations, and planning to implement. During the implementation phase, the focus is on implementing, monitoring progress and early successes, and improving the intervention. Once implementation efforts are underway and post-data have been collected, it is important to evaluate next steps based on successes, challenges, and lessons learned and determine feasibility of sustaining this change within the practice.

These steps are completed through execution of a series of implementation *activities*. Figure 1 outlines the activities selected for CMM implementation in primary care. While these activities are generalizable, their scope and definition should be contextualized to the purpose of the initiative (eg, initial implementation vs improved implementation), the stakeholders' needs and priorities, and the selected medication optimization intervention. As an example, one activity to assess your foundations for improved use of CMM (Step 4) is collection and examination of fidelity data related to the CMM patient care process. Briefly, the CMM patient care process articulates the essential functions of CMM and operationalizes its necessary tasks for consistent delivery.[14,20,21] Assessing fidelity to CMM as defined in the CMM Patient Care Process document[14] facilitates benchmarking and identification of potential opportunities to improve consistent delivery of CMM.

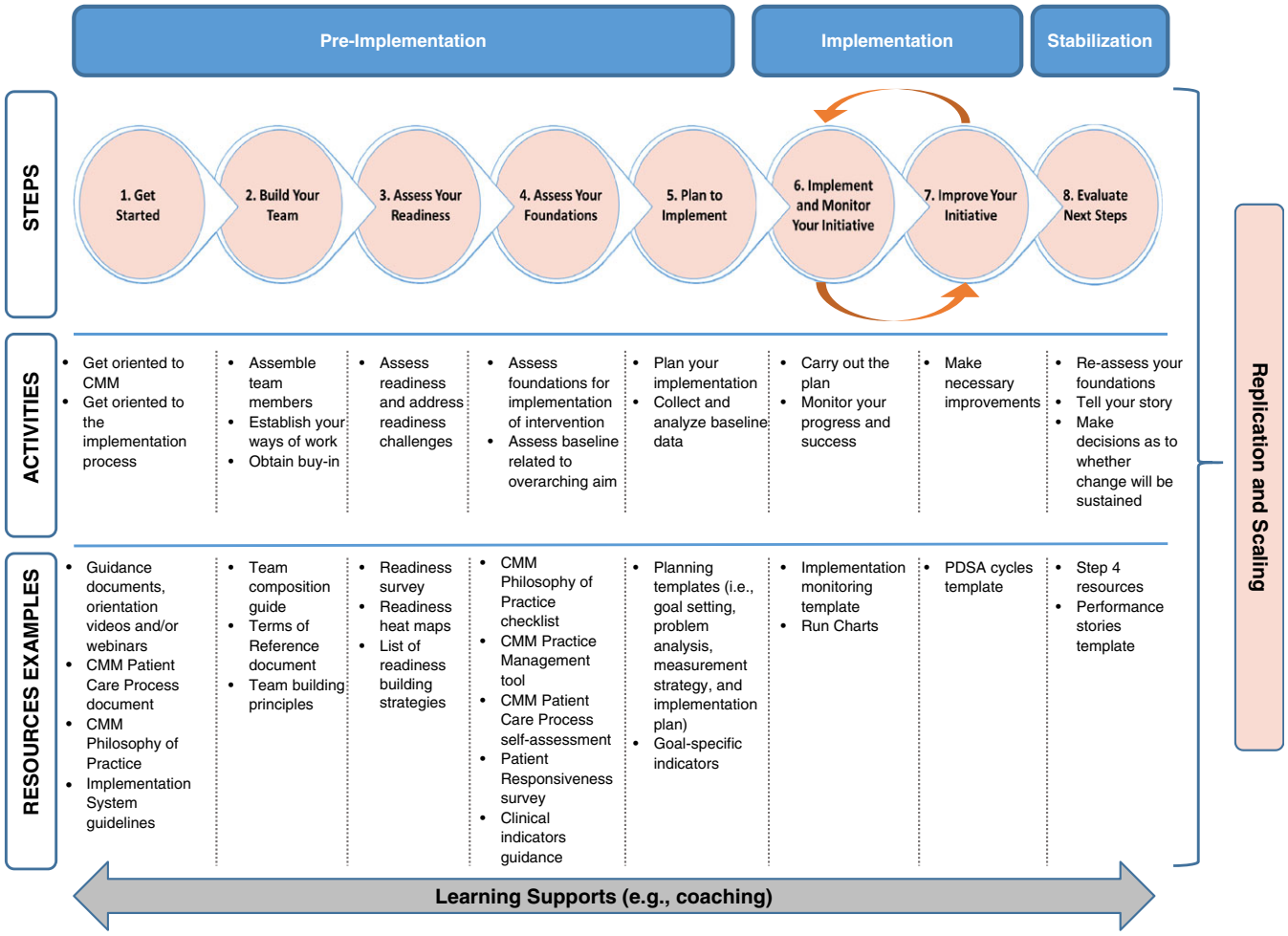

FIGURE 1 Implementation system. CMM, comprehensive medication management; PDSA, plan-do-study-act

Completion of each activity, can, in turn, be facilitated through use of supporting *resources*, including informational materials, process tools, and assessments. Resources are typically either tailored or created anew depending on the focus of the implementation initiative and selected intervention. Figure 1 details the resources needed to complete the CMM implementation activities. Incidentally, these resources have either been or are currently being validated as part of the parent study, and will eventually be compiled into a forthcoming technology platform that will be released to guide medication optimization efforts, including CMM. As an example, the resources available to become oriented to CMM and the implementation process (Step 1 activities) include the CMM patient care process document[14,20,21] (describing the CMM patient care process for use in practice) and the CMM Philosophy of Practice document[22] (Step 1 resources).

Finally, to facilitate uptake and improved use of CMM within primary care, it is essential for the implementing site to have access to *learning supports* early in the implementation process. Previous research in the implementation science literature has underscored the necessity and utility of these supports to build implementation capacity and facilitate quality implementation.[23] These supports can include ongoing webinars, in-person trainings, follow-on coaching, and access to a community of practice to facilitate shared learnings. Learning supports are designed to provide implementation teams with the knowledge and resources necessary to successfully engage in implementation activities, opportunities to practice the newly acquired skills, and an accountability process to ensure that learnings are successfully transferred for use in practice. These supports should be tailored to the specific intervention (ie, content), the level of intervention complexity and existing capabilities of the implementing sites (ie, intensity), and available financial resources (ie, support type and scope). Because there is solid evidence that the likelihood of implementation success will be greatly increased with availability of learning strategies,[24–28] implementing sites should explore options to receive these types of supports, at least initially. In addition to creating narrated videos, guidance documents, and webinars, the project team is working to create a CMM community of practice through the technology platform as well as options to access coaching.

3 | USING THE IMPLEMENTATION SYSTEM TO IMPROVE QUALITY USE OF CMM IN PRIMARY CARE PRACTICES: AN EXAMPLE

The following example illustrates the application of the proposed system to improve quality implementation of CMM in a primary care practice with an embedded pharmacist. This example is a composite of several of the sites that were involved in the parent study.[13] As such, it reflects actual experiences and lessons learned from the use of the implementation system. In this example, our lead clinical pharmacist is highly motivated to improve use of CMM in the two primary care practices that he works in. His overarching aim is to bring 80% of eligible patients to clinical goal within 2 years. This aim is informed by recently collected data at both practices indicating that only 50% of patients are at clinical goal, with implementation variability across providers and sites being the main underlying issue. The CMM patient care process does not seem to be implemented as intended in either practice for a variety of reasons (eg, medical providers unaware of exactly what the intervention or service is, no systematic process for identifying and resolving medication therapy problems [MTPs], lack of consistent follow-up to provide continuity of care). With buy-in from his clinic leadership, he sets out to optimize CMM use in both primary care clinics. He obtains all of the supporting resources from one of the "CMM in Primary Care" study[13] PIs. He also decides to engage with a Medication Management Collaborative with both CMM and implementation expertise. The Collaborative he contacts is just starting to work with a new cohort of sites interested in implementing or improving use of CMM. Our lead pharmacist is able to obtain funding from his leadership to participate in the Collaborative's regularly scheduled live webinars and receive monthly coaching for a year.

As part of getting started (Step 1), our lead pharmacist reviews all of the supporting resources. These include documents that overview CMM, such as the CMM patient care process document[14] that operationalizes the CMM patient care process for use in practice and the CMM philosophy of practice checklist that describes the shared principles underlying CMM.[22] These resources also include materials designed to provide a high-level description of the implementation system. These readings are supplemented by a training video and two live webinars conveying similar information. Coaching is also available should our pharmacist have any questions.

Once our lead pharmacist has been oriented, he pulls together an implementation team of six to eight members who are responsible for carrying out the CMM initiative (Step 2). Implementation teams are a critical success factor in change efforts, especially for complex interventions that require buy-in and execution across departments and disciplines.[29] In accordance with best practices, our lead pharmacist ensures that the team members he selects are representative of the needed roles and skillsets, namely, pharmacy practice, quality improvement, primary care, and leadership within the organization. Because the two primary care clinics he works in are part of the same health system, he decides to create one combined team with representatives from each clinic. The team creates a "Terms of Reference" document describing the overarching aim, the team's purpose and structure, and team members' ways of working together.[30]

Once the CMM implementation team is in place, it is now time to prepare to launch (Step 3). Before engaging in any implementation effort, it is necessary to ensure that the team and organization are ready—both willing and able - to carry out the work. Unfortunately, this step is often overlooked, resulting in avoidable implementation misadventures. In fact, failure to establish sufficient readiness prior to implementation accounts for half of all unsuccessful, large scale organizational change efforts.[31] With this in mind, our lead pharmacist completes the CMM implementation readiness survey with his team.[32,33] The survey results are summarized by an appointed coach in a brief report, which highlights areas of strength, as well as opportunities for improvement. After reviewing the report, the team realizes that they need to appoint a "champion" for the CMM initiative who will be responsible for sharing progress and showcasing success with clinic leadership. The team selects one of its members, a primary care physician, as its champion. This physician is an advocate for use of pharmacy services, and is well respected by clinic leadership at both

sites. As a result of the readiness assessment, team members also realize that they have varied levels of knowledge and expertise in CMM. To ensure that they all share a baseline understanding of CMM, the lead pharmacist proposes that the entire team review the orientation documents and videos.

With the implementation team members now ready to engage in the work, they turn their attention to assessing their foundations (Step 4). Because the baseline metrics associated with their overarching aim were collected previously, they only need to focus on assessing their foundations related to consistency of CMM implementation. Data from these assessments can be used as initial benchmarks. When the purpose of the initiative is to improve use of an existing intervention rather than initial implementation, these data can also be used to identify what needs to be improved. This information can be collected through surveys designed to assess fidelity to the philosophy of practice,[22] adherence to and satisfaction with the CMM patient care process,[34,35] and availability of the practice management infrastructure needed to support CMM implementation.[36] Based on the results of these assessments, the team decides to focus their improvement efforts on one specific aspect of the CMM patient care process: systematizing MTP documentation and resolution for patients in both clinics. This issue is identified as a crucial challenge to be resolved to ensure that CMM can be implemented as intended per the CMM patient care process document,[14] therefore facilitating consistency of implementation across both sites and positively impacting the likelihood of achieving the overarching aim.

With this goal in mind, the team starts planning for execution of their initiative (Step 5). The implementation strategy they decide to adopt is improvement cycles, which is designed to facilitate incremental change towards a consistent approach to CMM delivery. This strategy, rooted in both the AIFs[17] and the Institute for Healthcare Improvement (IHI) model,[37] includes goal setting, problem analysis, and selection of proximal measurement strategies as part of the improvement planning process. With their coach's assistance and feedback, the team uses the available planning templates to document their overall goal and desired outcome, the results of their problem analysis, their SMART (Specific, Measurable, Actionable, Realistic, and Time-bound) bite-size objectives, and their measurement strategy.[38] In this example, the team's goal is to have MTPs systematically identified and resolved for 80% of their CMM patients within the next year. Recall that the team's overarching aim is to bring 80% of patients in their panel to clinical goal within 2 years. They learned, through completion of the foundational assessments, that one major area of improvement resides in their need to more systematically identify and resolve MTPs, hence the focus of this particular initiative.

After identifying indicators of success (eg, number of pharmacists using the MTP framework and tool, percent of CMM patients with MTPs identified and resolved), they use the "5 whys" method to identify the root causes (eg, lack of a framework to categorize MTPs) underlying their issue. They then prioritize the root causes that they want to address within the 12-month timeline and develop bite-size goals (eg, by a given date, all pharmacists will have used the available MTP framework and tool for 3 months). They also identify relevant activities (eg, entering relevant information into the MTP tool) and outline an implementation plan. Prior to implementing this plan, they collect baseline data on the indicators identified above at both clinics.

As the team is carrying out their plan (Step 6), they are documenting progress and success using the implementation monitoring template. Aligned with the improvement cycles strategy, they use plan-do-study-act (PDSA) cycles to test each of their priority ideas for improving MTP identification and resolution. PDSAs support purposeful small tests of change that facilitate rapid integration of learnings into the implementation process.[39] To assess the viability of their changes, they collect data relevant to the indicators selected above through run charts. These data are used to determine whether the change that is being tested actually makes a positive difference on the desired outcome (ie, 80% percent of CMM patients with MTPs identified and resolved). As a result, decisions can be made to either abandon, adapt, or adopt each idea tested. Because PDSAs are iterative, these ideas can be improved over time (Step 7), until the desired outcome is achieved. The PDSA work is documented as part of the PDSA template, with decisions to abandon, adapt, or adopt used to identify what worked and what did not.

Once the desired outcome is reached, the team re-takes the foundational assessments mentioned above to ensure that CMM is being implemented as intended by the pharmacists at each site and that there has been some progress towards their overarching aim (Step 8). Depending on the results, the team might decide to address other root causes impacting consistency of CMM implementation (beyond MTP identification and resolution) or engage in additional change efforts (beyond enhancing CMM implementation) that would positively influence achievement of their overarching aim. In addition, our lead pharmacist prepares a brief report that summarizes successes, challenges, and lessons learned thus far. The information synthesized in this report can contribute to developing a business case that influences decision making around sustainability of the intervention.

4 | DISCUSSION

To optimize medication use, improve patient care, and control costs, it is necessary to demonstrate that interventions, like CMM, produce consistently positive outcomes. This goal can be accomplished in part by reducing implementation variability. Ensuring that medication optimization interventions are implemented as intended requires customizing and applying implementation systems that can serve as a roadmap to those interested in their delivery. This article describes such an implementation system, developed specifically for teams tasked with implementing or improving delivery of CMM in primary care practices. While operationalization of this system is specific to CMM, the system itself is generalizable to any medication optimization intervention (eg, targeted disease state management) with additional tailoring of implementation strategies. To our knowledge, this is the first published manuscript that provides pharmacists with a step-by-step blueprint to facilitate quality implementation of CMM that was prospectively grounded in implementation science theory and retrospectively refined based on lessons learned from application within a large study.[13]

While this implementation system is usable in its current form, it is worth noting that it is an early attempt at a useful implementation blueprint. As such, its use is bounded by the following assumptions and limitations. First, as previously noted, this blueprint can only be used with an intervention that has been well defined and is usable in practice. For this study, the CMM patient care process had to first be operationalized.[14] A deeper understanding of the resources and infrastructure necessary to successfully integrate CMM within primary care practices, also had to be obtained. Having a usable intervention is a necessary precursor to consistent implementation. Second, successful application of the implementation system assumes availability of learning supports, such as training and coaching. This is not to say that health care providers could not use the system without these supports, but being able to access this expertise will greatly increase the likelihood of adopting an accelerated pace to quality implementation. Finally, while evidence of the effectiveness of the proposed implementation system is supported by the implementation science literature,[17,40] as well as anecdotal evidence from the parent study, it does need to be validated more formally through prospective studies.

In moving toward value-based health care delivery, it is necessary to demonstrate that interventions, like CMM, can produce consistent results. This goal can only be achieved by optimizing implementation through application of customizable implementation blueprints that can be used to facilitate replication, effectiveness, and scalability.

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Conflict of Interest

Authors declare that they do not have a conflict of interest.

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