Evaluation of Comprehensive Medication Management Research and Identification of Gap Areas

Over the last decade, there has been progress in defining comprehensive medication management (CMM) processes and research as well as descriptive reports outlining the impact of implementing CMM as part of team-based care. Optimizing medication use through CMM in practice can save lives, increase quality of care and decrease health care costs. There are still gap areas that exist which would benefit from added research focus moving forward. Based on a review of current literature on implementation and impact of CMM, this report will outline the existing gap areas and recommendations on approaches to close those gaps.

Establishment of Value

It is well documented that CMM, performed as part of a team-based process of care where a clinical pharmacist working in collaborative practice with a physician and other team members, can affect surrogate markers such as HbA1c, blood pressure and cholesterol levels; however, a gap exists in the current literature in clear clinical outcomes, such as decreases in myocardial infarction, stroke, foot ulcers and foot amputations.[1] Although clear benefit in outcomes related to CMM have not been broadly validated, it could be possible to utilize existing data, apply them in the setting of CMM and conduct research to close that gap. CMM in practice, in both the inpatient and outpatient settings, routinely incorporates elements of care that have demonstrated improved outcomes in which a number needed to treat or a number needed to harm have been established. It is reasonable to assume that research can be conducted when outcomes have been validated as part of the CMM process of care.[2]

Recommendation 1. Studies are needed that can evaluate patient outcomes. While randomized clinical trials may not be feasible, alternative study designs that permit relatively strong causal inferences are needed.

From an economic perspective, there are gaps in the current literature for reporting return on investment (ROI) and costs avoided with the provision of CMM. Calculations included in ROI reports are not consistent in their methodology, leading to inconsistency and confusion among stakeholders such as payors and employers.[3,4,5,6] This ultimately negatively impacts widespread implementation and perception of value. Establishment and communication of the value of CMM from the patient perspective is also missing from the current literature. Studies that evaluate the impact of CMM on total cost of care would be ideal to show ROI.

When it is not feasible to study the CMM impact on total cost of care, it can be impactful to quantify costs avoided by preventing adverse drug events (ADE). When a patient experiences a preventable ADE, there may be both direct and indirect costs. Direct costs include use of additional medications, physician visits in an outpatient setting to restore the patient's health and medical costs to payors, such as an extended inpatient stay. Indirect costs

1   Greer N, Bolduc J, Geurkink E, et al. Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care. *Ann Intern Med.* 2016; 165(1):30-40. doi:10.7326/M15-3058.

2   Ibid.

3   Pellegrin KL, Krenk L, Oakes SJ et al. Reductions in medication-related hospitalizations in older adults with medication management by hospital and community pharmacists: A quasi-experimental study. *J Am Geriatr Soc.* 2017; 65(1):212-219. doi:10.1111/jgs.14518.

4   Brummel A, Lustig A, Westrich K, et al. Best practices: Improving patient outcomes and costs in an ACO through comprehensive medication therapy management. *J Manag Care Spec Pharm.* 2014; 20(12):1152-1158.

5   Ramalho de Oliveira D, Brumel AR, Miller DB. Medication therapy management: 10 years of experience in a large integrated health care system. *J Manag Care Spec Pharm.* 2010; 16(3):185-195. doi:10.18553/jmcp.2010.16.3.185.

6   Isetts BJ, Schondelmeyer SW, Artz MB, et al. Clinical and economic outcomes of medication therapy management services: The Minnesota experience. *J Am Pharm Assoc.* 2008; 48(2):203-211. doi:10.1331/JAPhA.2008.07108.

include "missed work, reduced quality of life, disability for the patient, costs to employers for temporary replacement staff or decreased productivity, as well as possible uncompensated expenses for the health care provider."[7] Several methods have been utilized to estimate the cost avoided by preventing an ADE; however, a modernized robust methodology is needed for application in future research.[8,9,10]

Recommendation 2. Implement studies that employ rigorous study design that includes impact on total cost of care.

Recommendation 3. To assess the value of CMM, a well-designed methodology is needed to quantify the costs saved by preventing ADEs. The methodology should account for both direct and indirect costs.

Recommendation 4. A tool should be developed to equip researchers with key principles and information needed to conduct studies which adequately address the gap areas for establishing the value of CMM.

Recommendation 5. CMS reimbursement based on patient satisfaction should be extended beyond hospitals and freestanding ambulatory and outpatient surgical centers. Private payors should also provide reimbursement based on patient satisfaction.

Care Delivery

While a care delivery model framework for comprehensive medication management (CMM) processes exist, there is a lack of consistent implementation at the primary care level, and in other settings.[11] In addition, expanding CMM delivery outside the walls of an institution to reach underserved populations is an identified need. The "10 Steps to Achieve Comprehensive Medication Management (CMM)" could be used as the foundation for expanding access with defined metrics for each component disseminated, making widespread adoption possible.[12] This would allow for measurable implementation and compliance with all elements for all practice settings. Those metrics should be designed as such that the electronic medical record (EMR) could capture details from the CMM visit. Metrics would need to be recorded for ease of entry into some centralized system that allows anonymity of actual patients. It would also be beneficial to explore infrastructure to facilitate expanded site participation and streamline ethics/regulatory issues (e.g., Central IRB) for studies including multiple practice sites that do not have shared EMR systems.

CMM collaborative care ensures a complete medication assessment and has been shown to improve outcomes and decrease cost by ensuring appropriate, personalized care while increasing patient engagement and satisfaction.[13,14] The delivery of CMM can occur via multiple care delivery modalities, including virtual care. Virtual care delivery has the ability to extend CMM to patients unable to make an in-person visit, especially those in underserved areas. While the ability to decrease cost and increase revenue exists, value can be quantified well beyond

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7   Lahue, BJ, Pyerson B, Iwaski K, et al. Am Health Drug Benefits. 2012 Nov-Dec; 5(7): 1-10.

8   Lee A, Boro M, Knapp K, et al. Clinical and economic outcomes of pharmacist recommendations in a Veterans Affairs medical center. *Am J Health-Syst Pharm.* 2002; 59:2070-7.

9   Field TS, Gilman BH, Subramanian S, et al. The costs associated with adverse drug events among older adults in the ambulatory setting. *Med Care.* 2005;43(12):1171-1176.

10 Bain K, Knowlton C, Matos A. Cost avoidance related to a pharmacist-led pharmacogenomics service for the program of all-inclusive care for the elderly. *Pharmacogenomics.* 2020; 21(10):651-661. doi:10.2217/pgs-2019-0197.

11 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

12 Get the Medications Right Institute. *10 Steps to Achieve Comprehensive Medication Management (CMM).* https://gtmr.org/wp-content/uploads/2019/04/GTMRx-CMM-10-steps-PDF.pdf.

13 Santos, B., Gonzaga do Nascimento, M., Batista de Oliveria, G., Nascimento, Y., at al. Clinical Impact of a Comprehensive Medication Management Service in Primary Health Care. Journal of Pharmacy Practice. 2019. doi: 10.1177/0897190019866309.

14 Fabel PH, Wagner T, Ziegler B, et.al. A sustainable business model for comprehensive medication management in a patient-centered medical home. J Am Pharm Assoc. 2019;59:285-90.

direct revenue by enhancing access and convenience, attracting and retaining new patients, reducing wait times, improving operational efficiency, decreasing provider and patient travel expenses, improving patient satisfaction and engagement and expanding coverage by a specialist in specialty areas.[15] The COVID-19 pandemic brought relaxation from restrictions on reimbursement from payors.[16] While it is unknown if the current process will be continued, it is imperative that the tenants of CMM be maintained when delivering CMM virtually, as the need for virtual care should be expected to increase.

In order to ensure that outcomes are improved and cost avoided, CMM in the virtual setting should occur with consistent fidelity. Assurance of initial and ongoing competence in this model is a crucial component. Virtual care relies on access to technology that could be further enhanced to better utilize this care delivery modality. Third party programs are available that can assist with identifying high-risk patients and ensure proper follow-up on tests or results as well as tracking missed appointments. The integration of such programs should be considered when implementing a virtual care delivery model as this could improve care, increase provider efficiency and address current gaps in literature. These gaps include data not completely captured or reported, improper documentation, communication errors and referral practices not clearly outlined.[17,18]

Recommendation 6. Resources should be developed for researchers that outline standardized language definitions and essential elements for study design measures across practice settings.

Recommendation 7. Studies are needed that evaluate the provision of CMM via virtual care modalities that demonstrate the core tenants are maintained and additional value is realized.

Patient Experience

There is limited research that has evaluated patient satisfaction and engagement when receiving CMM care.[4,19,20] Further, engagement, both at initial visit and during routine follow up, should be defined both by what it means and how it is measured. Validated patient centered outcome tools that measure patient satisfaction can guide researchers in their evaluation. These elements for CMM and patient satisfaction and engagement could be combined for use in structured protocols independent of practice site or disease state. In addition, evaluation of the patient's perception of the value of receiving CMM is lacking in the current literature.

Recommendation 8. A resource document should be developed that outlines definitions for measuring patient satisfaction and engagement and validated patient centered outcome tools available for evaluation. A method for patient assessment that incorporates questions familiar to providers and patients, such as those commonly assessed with the Consumer Assessment of Healthcare Providers and Systems (CAHPS) and Merit-based Incentive Payment System (MIPS), should be considered.

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[15] The Strategy That Will Fix Health Care. Porter, M., Lee, T. *Harvard Business Review.* October, 2013. https://hbr.org/2013/10/the-strategy-that-will-fix-health-care.

[16] Billing and reimbursement during the COVID-19 Public Health Emergency. https://telehealth .hhs.gov/providers/billing-and-reimbursement/?section=1,6#private-insurance-coverage-for-telehealth. Accessed August 20, 2020.

[17] Elbeddini A, Yeats A. Pharmacist intervention amid the coronavirus disease 2019 (COVID-19) pandemic: from direct patient care to telemedicine. *J Pharm Policy Pract.* 2020;13:23. doi:10.1186/s40545-020-00229-z.

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[19] McFarland MS, Wallace J, Parra J, Baker J. Evaluation of patient satisfaction with diabetes management provided by clinical pharmacists in the patient-centered medical home. Patient. 2014;7:115–121. doi.10.1007/s40271-013-0039-7.

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Clinician Experience

Team-based care encompasses a variety of health care professionals with differing levels of education, training and expertise.[21,22,23,24] This applies to individuals delivering CMM as well. Individual practitioners should continually evaluate their experience and expertise to determine when a higher level of care, expert consultation or referral is needed. Competing priorities and interests of varying stakeholders can further introduce barriers to effectively delivering CMM care and potentially lead to clinicians performing unnecessary tasks. In addition, advanced communication skills are critical to achieving optimal outcomes of CMM services. This includes not only the ability to develop clear, concise, credible and convincing messages, but also proficiency of communicating via different communication methods (in person, telephone, email, videoconferencing, etc.).[25]

Recommendation 9. Perform analysis of the elements outlined in the process of implementing CMM, including what steps/actions are currently being conducted and whether or not these steps are beneficial. This would inform an ongoing monitoring system and subsequent training program based on the data. This associated quality improvement program must include a root cause analysis to identify any areas of defect(s).

Recommendation 10. Conduct research to evaluate and outline clear clinical practice expectations that balance the business case, patient needs and the moral imperative to quality care with aligned performance measures.

Recommendation 11. Evaluate communication effectiveness. Experts in the human factor design, cognitive understanding, literacy assessment and linguistics fields should be involved in the monitoring, evaluation and subsequent training. They are ultimately responsible for the improvement of all communication messages and methods.

Technology

CMM care teams must use clinical and other relevant information at the point of care to monitor and evaluate obtainment of patient achieving clinical goals of therapy to ensure appropriate use and management of medications. In addition, care teams must use tools to rapidly evaluate eHealth content. This allows clinicians to use clinical data to make recommendations and respond to patient queries about eHealth information at the point of care. Since CMM is an iterative process, it is imperative that patients are able to fully engage and respond to information communicated electronically. Tools are needed to support the care team's selection of the appropriate eHealth information and to meet their patient's individual needs and learning style. Measures to differentiate the effectiveness of eHealth systems could include readability scores, such as the Gunning Fog formula which generates a grade level between 0 and 20 and measures the quality of the peer review process by clinical specialty content.[26] In addition, the timeliness of updates to eHeath content should be considered and made available to the care team.[27]

[21] Bodenheimer T, Sinsky C. From Triple to Quadruple Aim. Care of the Patient Requires Care of the Provider. Ann Fam Med. 2014 Nov; 12(6):573-576.

[22] Sisson EM, Dixon DL, Dildow C, Van Tassell BW, Carl DE, Varghese D, Electricwala B, Carroll NV. Effectiveness of a Pharmacist-Physician Team-Based Collaboration to Improve Long-Term Blood Pressure Control at an Inner-City Safety-Net Clinic Pharmacotherapy 2016;36(3):342-347.

[23] Zillich AJ, Jaynes HA, Bex SD, Boldt AS, Walston CM, Ramsey DC, Sutherland JM, Bravata DM. Evaluation of Pharmacists Care for Hypertension in the VA Patient-centered Medical Home: A Retrospective Case-Control Study. *The American Journal of Medicine* (2015) 128, 539, e1-539,e6.

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[25] National Steering Committee for Patient Safety. Safer Together: A National Action Plan to Advance Patient Safety. Boston, Massachusetts: Institute for Healthcare Improvement; 2020. www.ihi.org/SafetyActionPlan.

[26] Kher A, Johnson S, Griffith R. Readability Assessment of Online Patient Education Material on Congestive Heart Failure. Adv Prev Med. 2017;2017:9780317. doi:10.1155/2017/9780317.

[27] Baker TB, Gustafson DH, Shah D. How can research keep up with eHealth? Ten strategies for increasing the timeliness and usefulness of eHealth research. J Med Internet Res. 2014;16(2):e36. doi:10.2196/jmir.2925.

Information overload is a widespread concern amongst nearly all clinicians and extends to practitioners delivering CMM.[28,29] Efforts to overcome this barrier require the development of repeatable measures that can identify the amount of time the health care team spends in each of the overload areas (e.g., time spent reading and responding to email, social media, journal review and other non-direct patient care activities) which can all have an impact in the overall quality of the care delivered. These measures are currently available on cell phones and on other computer systems and, therefore, could be applied to workflow barriers in the delivery of CMM. These areas of information overload can then be dissected and further evaluated to reveal opportunities for improvement.

Ensuring the appropriateness of data entered into the EMR is essential for streamlining CMM processes. Inappropriate entry includes data that does not apply to the patient or condition, data that should be entered in structured elements and missing information. Research in this area could result in measures of unstructured data appropriateness and can identify opportunities to automatically populate structured data elements or identify inconsistencies or missing information with unstructured data in real time during dictation. Ultimately, this research will identify better ways to capture and use both structured and unstructured data.[30] The improved accuracy, coding, timeliness and accessibility of unstructured data should reduce fragmented care and errors, improve reimbursement and ultimately better support the delivery of CMM.

Recommendation 12. Measurable criteria need to be identified that differentiate the effectiveness of different eHealth systems.

Recommendation 13. Research should be conducted to identify the degree of information overload encountered by the care team and its impact on the provision of CMM.

Recommendation 14. Through the enhanced capabilities of artificial intelligence, unstructured patient health care data needs to be evaluated to identify inappropriate entry of structured data. This includes incorporating pharmacogenomic and other diagnostic data in discrete forms as a tool to facilitate the CMM process.

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28 Klerings I, Weinhandl AS, Thaler KJ. Information overload in healthcare: too much of a good thing?. *Z Evid Fortbild Qual Gesundhwes.* 2015;109(4-5):285-290. doi:10.1016/j.zefq.2015.06.005.

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