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Medication Therapy Management Services

Definitions and Outcomes

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Abstract

In the US, the Medicare Modernization Act of 2003 required that Medicare Part D insurers provide medication therapy management (MTM) services (MTMS) to selected beneficiaries, with the goals of providing education, improving adherence, or detecting adverse drug events and medication misuse. These broad goals and variety in MTM programmes available make assessment of these programmes difficult. The objectives of this article are to review the definitions of MTMS proposed by various stakeholders, and to summarize and evaluate the outcomes of MTMS consistent with those that may be offered in Medicare Part D or reimbursed by State Medicaid programmes.

MTM programmes are approved by the Centers for Medicare and Medicaid Services (CMS). Pharmacy, medical and insurance organizations have provided guidelines and definitions for MTM programmes, distinguishing them from other types of community pharmacy activities. MTM has been distinguished from disease state management because of the focus on medications and multiple conditions. It differs from patient counselling because it is delivered independent of dispensing and involves collaboration with patients and providers. There is no consensus on the recommended mode of delivery (i.e. face-to-face or by telephone) for MTM.

A MEDLINE search was conducted to identify articles published after 2000 using the search terms 'medication therapy management' and 'medication management'. Studies with outcomes evaluating community-based programmes consistent with MTMS, regardless of MTMS reimbursement source, were included in the review. Seven publications describing four MTMS were identified. For each of the identified articles, we describe the study design, service setting, inclusion criteria and outcomes. An additional three surveys describing multiple MTMS were identified and are summarized. Finally, ongoing efforts by CMS to evaluate the success of MTMS in the US are described.

To date, there are limited outcomes available for MTMS. The wide variety of MTMS offered means that evaluations of individual programmes are necessary. Despite the potential benefits of MTMS, there are numerous challenges to providing MTMS, including reimbursement, justification of the

service and stakeholder acceptance of the services. There remains a need for adequately funded, prospective, controlled studies of MTM programmes using strong designs to advance our knowledge of the effectiveness of various interventions and methods of delivery, and for naturalistic studies assessing the impact of CMS approved MTM programmes.

The concurrent use of multiple medications has been linked to adverse outcomes. The more medications an individual is taking, the higher the risk for inappropriate therapy and adverse events.[1-3] Poor adherence to medications is a common occurrence with fewer than 50% of individuals remaining adherent after 12 months.[4-6] Poor adherence is also associated with poor outcomes and is responsible for an estimated 125 000 deaths per year, 10% of all hospitalizations, 23% of nursing home admissions and $US100 billion in direct and indirect costs.[7,8]

The US Congress approved the Medicare Prescription Drug, Improvement and Modernization Act (MMA) in 2003.[9] The MMA adds a prescription drug benefit, via Medicare Part D, administered by insurers. The MMA also requires insurers provide medication therapy management (MTM) services (MTMS) to a defined subset of beneficiaries to optimize therapeutic outcomes by improving medication use and reducing adverse drug events. The MMA purposely left enrolment criteria and details about MTMS requirements vague to encourage innovation and competition. Oversight for these programmes was entrusted to the Centers for Medicare and Medicaid Services (CMS), with each MTMS requiring approval prior to implementation. As such, there is a mechanism in place for CMS to change the requirements for MTMS approval as evidence on programme costs and effectiveness emerge.[9-11] Given the variety of MTMS that have been developed under Medicare Part D,[12,13] there is a need to revisit the definitions of MTMS and published outcomes of these programmes. The objectives of this article are to review the definitions of MTMS proposed by various stakeholders, and to summarize and evaluate the outcomes of MTMS consistent with those that may be offered Medicare Part D or reimbursed by State Medicaid programmes.

1. Defining Medication Therapy Management Services (MTMS)

The MMA identifies the following three key goals of MTMS: (i) provision of education and counselling to improve enrollees' understanding of their medications; (ii) improvement of medication adherence; and (iii) detection of adverse drug reactions and patterns of improper prescription medication use. These services were to be developed in cooperation with licensed pharmacists and physicians, although the bill did not specify that services needed to be provided by one of these clinicians. The document also disclosed that payment would be provided for these professional services, but did not specify a fee schedule. By allowing clinicians to bill for this service, CMS acknowledged the value of a MTMS clinician's time. It outlined a potential niche for pharmacists as integral members of the healthcare provider team.

As the legislation did not clearly define all MTMS activities, the details of service provision were left to be determined by the insurers. Pharmacy and other healthcare provider organizations have subsequently prepared additional recommendations and guidance for MTMS. For example, 11 national pharmacy organizations developed a consensus definition of MTMS.[14,15] In the consensus definition, MTMS was defined as "a distinct service or group of services that optimize therapeutic outcomes for individual patients [that] are independent of, but can occur in conjunction with, the provision of a drug product". Nine MTM activities and five operational aspects of delivering comprehensive MTMS from a MTMS provider's perspective were included in the definition, outlined in table I. The consensus statement emphasizes the importance of the pharmacist in delivery of the MTMS through identification and prevention

Table I. Definition of medication therapy management (MTM) services (MTMS), as proposed by the Centers for Medicare and Medicaid Service (CMS), and pharmacy and managed care organizations

Group/document	Features of MTMS	Operational aspects of MTMS	Preferred mode of MTMS delivery
CMS (MMA)[9]	1. Provisions of education and counselling to improve enrollee's understanding of their medication 2. Improvement of medication adherence 3. Detection of adverse drug reactions and patterns of improper prescription medication use	NA	Not specified
11 Pharmacy organizations (consensus definition)[15]	1. Performing or obtaining necessary assessments of the patient's health status 2. Formulating a medication treatment plan 3. Selecting, initiating, modifying or administering medication therapy 4. Monitoring and evaluating patient's response to therapy, including safety and effectiveness 5. Performing a comprehensive medication review to identify, resolve and prevent medication-related problems, including adverse drug events 6. Documenting the care delivered and communicating essential information to the patient's other primary care providers 7. Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications 8. Providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens 9. Coordinating and integrating MTMS within the broader healthcare management services being provided to the patient	1. Patient-specific care 2. Face-to-face interaction 3. Routes for identifying patients in need of MTMS 4. Payment based on level of service 5. Process to improve continuity of care, outcomes and outcome measures	Face-to-face
APhA and NACDS (core elements)[16,17]	1. Medication therapy review: identification of all patient's medications, prioritizing medication-related problems and planning issues resolution 2. Personal medication record: complete list of a patient's prescription and non-prescription medications, and herbal products or other dietary supplements 3. Medication action plan: document created in collaboration with the patient and the pharmacist to aid a patient in the proper management of his or her own care 4. Intervention and/or referral 5. Documentation and follow-up	NA	Face-to-face preferred, others acceptable

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Table I. Contd

Group/document	Features of MTMS	Operational aspects of MTMS	Preferred mode of MTMS delivery
AMCP sound MTM programmes[18,19]	1. Patient-centred approach 2. Interdisciplinary, team-based approach 3. Communication 4. Population and individual patient perspective 5. Flexibility for broad application 6. Evidence-based medicine 7. Promotion of MTMS	1. Patient identification and recruitment 2. Services to meet the needs of individual patients 3. Services tailored for setting, cultural differences 4. Coordination of care 5. Appropriate documentation and measurement 6. Quality assurance 7. Communications by the MTM programme 8. Practitioners who can coordinate and provide MTM 9. Adoption of standardized documentation, billing and payment systems	Telephonic preferred (unless evidence supports face-to-face)

AMCP = Academy of Managed Care Pharmacy; **APhA** = American Pharmacists Association; **MMA** = Medicare Prescription Drug, Improvement and Modernization Act; **NA** = not applicable; **NACDS** = National Association of Chain Drug Stores.

of adverse drug reactions, education of patients to improve adherence, documentation of progress and serving as a liaison to a patient's other healthcare providers.

The American Pharmacists Association and the National Association of Chain Drug Stores Foundation developed a framework for providing MTMS in the community setting, building on the 2004 MTM consensus definition.[14,15] This document outlines recommended core elements of MTMS from the community pharmacy perspective, as shown in table I.[16] Compared with the consensus statement, greater detail was provided regarding the rationale and procedures surrounding each core element. An updated version was subsequently published, providing additional insight and updated forms for providing care under the framework.[17]

The Academy of Managed Care Pharmacy (AMCP) also developed a set of MTM programme guidelines based on consensus panel discussions from a group of physician, pharmacist and government organizations.[18] Compared with the pharmacy organizations' consensus guidelines,[14,15] the AMCP guidelines focused on the delivery of MTMS from the insurers' perspective, placing greater emphasis on the need for coordination of care, outcomes assessment, patient identification, promotion of MTMS and use of an interdisciplinary team-based approach. Although the document was generally supportive of services as recommended by the pharmacy organizations' consensus guidelines, an explicit statement was made that not all of these services need to be provided by any one MTMS. A second version of the AMCP MTM programme guidelines was developed following a stakeholders' meeting to determine the acceptability of the initial guidelines by MTM programme administrators and an internet-based survey detailing how the initial consensus document compared with 20 different MTM programmes.[19] The following recommendations updating the original consensus documents were made: (i) the term MTM should apply to all programmes that improve medication management, not just those that meet the Medicare Part D criteria; (ii) MTMS should not be mandated as face-to-face unless adequate

data support this method over other pharmacist-patient interaction; (iii) more specific criteria should be used in the identification and recruitment of patients; and (iv) MTM programmes should measure results across the population of patients as well as individual patients.

The definitions and guidelines established by the above organizations distinguish MTM from the standard care that patients receive in a community pharmacy and from disease state management programmes.[20] In the US, patient counselling (as defined by the Omnibus Budget Reconciliation Act of 1990)[21] requires that pharmacists explain the purpose of a medication, its proper administration, including length of therapy, directions, storage and refill instructions. Patient counselling is provided at the time of medication dispensing with a focus that does not necessarily consider a patient's other medications or conditions. Patient counselling is also typically a one-way communication from the pharmacist to the patient. In contrast, MTM is a much more comprehensive (and time consuming) two-way communication process that occurs independently of medication dispensing. This distinction between patient counselling and MTM is crucial because patient counselling is required by law but is not directly reimbursable, while MTM is not required for all patients and is generally reimbursed.

Disease state management is defined by the Disease Management Association of America as "a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant".[22] These programmes can include physicians, nurses, nutritionists and pharmacists who provide patients with education and tools in order to improve that particular disease. Programmes in practice often meld disease state management and MTMS, which makes categorization and interpretation of outcomes difficult. MTMS are broader in scope than disease state management, in that all of the patient's current medications and medical conditions are considered. Furthermore, the focus of MTMS is on the medications, whereas disease state management may focus on other factors such as foot care, nutrition or exercise.

2. Published Outcomes of MTMS

To describe the outcomes associated with Medicare and Medicaid reimbursable MTMS, we conducted a review of the literature. A MEDLINE search was conducted to identify articles published after 2000 using the search terms 'medication therapy management' and 'medication management'. Studies and service evaluations were included if the service (i) evaluated a programme fitting the description of an MTMS; (ii) was community based; and (iii) was consistent with services delivered under Medicare Part D, or was reimbursed by State Medicaid or other insurance programme. We deliberately excluded disease state management programmes as numerous previous systematic analyses have evaluated these programmes.[23-27] We also excluded programmes that occurred prior to 2000 or those that were conducted in an information-rich academic or clinic setting, atypical of community MTMS offered under Medicare Part D whose services are usually not reimbursed or were developed specifically for research purposes. Many of these services have also been summarized in reviews.[28-32] However, we did include analyses of community-based programmes that were implemented prior to enactment of the MMA and which may be reimbursable under Medicare Part D. For each of the identified articles, we described the study design, service setting, inclusion criteria (for both the service and the analysis where available) and outcomes. These outcomes can be categorized as clinical (adverse events identified and prevented, adherence), economic (medication costs, total cost of care) and humanistic (patient satisfaction and quality of life).[33]

2.1 Clinical, Economic and Humanistic Outcomes of MTMS

Two studies have been published describing the Iowa State Medicaid Pharmaceutical Case Management (PCM) programme.[34,35] Iowa Medicaid enrollees had to be taking at least four chronic medications and have at least 1 of 12 listed chronic conditions. The service consisted of a visit where medication and medical history reviews were

completed. Documentation and drug therapy plans were faxed to the primary physician. Initial visits were followed by periodic (at least quarterly) visits for monitoring, self-management training related to medication taking behaviours and healthy lifestyle reinforcement. MTMS were reimbursed by Iowa State Medicaid.

One report of this MTMS compared the impact of PCM services on medication appropriateness index score with baseline (pre-PCM) and on the use of high-risk medications and healthcare utilization with a cohort of patients who were eligible for, but did not receive PCM services.[34] The medication appropriateness index score decreased from 9.4 (pre-PCM) to 8.3 (post-PCM), with statistically fewer medications deemed inappropriate or ineffective, having an incorrect dosage, posing a drug-disease interaction risk or with an inappropriate duration of use. PCM patients had a significantly greater decrease in the use of high-risk Beers' list medications.[36] Healthcare utilization was not different between PCM and the non-PCM cohort of patients. This study displays several strengths, including a concurrent control of similar patients who were not receiving the PCM and a statistical analysis adjusting for confounding, where present. Limitations of this study include limited evaluation of terminal outcomes, such as adverse drug events and lack of randomization.

A retrospective chart review of a single high-volume pharmacy within the PCM programme was conducted with the objective of describing drug-related issues, associated medications and the actions taken by the collaborative team.[35] During the 2-year follow-up time period, 203 patients had at least one pharmacist visit, 150 of whom had sufficient data collected for inclusion in the analysis. A total of 886 drug-related issues were identified by the study pharmacists and 74.4% (659) were associated with recommendations. The remaining issues, related mainly to adherence, were handled directly by the pharmacist through education or counselling. Respiratory, cardiovascular, analgesic and CNS agents were most commonly associated with drug-related problems. Patterns of drug-related problems varied by drug class. For example, adherence was the biggest issue for respiratory medications, while CNS agents were more often associated with safety issues. Physician acceptance of pharmacist recommendations ranged from 42% to 50%, depending on the type of recommendation. Major limitations of this study were that the impact of the recommendations on patient outcomes was not determined and that only a single community pharmacy participated, limiting external validity.

A prospective, uncontrolled study of patients enrolled in the Senior PHARM*Assist* programme between June 1994 and December 2001 assessed the clinical outcomes of medication therapy management in a senior patient population.[37] The programme was supported by Durham County, North Carolina, USA. In order to qualify for the programme, patients had to be at least 65 years old, reside in Durham County, have a low income and be without insurance coverage for their prescription medications. Patients or their caregivers were seen by programme staff, including a pharmacist, in the programme office or in their home at baseline, 6, 12 and 24 months during the study. The MTMS were comprehensive and included the following: (i) assistance with medication management; (ii) access to a formulary of subsidized medications tailored to the senior patient population; (iii) patient advocacy and education; (iv) coordination of care with other healthcare providers; and (v) regular assessments by pharmacists. During each visit, data on medication knowledge, adherence, health service use, and health and functional status were collected through interviews with the study patient or caregiver. The analysis included 506 of the 794 patients that qualified for the programme and had at least one baseline and one follow-up visit. Patient knowledge of the reasons for their medications increased during the first 6 months with no further increases beyond that period. Knowledge of subsidized medical-related transportation doubled from baseline to 12 months (13% vs 26%, respectively). The use of reminder aids also increased. The number of prescription medications and adherence did not change over time. Emergency room visits and hospitalizations decreased during the first year and self-reported health status improved at the end of the study

period. Functional status remained relatively stable throughout the study period. This study represents one of the most comprehensive reports of a MTMS available. Numerous patient outcomes are reported, including some terminal outcomes. However, the lack of a control group is a major limitation in this study, resulting in an inability to determine if regression to the mean exists (e.g. it is likely that patients would learn about medical transportation or the reasons for taking their medications even if an educational programme were not present) and if time was a potential confounding factor (i.e. the possibility that care for patients improved during the study period resulting in improved outcomes due to factors unrelated to the programme being evaluated). Another limitation is that, assuming the MTM programme was responsible for the observed beneficial outcomes, it is not clear which components of the intervention were responsible for the observed outcomes.

Another study evaluated a North Carolina (USA) State Health Plan employees MTMS consisting of a 'brown bag' session, with the objectives of describing potential drug therapy problems and their resolution, determining drug costs or savings, and assessing patient satisfaction with the service.[38] The study used two adjacent counties in North Carolina to identify potential study and matching control participants, with a third county used to identify a second control population. Both control groups were selected using the initial study enrolment criteria and then the investigators utilized propensity scoring to match control to study patients. Reimbursement rates were set at $US120 for the initial visit (limited to 60 minutes) and $US60 for a one time follow-up visit (limited to 30 minutes). Qualifying patients were identified using prescription claims. The first 130 responders of 1000 patients who utilized the highest number of prescriptions in the first 6 months of 2004 were referred to study pharmacists. During the 'brown-bag' sessions, the study pharmacists performed a comprehensive drug review to identify any potential drug therapy problem and document recommendations for the patient's primary healthcare provider. Either the pharmacist or the patient was allowed to request one follow-up visit to determine if the drug therapy problems were resolved.

Of the 130 patients identified for pharmacist visits, 80 were seen by pharmacists (of whom 67 were evaluable) and 30 had follow-up visits performed either in person or by telephone. The pharmacists detected an average of 3.6 and 4.0 problems per patient in the first and second visits, respectively. Potential under use (70% of patients), treatment with a more cost-effective agent (60% of patients) and treatment with a suboptimal drug (50% of patients) were the most commonly identified problems. The most common recommendations from the pharmacists were to change (45% of patients) or add drug therapy (40% of patients). The pharmacists consulted the patients' physicians regarding the visit about 85% of the time. Patients exposed to the 'brown bag' review were more frequently provided education services. Pharmacists located in medical clinics were more likely to provide education on adherence and behavioural assessments than those in a community setting. Prescription utilization decreased in both control groups but not the intervention group during the 6-month study. Co-payments paid by control patients decreased while study patients had no significant change. The satisfaction survey showed over 80% of patients were satisfied with the amount of time pharmacists spent reviewing their medications, the medication evaluation itself, the quality of information given, the courteousness of the pharmacist, and agreed that the service should continue to be offered. Important limitations of this study include a short duration, limited sample size and a lack of terminal outcomes. Despite these limitations, this study does provide some useful information about an employer-based MTMS and highlights the large number of potential drug therapy problems in patients taking numerous medications.

Another report describes a 1-year prospective naturalistic intervention study with an historical control of MTMS conducted in Blue Cross Blue Shield of Minnesota (USA) beneficiaries managed by Fairview Health Services.[39-41] The practitioners used a systematic process that included assessment of therapy for drug-related problems,

development of a care plan and conducted follow-up visits to monitor outcomes. This process occured in the medical clinics, in collaboration with the patient's primary care physician, and documentation of interventions were made directly in the patient chart. The objectives of this study, as described in three separate reports,[39-41] were to measure clinical (proportion of patients meeting hypertension and hyperlipidaemia goals), economic (total health expenditures) and humanistic (patients' perceptions of care and health-related quality of life) outcomes related to the MTMS. For inclusion in the study, patients had to be at least 18 years old, receiving care at one of the six clinics that were providing MTMS, diagnosed as having 1 or more of 12 study conditions, with two or more health claims related to those 12 study conditions during the study period of November 2000 to April 2001. For most analyses, MTMS patients served as their own controls. Patients were provided the MTMS at no charge.

A total of 2834 patients were recruited through the use of mailers and healthcare provider-based referrals. Patients had to have at least one documented initial visit during the 6-month enrolment period and at least one follow-up visit during the year-long intervention period. In one report, a total of 285 patients received MTMS with 684 pharmacist encounters during the study period.[41] Of the drug therapy problems found, 20% were related to a low dose. Overall, the proportion of patients meeting their therapy goals increased from 76% to 90% in the MTMS group. Of those enrolled for the 2-year period of the analysis (n = 186), the total per person expenditure was decreased by 31.5% from the pre- to post-intervention period. Facilities fees decreased by 57.9%, professional claims decreased by 11.1% and prescription drug costs increased by 19.7% during the intervention period. Total cost of care was significantly decreased by $US3678 per person per year with a return on investment of $US12.15 for every $US1 spent on the MTMS. In a second report of the MTMS, patients perceptions of effectiveness of care trended towards improvement and 12-item Short Form Health Survey version 2 (SF-12v2) physical role, social functioning and physical component summary scales were significantly improved 6 months post MTMS.[39] These reports constitute one of the few published studies that assess clinical, economic and humanistic outcomes related to an MTMS. A major limitation of this study was the lack of a concurrent control group for all outcomes.

Another analysis of the Fairview Clinics System of Minneapolis-St Paul, MTMS was conducted with the goal of evaluating the quality of therapeutic determinations made by pharmacists.[40] A total of 4779 evaluations of MTMS clinical decisions were made by a review panel of eight physicians and four other practitioners. The reviewers agreed or strongly agreed with the MTMS practitioner in 94.2% of the cases, were neutral in 3.6% and disagreed in 2.2%.

2.2 Acceptance and Opinions of MTMS

In 2005, a survey of North Carolina, USA, pharmacy managers was conducted to (i) assess the types of cognitive services currently being offered by and number of patients being served in community pharmacies; (ii) identify the number of pharmacies planning on providing MTMS through the Medicare Part D benefit; and (iii) determine whether the current and anticipated practices meet the potential needs of Medicare Part D enrollees.[42] Of the 1593 pharmacy managers contacted, 262 (16%) provided usable data. A total of 42% of pharmacies provided some type of cognitive services, with 76% of these being a consult- or as-needed-based service and 24% listed as a continuity of care service. Cognitive services were provided to an average of 25 patients per week. The components of existing services offered ranged from basic to comprehensive and included providing verbal education/training to enhance understanding/use of medications, coordinating/integrating services with other healthcare management services, comprehensive medication review, education/support service to increase adherence, and selecting, initiating, modifying and administering medication therapy. Pharmacies with a prescription volume of greater than 200 prescriptions per day were more likely to offer cognitive services.

In 2007, a national survey of 687 respondents from over 6800 contacted pharmacists (10% response rate) evaluated whether MTMS were performed, the perceived costs and benefits of the services, and to identify barriers to providing MTMS from both the provider and payer perspectives.[43] Of completed surveys, 65% performed MTMS, 27% did not perform MTMS, while 8% were unsure if they performed MTMS. For those performing MTMS, 69% reported incurred costs, 18% no incurred costs, while 13% were unsure if any MTMS costs were incurred. A total of 70% of the respondents were unsure if quality indicators were measured, 20% reported collecting general indicators (e.g. patient and professional satisfaction) and 10% reported measuring clinical quality indicators (e.g. glycosylated haemoglobin, blood pressure). The three most documented criteria for performing MTMS were (i) increased professional satisfaction; (ii) increased quality of care; and (iii) increased patient satisfaction. Respondents not providing MTMS identified inadequate time, insufficient staffing, high dispensing workload and difficult billing procedures as the four main barriers to providing MTMS. In a second survey conducted, a perceived lack of need from patients and lack of physician acceptance were identified as barriers encountered to the provision of MTMS from the payer (insurer) perspective.[44]

3. Efforts to Assess MTMS Quality by the Centers for Medicare and Medicaid Services

Since 2006, Medicare Part D MTM programmes have been required to submit annual reports to CMS including MTM programme enrolment methods, numbers meeting enrolment criteria, number of participant beneficiaries, numbers who declined participation or disenrolled, and the number of monthly medications and total monthly prescription cost for MTM programme enrollees.[45,46] For 2008, CMS added patient identifiers to the reporting requirements. By adding patient identifiers, medical data from the patient's Medicare medical coverage can be linked to their Medicare Part D drug coverage, potentially allowing for analysis of outcomes.[45] In May 2008, Medicare Part D data collected after 1 January 2006 was approved for use in research.[10] However, the initial release of the dataset is not expected to contain information specific to MTM programmes.

In response to the call for measurement of outcomes related to pharmacy performance related to Medicare Part D, the Pharmacy Quality Alliance (PQA) was formed.[46] The mission of the PQA is to (i) improve healthcare quality and patient safety through a collaborative process in which key stakeholders agree on a strategy for measuring performance at the pharmacy and pharmacist levels; (ii) collect data in the least burdensome way; and (iii) report meaningful information, to help make informed choices, improve outcomes and stimulate the development of new payment models. Items evaluated for inclusion in the assessment tools of the PQA are as follows: percentage of patients qualified for MTM that receive the service; percentage of patients/caregivers who receive a comprehensive medication review as part of their MTMS; percentage of beneficiaries identified as being eligible for MTM that opt in or do not opt out; percentage of patients/caregivers receiving MTM that report increased knowledge or improved understanding of their medication therapy and related medication conditions; and percentage of patients receiving MTM where presence of a personal medication list is documented. These measures continue to be refined and tested.[47]

The validity and usability of these measures are being tested in two phases. PQA has created five phase I projects with the overall goal to involve payers and providers in testing new models for data aggregation, report generation and quality improvement related to pharmacy services and the utilization of medications.[48] In 2009, phase II is planned, focusing on the use of performance reports in stimulating improvement in the quality and value of care. It is believed that pay-for-performance programmes in ambulatory and community pharmacy may eventually be developed using these performance measures.[48] The PQA has also allocated funds to develop educational programmes for quality measurement

and improvement, but additional information is currently not published.[49]

4. Discussion

Appropriate medication usage by patients in the community setting continues to be a major problem in the US and elsewhere.[50-55] Despite the potential benefits of MTMS, there are numerous challenges facing community programmes designed to improve medication usage. Among those challenges, the following three related, pressing and intertwined issues rise to the top: (i) reimbursement; (ii) evidence-based justification; and (iii) stakeholder acceptance of the services. Although not unique to programmes in the US, variation in healthcare delivery and policy in other countries create different opportunities and challenges. While a discussion of how MTMS applies to countries other than the US is beyond the scope of this article, an excellent series on healthcare policies related to pharmaceutical care in a number of countries is available.[56-69]

In the US, reimbursement has traditionally been associated with provision of a medication or procedure with cognitive services seldom having been covered. Reimbursement for community services such as MTMS started with State Medicaid demonstration programmes[34,40] and employer-based disease state management programmes.[70] The passage of the MMA has created opportunities nationally for community pharmacists and other clinicians to be reimbursed for cognitive services. However, there is little consistency in covered MTMS or how those services are delivered. Programmes offered by insurers through Medicare Part D vary considerably.[12,13] The wide variety of MTMS currently offered by insurers makes it difficult for community pharmacies and pharmacists to become actively involved. Since reimbursement usually depends on delivering a specific type of intervention, familiarity and contracting with multiple insurers' MTMS is necessary (since a pharmacy's patients are beneficiaries of numerous insurers). Another confusing reimbursement issue is the preferred delivery method of MTMS. Telephone-based methods appear to be preferred by AMCP,[19] while pharmacy organizations strongly support face-to-face delivery of MTMS using community and/or clinic pharmacists.[14,17] Recently, billing codes were approved for cognitive pharmacist services delivered face-to-face (but not via telephone).[71] The establishment of these codes could facilitate the provision of face-to-face MTMS by encouraging pharmacists to bill for services and increase the likelihood of receiving reimbursement from payers.[72,73] However, many insurers currently offer mailed information and telephone-based MTMS, and not face-to-face.[12,13,44]

Evidence for the value of individual MTMS is limited and comparisons between different MTMS are non-existent. However, a number of clinic-based studies support the impact of polypharmacy services in information-rich academic settings.[28-32] In the community setting, there is some support for face-to-face MTMS, as detailed in this review. Interestingly, there is little evidence supporting the effectiveness for mailed information or telephone-based MTMS. No published studies were identified that described or supported the use of mailed information. In other reviews, mailed information appears to have a minor impact on some factors and no effect on outcomes.[74] Only one description of a telephone-based MTMS was found in our review but outcomes were not included in the report.[75] Telephone-based interventions have had mixed results in other areas of healthcare.[76] It is likely that mailed information, telephone-based and face-to-face MTMS all play an important role for certain individuals and in certain settings; however, elucidation of relevant factors for the use of each requires considerable further research.

Acceptance of MTMS by stakeholders (namely patients, physicians, pharmacists, insurers and community pharmacy owners) is crucial for the success of these programmes. Each stakeholder presents a different set of challenges for the long-term success of community MTMS. Personal experience from our own MTM research programme,[77] MTMS,[78] AMCP[19] and publications identified in this review have pointed to identification and engagement of patients as key issues. Algorithms have been used to identify patients with high resource utilization,[79] but research is

needed to identify factors that respond best to certain types of MTMS to further refine the efficient selection and triaging of patients to appropriate services. After patients have been identified, engaging the patient and enlisting his or her participation is crucial. Low participation rates by patients are common, especially with more intensive programmes that require more patient time and participation.[44,75] Some community disease state management programmes have utilized patient payment or pay-for-performance as a way of engaging patients. In our experience, MTMS patients are difficult to engage initially, but those who do choose to participate are often satisfied with the service and are willing to return; patients must perceive value for their time spent. As patients become more familiar with MTMS through word of mouth, advertising and their physicians, it is likely that early engagement will become easier. For certain patients (poor physical health, poor ambulation, decreased cognition), access to care will continue to remain an issue regardless of engagement. Telephone-based MTMS or home visits by practitioners may be effective alternatives in these situations, but require further research.

Physician acceptance of MTMS is important for, among other things, identification of eligible patients and acceptance of MTMS clinician recommendations.[19,44] Despite evidence that pharmacists provide useful advice in MTMS patients,[40] physician acceptance rates of pharmacist recommendations are often low at around 50%.[35,38] More research is needed to identify MTMS factors perceived by physicians as being useful in the care of their patients. Once these factors have been solicited, insurers and other MTMS providers should consider physician opinions when developing their programmes and attempt to engage physicians to encourage their eligible patients' participation in those MTMS.

Acceptance of MTMS by pharmacists and pharmacies continues to increase. However, numerous barriers to the delivery of care have been identified, including inadequate time, insufficient staffing, high dispensing workload and difficult billing.[44,75,80] Pharmacists are generally confident about their ability to provide MTMS.[80] Competition for limited pharmacists time between dispensing and MTMS is a major determinant of the availability of programmes in the community setting. Because MTMS sustainability depends on profit (reimbursement minus cost to provide service), provision of MTMS by community pharmacies will become widespread when reimbursement is perceived to be sufficient to consider replacing current dispensing practices. Similarly, acceptance and programme design of MTMS by insurers depends on the potential for profit or perceived value. The economic evaluation of MTMS is complicated by the wide variety of available programmes and uncertainty surrounding clinical benefits.

5. Conclusions

In business, it is common and often necessary to make decisions in the absence of quality information to maintain market competitiveness. In healthcare, with the movement towards evidence-based medicine, the trend is towards waiting for detailed factual evidence before decisions are made to prevent harm from occurring. In the case of MTMS, the clash of these two ideologies, and other reimbursement and policy-related factors has resulted in the adoption of a competitive, proprietary system for MTMS. Unfortunately, published evaluations of programmes have been limited as a result of the proprietary nature. Moreover, delivery and evaluation of MTMS is complicated by a lack of uniformity in the services. Continued efforts are needed to standardize definitions and to evaluate novel methods of improving medication usage in the community setting.

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