

T.R.N.C

**NEAR EAST UNIVERSITY
INSTITUTE OF HEALTH SCIENCES**

Medication Therapy Management (MTM)

**A GRADUATION PROJECT SUBMITTED TO THE GRADUATE
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BY:

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**In Partial Fulfillment of the Requirements for the Degree of
Master of Science in Clinical Pharmacy**

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Master of Science in Clinical pharmacy

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NICOSIA 2017

DEDICATION

I dedicate this thesis to my great parents, supportive sisters, brother
and all of my family and all friends for their endless love and support

Especially for my father, SafwatAyash who provided unflagging patience and support, to the
best pharmacist in the world who believe on me and make all my dreams come true Dr.

WafaaAyash my mother.

Approval

This thesis submitted to the Institute of Health Sciences of Near East University in partial fulfillment of the requirements for the degree of **Master of Science in Clinical Pharmacy**.

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“In the name of Allah, the Most Gracious, the Most Merciful”

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Abstract

Background: Medication therapy Management (MTM) and Comprehensive Medication Review (CMR) have been shown effective in reducing inappropriate medication use, adverse events due to drug-drug interactions, and medication nonadherence. Pharmacist review of a patient's medication regimen, including indications for the medications, adverse event profile, and pharmacokinetic and pharmacodynamic properties, may identify ineffective and/or harmful drugs and drug combinations that can be changed and lead to improved health outcomes.

Objective: our main aim is to understand the medication therapy management and review it using the trials performed recently.

Methods: utilize PubMed, a search engine service of the National Center for Biotechnology Information (NCBI), using the following set of keywords: Medication therapy management, Medication therapy management background, MTM core elements, randomized controlled trials on medication therapy management. And outcomes are written by picking up the randomized recent date trials performed.

Results: most of the trials lead to economic outcome, some as well important in healthcare benefit. Quality measures such as adherence and prescription habit shown significant growth. Thus, MTM proved to be significant in decreasing cost of drug and re-admission as well as improving health.

OZET

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List of Abbreviations

S/No.	Abbreviations	Meaning
1.	MTM	Medication Therapy Management
2.	CMR	Comprehensive Medication Review
3.	NCBI	National Center for Biotechnology Information
4.	OTC	Over The Counter
5.	MMA	Medicare Prescription Drug, Improvement, and Modernization Act
6.	MTMPs	Medication Therapy Management Programs
7.	CMS	Medicare & Medicaid Services
8.	MTR	Medication Therapy Review
9.	PMR	Personal Medication Record
10.	MAP	Medication-Related Action Plan
11.	DRPs	Drug Related Problems
12.	CRCT	Cluster Randomized Controlled Trial
13.	G	Group
14.	Med	Medicine
15.	m/f	Male/female
16.	CTRL	Controlled
17.	ED	Emergency Department
18.	Pts	Patients
19.	MPR	Medication Possession Ratio

20.	ROI	Return On Investment
21.	MAI	Medication Appropriateness Index
22.	d\c	discharge counseling
23.	OR	Odd Ratio
24.	CVD	Cardiovascular Disease
25.	SD	Standard Deviation
26.	BL	Baseline

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Chapter 1: Introduction

1.1 Medication Therapy Management MTM

MTM definition developed depend on Eleven national pharmacy organizations as “a service or group of services provided by pharmacist or other health team in order to optimize therapeutic outcomes for individual patients that are independent of, but can occur in combination with, the provision of drug product.” (Burns, Anne.2008).

In order to each patient’s medications (include: prescription, OTC, alternative, vitamins and supplements) are individually assessed to determine if each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, affordable and able to be taken by patient as intended (Burns, Anne.2008).

By using appropriately, medications can improve controlling symptoms, prevent many acute and chronic illnesses, and improve patient’s health. However, In the United States, there are more than 1.5 million medication-related adverse events occur each year, accounting for an excess of 177\$ billion in terms of medication-related morbidity and mortality. This is because of patients with multiple chronic conditions, high drug cost, diverse therapeutic values and side effect of drugs on each other doses (www.cms.gov, Accessed October 18, 2014).

1.2 MTM services include:

- Educating and counselling to patients.
- Performing a comprehensive medication review for prescription and nonprescription medications.

- Detect adverse drug events and any medication misuses.
- MTM provides outpatient prescription drug insurance to disabled and older adult.
- Formulating a medication treatment plan (Burns, Anne.2008).

1.3 Background on MTM Programs

The federal government in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was officially recognized Medication therapy management (MTM) in 2003, which requires Medicare Part D plans that offer prescription drug coverage to establish MTM programs (MTMPs) for eligible beneficiaries especially to old patients (over 65 age) or who with disability. Although the term Medication Therapy Management “MTM” was introduced with the Medicare in 2003, pharmacists have previously developed and implemented similar programs called “pharmaceutical care.” (www.cms.gov, Accessed October 18, 2014). Whereas MTM in the MMA 2003 is specific to patients with Part D enrollees which part of health insurance, pharmaceutical care can be provided to anyone. MTM provided to Part D patients is a logical extension of the provision of pharmaceutical care services to diverse groups of patients, which has been performed by pharmacists for many years. Programs of this kind represent the pharmacy profession’s shift from a product focused to patient-centered practice (www.gpo.gov, October 18, 2014).

But according to the Centers for Medicare & Medicaid Services (CMS) guidelines in 2009, the individual that is eligible to gain the MTM services should have following three criteria

- Have multiple chronic condition (Diabetes, Heart Failure, Dyslipidemia Respiratory Diseases, Hypertension, Mental Health, renal and Bone Disease).
- Use multiple covered drugs.
- Be likely to incur \$4,000 or more in annual Part D drug costs. (Burns, Anne.2008).

1.4 The next question is how MTM works?

The patient comes to the pharmacist along with the number of prescriptions and the pharmacist makes changes in the medication to save money or in other terms they make changes to overcome the adverse drug events. Then they evaluate the effectiveness of the program. If the plan works, stick to it and educate the patient about the drugs (adverse side effect/ effectiveness). (Burns, Anne.2008).

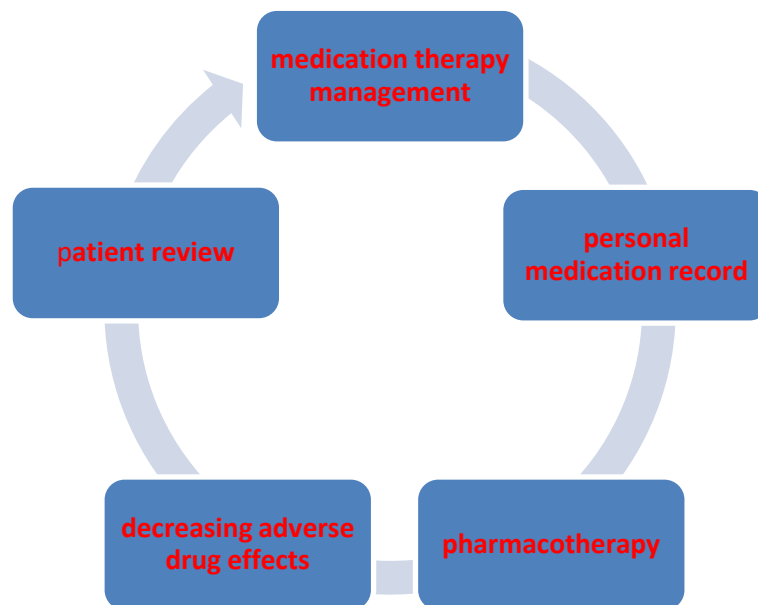


Figure1: Medication Therapy Services

1.5 Core elements of MTMs

There are five core elements of MTM:

1. Medication Therapy Review (MTR).
2. Personal Medication Record (PMR).
3. Medication-Related Action Plan (MAP).
4. Intervention and Referral.
5. Documentation and Follow-up. (Burns, Anne.2008).

1.5.1 Medication Therapy Review (MTR)

The medication therapy review (MTR) involves systematic collection of the patient's drug therapies information to identify Drug Related Problems (DRPs) and inappropriate medication utilization patterns. In addition, MTR involves determining DRPs and patterns that should be targeted for intervention together with developing a care plan to address them. (Burns, Anne.2008).

The MTR can be comprehensive or targeted to an actual or potential medication-related problem. In a comprehensive MTR, the patient brings all current medications to the pharmacist, including all prescription and nonprescription medications in order to review it and determine efficacy and safety. Targeted MTRs are used to address an actual or potential medication-related problem. (Amy L.2014).

1.5.2 Personal Medication Record (PMR)

This is the patient-specific record of all the patient’s current prescription and non-prescription drugs that is created by the MTM pharmacist through interaction effective communication with the patient. (Burns, Anne.2008).

MY MEDICATION RECORD										
Name: _____ Birth date: _____								LOGO		
Include all of your medications on this record: prescription medications, nonprescription medications, herbal products, and other dietary supplements. Always carry your medication record with you and show it to all your doctors, pharmacists, and other healthcare providers.										
Drug		Take for...	When do I take it?				Start Date	Stop Date	Doctor	Special Instructions
Name	Dose		Morning	Noon	Evening	Bedtime				
<i>Glyburide</i>	<i>5mg</i>	<i>Diabetes</i>	<i>1</i>		<i>1</i>		<i>1/15/08</i>		<i>Johnson (000-0000)</i>	<i>Take with food</i>

This sample personal medical record (PMR) is provided only for general informational purposes and does not constitute professional healthcare advice or treatment. The patient (or other user) should not, under any circumstances, solely rely on, or act on the basis of, the PMR or the information therein. If he or she does so, then he or she does so at his or her own risk. While intended to serve as a communication aid between patient (or other user) and healthcare provider, the PMR is not a substitute for obtaining professional healthcare advice or treatment. This PMR may not be appropriate for all patients (or other users). The National Association of Chain Drug Stores Foundation and the American Pharmacists Association assume no responsibility for the accuracy, currentness, or completeness of any information provided or recorded herein.

Figure2: Sample Personal Medication Record

1.5.3 Medication-Related Action Plan (MAP)

This is a patient-specific document that identifies the series of actions that should be taken by the MTM pharmacist in order to resolve DRPs via interventions and to track the status of each DRP's resolution. (Burns, Anne.2008).

MY MEDICATION-RELATED ACTION PLAN	
Patient:	
Doctor (Phone):	
Pharmacy/Pharmacist (Phone):	
Date Prepared:	
<p>The list below has important action steps to help you get the most from your medications. Follow the checklist to help you work with your pharmacist and doctor to manage your medications AND make notes of your actions next to each item on your list.</p>	
Action Steps → What I need to do...	Notes → What I did and when I did it...
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
My next appointment with my pharmacist is on: _____ (date) at _____ <input type="checkbox"/> AM <input type="checkbox"/> PM	

Figure3: Sample Medication _Related Action Plan

1.5.4 Intervention/Referral

This is referring to that; the MTM pharmacist provides recommendations for enhancing therapeutic care, preventing DRPs and provides some information related to patient condition and the treatment.

Pharmacist work together with physician in effect, an MTM pharmacist can use his/her clinical training to directly intervene by changing a drug, adjusting the dose of a drug, removing a drug from the medication list. The intervention done by pharmacist if feels that there needed to make some suggestions, he/she can refer the patient to other healthcare professionals for further evaluation and intervention as well. (Burns, Anne.2008).

1.5.5 Follow-up/Documentation

This is a vital and ongoing step of MTM services where the medication action plan (MAP) and their targeted outcomes are consistently documented for regular follow-up visits with the patient, and make it easy for pharmacist and physician to reach for patient data. (Burns, Anne.2008).

1.6 Benefits of MTM Program

Pharmacist or other health teams who can help manage these medication regimens contribute to both the well-being and safety of the patient. Heath care team who offer MTM services benefit both in efficiency and in savings. They also create a work environment that encourages wellness for all. Advantages include:

- Enhanced patient adherence and utilization of medications.
- Increased percentage of patients meeting their treatment goals (e.g., blood pressure, blood glucose, cholesterol).

- Reduced drug duplication, harmful side effects, or interactions between medications, vitamins, and supplements.
- Medication cost savings, and medical resource cost savings (e.g., fewer emergency department visits), due to more effective use of drug therapy.
- Decrease drug cost
- It reduces clinical risks. (Burns, Anne.2008).

1.7 Uniqueness of MTM from other related services

- Various pharmacy, medical, and insurance organizations have provide the basic differences between MTM and other services.
- MTM programs differ from disease state management in their focus on medications and multiple conditions.
- MTM programs also differ from patient counseling because of the emphasis on collaboration with patients and providers, which is conducted independently of dispensing.
- MTM focus in encourage patients to take an active role in managing their medications.

Medication therapy management allow the pharmacist to engages in a wide range set of activities that include: education and counseling about disease and medications, detection and prevention of adverse drug reactions/drug related problems (DRPs) and patterns of improper prescription medication use and active participation efforts in improving medication adherence. And help in breaking the traditional view of pharmacists as drug dispensers whose major duty is to count and dispense medications to patients according to a prescription. (Amy L.2014).

Chapter 2. Methodology

2.1 Setting

This project assesses the effectiveness of MTM on patient, MTM outcomes identify intervention features and the effect of an intervention on outcomes; and assess harms associated with interventions

To identify articles relevant to our project, we began with a focused Utilize PubMed, a search engine service of the National Center for Biotechnology Information (NCBI), search for MTM interventions using a combinations of medical subject headings and title following set of keywords: Medication therapy management, Medication therapy management background, MTM core elements, randomized controlled trials on medication therapy management.

Additional searches were conducted for key articles in recent reviews. And outcomes are written by picking up the randomized recent date trials performed. We identified full text copies of published articles that related to MTM intervention and its outcomes, and limiting the search to English-language and human-only studies.

2.2 Inclusion/Exclusion Criteria

We specified our inclusion and exclusion criteria based on the population, intervention, outcome, timing. Our literature search results through the last 10 years, for old population and with multiple disease who can enrolment in MTM program.

We excluded studies published in languages other than English. We excluded study designs without control groups to ensure that all of included studies can inform the causal link between the intervention and outcomes.

Chapter 3. Outcomes:

We provide a summary of results of newest trails done to asses MTM intervention and its outcomes.

Table 1: trials about medication therapy management

Authors, Publication Year, Reference Number	Type	Patients/Subjects	Interventions	Outcomes
Sarangarm et al., 2013 ⁹	Cluster Randomized Controlled Trial(CRCT)	Internal med. Patients Aged > 18years. Assigned 6 teams from new Mexico hospital to G1(n= 140, 53.6\46.4% m\f) and CTRL(n= 139, 58.3\41.7% m\f). Baseline BL 30 days Post-discharge.	G1 = discharged/c counseling by pharmacist, usual care, follow up phone call from pharmacist; CTRL = usual care.	20.7% of patients had readmission or ED visit within 30 days of d/c, no difference between groups (p > 0.05); G1 higher Pt. satisfaction; mean summative scores were 40.4 (CTRL) and 43.1(G1)out of 45 (P < 0.0001); G1 Greater med. adherence (58.5% Vs. 75.7%, P = 0.05).

<p>Moore et al., 2013⁷</p>	<p>Pre-post retrospective intervention /matched control study</p>	<p>Adult pts. With ≥ 14 claims over 120- day period. Participation voluntary; G1 (n = 2,260); CTRL (n = 6,463). 1 yr. pre, 1 yr. post.</p>	<p>G1 = MTM program, 3+ consults with clinical pharmacist; CTRL = declined program, usual care.</p>	<p>G1 reduced plan-paid health care costs by 10.3% or \$977 vs. CTRL increase of 0.7% or \$62 ($P = 0.048$); G1 vs. CTRL decreased hospital visits (18.6% vs. 24.2%, $P < 0.001$); G1 average days' supply increased of MTM 72.7; CTRL decreased by 111.1 days ($P < 0.001$). G1 pts. with HTN and dyslipidemia had pre-post increases in MPR of 2.29% and 2.10% vs. decreases of 2.31% and 2.61% (both $P < 0.001$) for CTRL</p>
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Wittayanukorn et al., 2013 ¹⁰	2 pre-post Retrospective cohort study	Beneficiaries diagnosis with CVD conditions and enrolled in public university sponsored insurance plan, 2008-2010. Matched groups design; G1 (61.9/38.1% m/f, age 58.3 ± 9.3); CTRL(61.3/38.7% m/f, age 56.9 ± 9.6).	G1 (n = 63): MTM services; CTRL n = 62): (comparison group, no MTM services.	G1 had statistically significantly lower costs/pt. for Pharmacy: (difference of -31.9 ± 25.1, <i>P</i> < 0.0001), medical: (difference of - \$325.6 ± 271.2, <i>P</i> < 0.0001), and total direct expenditures (difference of - \$359.3 ± 219.2, <i>P</i> < 0.0001); return on investment (ROI) was \$1.67 per \$1 in MTM cost.
Hui et al., 2014 ⁵	Retrospective cohort study	Pts. of California health care delivery system; Rx ≥ 2 Medicare Part D meds., diagnosis ≥ 2 chronic conditions. Participation voluntary; G1 (age 74.8±7.9/42.5/57.5% m/f); matched group =CTRL (age 74.8±7.9., 42.5/57.5% m/f). baseline 1 yr.	G1 (n = 34,532): MTM services; CTRL(138,128): no MTM services.	G1 vs. CTRL: significantly reduced mortality (hazard ratio HR = 0.86, 95% CI = 0.84-0.88; <i>P</i> < 0.001), reduced odds for hospital admin. (OR = 0.97, 95% CI = 0.94-0.99; <i>P</i> = 0.018), higher odds for ED visits (OR = 1.17, 95% CI = 1.14-

				1.20; $P < 0.001$), and no difference in change in daily med. costs.
Rose et al,215 ⁸	Cluster Randomized Controlled Trial(CRCT)	162 patients were enrolled in the study; 142 were included in The intention-to-treat analysis(53.3% women, mean age76.8 ± 6.3 years)	MTM performed, which involved the collection of information on the drugs each patient took evaluated over a period of 15 months Follow up each 3 months as assessed with the Medication Appropriateness Index (MAI)	The mean total Medication Appropriateness Index (MAI)score decreased significantly ($p \leq 0.001$ from the control phase (29.21, 95% CI [26.09 ; 32.33]) to the intervention phase (22.27 [19.00; 25.54]), The number of drug-related problems declined as well.

3.1 Summary of trails

1. Case control study at the University of New Mexico Hospital evaluated the impact of pharmacist medication counseling and disease education at discharge. Control patients received usual hospital discharge care; intervention patients received usual care with discharge counseling from pharmacist who provided information about proper medication administration, side effects, disease state education and a follow-up phone call. In all, 279 patients were enrolled: 139 in the control and 140 in the intervention group. Pharmacists made 198 interventions. The rate of hospital reutilization within 30-days of discharge was 20.7% and similar between the intervention and control groups.

Patients receiving the pharmacist intervention demonstrated improved primary medication adherence and increased patient satisfaction. Patient satisfaction in a survey: 40.4 (control) versus 43.1 (intervention) out of a possible 45 ($P < 0.0001$) (Sarangram et al. 2013).

2. Retrospective match-paired controlled study assessed the impact of MTM on plan-paid health care costs, utilization of medical services, overall days' supply of targeted medications, and medication possession ratios (MPRs). They evaluated 2,250 patients receiving interventions matched to 2,250 patients without interventions through propensity score matching. Over the 12-months period of this study the MTM group reduced hospitalization by 15%, compared with an increase in the control group by 7.6% ($P < 0.001$). There were no significant differences in the similar changes in ED visits between the 2 groups. However, the findings showed that the MTM group significantly improved its medication adherence, as measured with medication possession ratios (MPRs). MPR mean in the MTM group for hypertension was (2.29%) and for dyslipidemia (2.10%) that show increased in adherent for MTM group, whereas it decreased in the control group for these conditions (2.31% and 2.61%, respectively, $P < 0.001$). An average post-period reduction in total health care plan-paid costs of \$977, compared with the control group's increase of \$62 ($P = 0.048$). The total health care savings per patient due to program impact was estimated to be \$977, with program costs per patient of \$478, yielding a return on investment (ROI) of 2.0 in 2009 (Moore et al. 2013).
3. Small-scale pre-post cohort study to compare economic outcomes MTM services ($n = 63$, mean age 56.8) with that of non-MTM usual care ($n = 63$, mean age 56.9) for patients with cardiovascular disease (CVD). The MTM group received MTM services at a pharmacist-provided pharmaceutical care center on a university campus via face-to-face consultation for 30-60 minutes per encounter. At the 6-month follow-up, results of chi-square tests showed that the MTM group saved costs, as indicated in the mean costs (SD) for CVD-related pharmacy, all-cause medical, and total expenditures by \$22 (19.1), \$79.2 (99.6), and \$75.1 (136.2), respectively. However, those indices increased in the non-

MTM group by \$10.7 (24.2), \$24 (6.4), and \$289 (269.5), respectively. The MTM group had significantly lower expenditure per patients for all 3 measures ($P < 0.0001$). The ROI was \$1.67 per \$1 in MTM cost (Wittayanukorn et al.2013).

4. Retrospective cohort study assessed the impact of a MTM program in a large integrated health plan on patient mortality, hospitalization and emergency department (ED) utilization, and daily prescription costs. Statistics included 34,532 study members (given MTMs) and 138,128 control patients. The MTM group was found to have a significantly reduced mortality (hazard ratio 0.86, 95% confidence interval [CI], 0.84-0.88; $P < .001$), lower odds for hospitalization (odds ratio [OR] = 0.97, 95% CI, 0.94-0.99; $P = .018$), higher odds for emergency department visits (OR = 1.17, 95% CI, 1.14-1.20; $P < .001$), and no differences in change in daily medication costs when compared to the matched group (Recently Hui et al. 2014).
5. Cluster-randomized controlled trial demonstrated the effective use of MTM in multimorbid patients by using interventions included drug analysis. The evaluation is based upon improvement in drug therapy through drug related events. In the study quality of medication therapy measured by 12 primary care physicians PCP collaborative with pharmacist at baseline (BL), 3month post BL, 6 month post BL, for 3 groups (cohort1: n=59, cohort2: n=40, cohort3 n=43) by assessments with the Medication Appropriateness Index (MAI): indication, effectiveness, dose, correct directions, practical directions, drug-drug interactions, drug-disease interactions, duplication, duration and cost.

3.5.1 Inclusion criteria: Age ≥ 65 years ,a minimum of three chronic disorders affecting two different organ systems , at least one cardiovascular disease , at least one visit to the PCP in each of the preceding three-month intervals, five or more long-term drug treatments (>3 months) with systemic effects and ability to complete questionnaires, with assistance if required.

The mean age of the 142patients was 76.7 ± 6.5 years, and the collective included 76 (53.5%) women. The difference in scores between the control period and the first intervention period reached significance with a mean of -4.51 units (95% confidence interval $[-6.66; -2.36]$, $P < 0.001$. The number of drug-related problems dropped (-0.45 , $[-0.81; -0.09]$; $P = 0.014$ and up to 60% of drug-related problems were solved.

The study showed a statistically significant effect of the intervention on the quality of medication therapy; the number of drug-related problems decreased as well. Both aspects are regarded as indicators in medication safety (Rose et al. 2015).

It is strongly believed that the future of optimizing a patient's therapy as well as reducing patient's drug risks can only be provided by a collaborative health care team consisting of different professions.

Chapter.4. Conclusion

Although we found the evidence insufficient in order to give definitive conclusions about the effectiveness of MTM for most outcomes that we evaluated, our findings do suggest some implications for practice and policy. MTM is already in widespread practice and is now shaped in the United States largely by Medicare Part D policy: this presents both challenges and opportunities. MTM programs of the future, sponsored and administered by Part D drug benefit plans, may be less integrated into routine health care for Medicare beneficiaries than many of the pharmaceutical care interventions included in our review. We were unable to answer definitively whether level of integration matters for effectiveness, but may need to consider expectations about the impact that MTM might have on patient-centered outcomes and resource use in the context of other health care delivery transformation activities or quality improvement initiatives that are also occurring. More integration of MTM services with other activities may be effective; however, the more integrated MTM becomes within routine medical care, the more difficult it becomes to isolate it as a discrete intervention for evaluation.

Medication therapy management is an only one of its kind for the pharmacy profession, allowing pharmacists to apply their extensive medication knowledge as medication experts with the intent of improving patient outcomes. MTM proves throughout to be a promising approach that helps patients in improving their health, reducing drug cost, minimizing adverse effects of drugs. Its role expanded with the passage of Medicare Part D. and it's been proving important role in combating multiple chronic conditions in an aging society.

In other hand, MTM evaluation remain need more research to emphasis on patient-centered health outcome evaluation. More trial need to show not just the impact of MTM services on economic and clinical outcomes but also for humanistic outcomes as improved patient quality of life.

Future training of MTM providers would benefit from a better understanding of which MTM components really matter.

Finally, considering both patients and prescribers in future design and delivery of MTM services may be needed. In our current framework, MTM interventions require a significant element of engagement by both patients and prescribers if the interventions are to have a reasonable likelihood of improving outcomes. For more engaged in the intervention between patients and prescribers a amount of time may be the key to translating the potential of MTM interventions into actual improvements and to have a good outcomes.

4.1 Limitations

Several challenges in the literature exist, as were also noted by previous authors.

- Lack of Outcome information for major MTM programs. This is primarily because public use Part D data do not include the MTM program-specific information. Therefore, researchers have no access to data on the structure of MTM programs or to the populations that received MTM intervention.
- The main limitation for this project was the timing and duration of implementation of services. Because the short duration of the project led to limited data on sustainability of services for each pharmacy setting and long-term effects on adherence rates (www.cms.gov, Accessed October 18, 2014).
- Omission of training expenses for implementation of MTM services in the financial analysis. This type of expenditure would vary greatly between pharmacies depending on baseline experience and knowledge of the staff and was therefore difficult to estimate in this study.

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