Title: Evaluation of Data Collection Software for Medication Therapy Management in the Community Pharmacy Setting

Principal Investigator: Ronald DeVizia, Pharm.D.

Investigators: Debra Pruss Pharm.D., Stefanie Ferreri Pharm.D., CDE, Joe Heidrick Pharm.D., Melissa Finch Pharm.D., Beverly Lingerfeldt RPh, Dianne Higgins Pharm.D., Kasey Grifith Pharm.D., Amanda Downs Pharm.D, Lori Brown Pharm. D., Daniel Forester, Pharm.D., Gretchen Jenkins, Pharm.D., Jennifer Hopson Pharm.D., Angie Giles Pharm.D., Dana Arrington Pharm.D. Julie Langley, Pharm.D.

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Background

Regardless of one's experiences within the healthcare system, one fundamental fact that none of us can escape is that we have a healthcare system that is broken in regard to medication safety and drug-related morbidity and mortality. The Institute of Medicine has reported this to Congress and to the public in two seminal reports, "To Err is Human: Building a Safer Health System", and "Crossing the Quality Chasm: A New Health System for the 21st Century ". [1,2] Despite our awareness as a country, there have been no mandates around medication safety. The reality is that, on an annual basis in the U.S., we spend more money repairing the problems caused by improper use of medications than we do on the actual medications. Though difficult to fathom, should we really expect any other result when we as a country fail to recognize and fully engage our nation's drug therapy experts as healthcare providers? We will not realize different outcomes unless we all work together to do things differently.

What is the solution... In 2003, the Medicare Modernization Act established Medicare Part D, and this benefit includes a provision that requires all Part D plans to have a Medication Therapy Management (MTM) program.[3] The MTM provision of the Medicare Law describes beneficiaries who will be eligible to have MTM services (MTMS) covered by Medicare Part D. Although, the language of the law did describe potential elements of the MTM program, it did not define MTMS. The Centers for Medicare and Medicaid Services, which developed the final regulations for implementing the Medicare Modernization Act of 2003, provided little guidance for the structure of MTMS.

Building on the definition described by the Medicare Law, eleven national pharmacy organizations achieved consensus of a definition of MTM in July 2004. These organizations defined MTM as being "a distinct service group of services that optimize therapeutic outcomes for individual patients".[4] Building on the consensus definition, the American Pharmacists Association (APhA) and the National Association of Chain Drug Store (NACDS) Foundation have developed a model framework for implementing effective MTMS in the community pharmacy setting. Although the adoption of this model is voluntary, CMS, other payers, and many others in health care have recognized the importance of MTMS, but consistently defined parameters are lacking. The APhA/NACDS Foundation model framework of MTM in community pharmacy is designed to improve care, enhance communication among patients and providers, and optimize medication use that leads to improved patient outcomes.[5] Ideally, patients or caregivers will receive MTMS at the pharmacy where they have their prescriptions filled. MTMS will enhance patients' understanding of appropriate drug use, increase their adherence with prescribed medications, facilitate collaboration between pharmacists and other healthcare providers, improve detection of adverse drug events, and optimize therapeutic outcomes.[6]

The MTM Current Procedural Terminology (CPT) for billing codes: 0115T, 0116T, and 0117T, were developed by the Pharmacy Service Technical Advisory Coalition in Collaboration with American Medical Association (AMA).[7] The MTM provision of the Medicare law specially recognizes pharmacists as potential providers of MTMS and allows for payment to pharmacists for providing these services face-to-face. However, the MTM CPT billing codes are still considered as an experimental code (level III) and will be evaluated for there use. The goal of the pharmacy profession is to increase the number of third party-payers who accept these codes. Currently, theses CPT codes are becoming more widely practiced and recognized but have not been adapted by most third-party payers.

Kerr Drug, Inc. is a regional pharmacy chain with more than 100 stores located throughout North and South Carolina and headquartered in Raleigh, NC. This pharmacy-focused company's goal is to be true to its mission statement of being a health care destination; a market leader in the clinical pharmacist delivery of quality dispensing services, MTMS, preventive health care programs by KDI Clinical Services (KDICS), and a wide variety of durable medical equipment and health-related products provided by professional, experienced staff.

KDICS is a team of clinical pharmacists who practice in Kerr Health Care Centers (KHCC), located in approximately 15% of Kerr Drug Stores throughout North and South Carolina, as well as employer worksites and medical practices. The KDICS staff includes residency-trained pharmacists with advanced training and certifications in diabetes, hyperlipidemia, hypertension, asthma, chronic obstructive pulmonary disease, smoking cessation, osteoporosis, and immunizations. The American Diabetes Association (ADA) has recently recognized five KHCC as meeting the national standards for Diabetes Self-Management Education (DSME). These certifications, among others, allow the KDICS team to participate in a mix of activities including disease prevention, detection, and monitoring; management screenings; immunizations; and disease/medication management in-store and/or onsite at employer groups and community organizations. KDICS is committed to enhancing the profession of pharmacy through its quality community pharmacy-based clinical offerings.

KDICS has been performing MTM for the last 10 years. Below are some of the areas KDICS pharmacists are performing MTMS:

MTM with Self-Insured Employer Groups

- *Fostering the role of multidisciplinary health care teams in improving medication persistence and adherence*
- *Adoption of or adherence to national treatment guidelines*
- *Preventing and eliminating adverse drug events*
- *Innovation in the management of drug therapy while significantly improving patient outcomes*

KDICS provides MTM and disease state management for many self-insured employer groups including, but not limited to, the City of Asheville, Mission Hospital, Blue Ridge Paper, Vanity Fair Corporation, Southeastern Container, Sullivan County, and Glen Raven Textiles. KDICS pharmacists manage nearly half of the Asheville Project participants and have utilized the positive outcomes from the study to promote MTM growth to other employers. KDICS pharmacists collaborate with physicians, physician assistants, nurse practitioners, nurses, dietitians, and other healthcare providers employed by or responsible for the care of the self-

insured groups' covered lives, reviewing each patient's prescription and non-prescription medications and making appropriate recommendations based on national treatment guidelines. These recommendations focus on appropriate dosing, minimizing side effects, preventing drug interactions, and ensuring each patient has cost-effective therapy. Additionally, the pharmacist educates the patient on appropriate monitoring and management of his/her chronic disease, and often facilitates this process (i.e. assisting patients with selecting and obtaining a blood glucose meter). The education piece is personalized and specific for each individual and often includes management of more than one chronic disease. Patients also benefit from KDICS pharmacists' provision of point-of-care testing, including lipid panels, blood glucose, and hemoglobin A1c. Knowledge of these pertinent values allows the pharmacist to more thoroughly assess the patient's response to therapy, as well as to recommend adjustments to lifestyle and/or medication that can improve outcomes. Regular follow-up allows the pharmacist to ensure that patients understand their medications, adhere to their treatment plan, and maintain appropriate lifestyle changes. Similarly, KDICS pharmacists communicate frequently with patients' other healthcare providers, facilitating progress toward individualized treatment goals. KDICS pharmacists continue to replicate the Asheville Project's positive outcomes in other NC employer group models.

Diabetes Self-Management Education

- *Fostering the role of multidisciplinary health care teams in improving medication persistence and adherence*
- *Adoption of or adherence to national treatment guidelines*
- *Preventing and eliminating adverse drug events*
- *Innovation in the management of drug therapy while significantly improving patient outcomes*

The Mission Statement of the Kerr Drug Diabetes Education Program (DEP) is to help people with diabetes and their families by providing them with access to a collaborative education team and the skills and knowledge to manage diabetes appropriately with the goal of improving their overall quality of life.

KDICS recently gained recognition from the ADA for its interdisciplinary DSME Program at five locations and is currently in the application process for five additional sites. The ADA recognition is quite valuable in reflecting the quality of the diabetes program and enables Medicare reimbursement to pharmacists for diabetes education. This, of course, is a tremendous asset in building a successful clinical and MTMS. The ADA has developed national standards for DSME and the requirements met by KDICS include:

1. One sponsoring organization and a qualified coordinator
2. An advisory system that annually plans and evaluates the services offered, and reviews the participants' outcomes
3. Instructional team that include at least a registered dietitian (RD) and a registered nurse (RN) who have continuing education and experience in both diabetes and behavioral teaching/counseling skills
4. Instructional staff that includes at least two health care professionals from at least two different health care disciplines who have continuing education and experience in both diabetes and behavioral teaching/counseling skills
5. A written curriculum with measurable learning objectives based on the National Standards 10 content areas

6. Participant education records that document individualized assessment related to the National Standards content areas, education plan with learning and behavioral objectives, interventions, evaluations, and team collaboration
7. Tracking of participants' behavioral and other outcomes as part of a continuous quality improvement (CQI) process to evaluate the effectiveness of the diabetes education services

The KDICS DSME program is intended for patients ≥ 18 years old with Type 1 or Type 2 diabetes and their families. Classes 1, 4, and 5 are group sessions, delivered using live lecture and visual aids projected on a screen. Classes 2 and 3 are one-on-one session with demonstrations and visuals presented by handouts. Participant involvement and self-motivation are encouraged through self-assessment and goal setting. The participant, with guidance and support from the educator and physicians, helps determine the order of educational modules and frequency of visits. Participants access the program through referral by their physicians or pharmacists, and via in-store marketing and self-referral. Educational goals are assessed through diabetes knowledge exam and patient self-assessment materials. Behavioral modification goals are assessed using the behavior change goal contract. At each visit, educator may make additional goals, modify current goals, change current goals and/or enforce visit's previous goals.

Currently, a group of health plans that have designed MTM programs for qualified beneficiaries: Humana, Community Care Rx, Walgreens Health Initiative, and NC Medicaid in which KDICS have been participating in these MTM programs since July, 2006. The main issues involving each MTM program is the diversity of each program for documentation, beneficiary eligibility, and billing which can leave pharmacists with uncertainty on how to execute each program effectively. The Centers for Medicare & Medicaid Services is expecting MTM providers to document the core elements: review of pertinent patient history, medication profile, and recommendations for improving health outcomes and treatment compliance. With all of these MTM elements required by CMS and health plans designing their own requirements for their own MTM program, pharmacies and pharmacists need to design there own documentation and evaluation tools for MTMS.

iMetrikus, is a health care technology company in the business of providing a modern, interactive connection between those who are chronically ill and the health professionals who care for them. iMetrikus has developed an advanced population health, chronic care management online application called Medicompass®. iMetrikus has products and services that will enable pharmacists to upload healthcare data from patient's devices such as blood glucose meters, blood pressure monitors, digital spirometry, lipid testing, and insulin pumps. This interactive web-based system allows pharmacists to create their own patient registry to help patients comply with their treatment regimens. This application is divided in three chronic care management sections: cardiovascular (hypertension and hyperlipidemia), diabetes, and asthma, which are in compliance with the disease states, listed in the MTM Provision of the Medicare law.

Medicompass® could be a key component in evaluating objective data that can be collected by the patient in order for pharmacists to perform MTM services. For MTM to be transposed to any pharmacy across the country, this device could be used and evaluated during the workflow of a staff pharmacist's day-to-day responsibilities in order to perform a face-to-face MTM intervention in the community pharmacy. The objective from the data collection application could be communicated to other health care professionals along with recommendations which will help determine the appropriateness of their medication use and manage chronic conditions.

A pharmacy that provides patient care services using the current CPT codes for MTM should include a process to improve continuity of care, a continuous assessment of quality improvement, documentation, and means to measure the outcomes of the MTM intervention. Pharmacists need to develop ways to collect, evaluate, and measure these MTM outcomes in order to have the MTM CPT codes be more widely accepted by third party-payers and publish these outcomes in order for the Pharmacy Service Technical Advisory Coalition in Collaboration with AMA to establish these codes as existing patient care services (level 1).

Objectives

To compare the effectiveness of two different approaches of MTM in the community pharmacy: Medicompass® is an online personal medication record and documentation application versus the standard paper documentation.

1) To evaluate Medicompass® as a data collection program for its use in MTM
2) Analyze the following MTM outcomes via descriptive statistics for diabetes and hypertension MTM services
   - Diabetes MTM
     - Change in hemoglobin A1c
     - % of patients with hemoglobin A1c < 7% at third MTM intervention
   - Blood Pressure MTM
     - Change in systolic and diastolic blood pressure readings
     - % patients with BP < 140/90 mm Hg
     - % patients at BP goal (<130/80 mm Hg) at third MTM intervention if has diabetes

3) To evaluate the acceptance of recommendations made to physicians from MTM interventions

4) Evaluate consumer acceptance of, and willingness to pay for participating in the use of the Medicompass® application and the pharmacist MTM intervention

Methods

Five rural and urban North Carolina KHCC sites were selected to use Medicompass® for documenting MTM interventions for hypertension and diabetes and will be compared to five other North Carolina KHCC sites that documented MTM interventions using a standard paper chart. A minimum of 10 participants (5 diabetes MTM interventions, 5 hypertension MTM interventions) were enrolled at each of the ten sites. Each participant completed three MTM interventions for 30 minutes per visit. Participants were not charged for the MTM intervention in order to collect data on the participant's willingness to pay for the program, which may be used to present to manage care plans in conjunction with the clinical outcomes.

This study was in KHCC, which are private patient care areas. See below for locations:

Kerr Health Care Center Locations	
403 East Main Street **Benson, NC 27504** **(919) 207-1221**	**816 North Main Street** **Fuquay-Varina, NC 27526** **(919) 567-1051**
South Hills Mall **1219 Buck Jones Road** **Raleigh, NC 27606** **(919) 535-0091**	**University Mall** **201-10 South Estes Drive** **Chapel Hill, NC 27514** **(919) 918-7595**

Triangle East Center **1016 N. Arendell Avenue** **Zebulon, NC 27597** **(919) 646-7367**	**Towne North Plaza** **8385 Creedmoor Road** **Raleigh, NC 27612** **(919) 847-0751**
The Lassiter- North Hills **4441 Six Forks Road** **Raleigh, NC 27609** **(919) 534-1393**	**Community Health Center** **625 Harper Avenue** **Lenoir, NC 28645** **(828) 758-8932**
1124 Patton Ave **Ashville, NC 28806** **(828) 225-7132**	**503 East Third St** **Pembroke, NC 28372** **(910) 521-2393**

Red: Med*i*compass Device site

Inclusion Criteria

1. Male or female between the ages of 18 and 75
2. Patient on 4 or more chronic medications
3. Patient has at least one chronic medication for treatment of diabetes or hypertension
4. Total monthly cost of medication exceeds $200
5. Signed consent from the participant (appendix 3)

Exclusion Criteria

1. Participants that cannot obtain transportation to the KHCC
2. Participants that cannot speak and/or read English
3. Participants who are pregnant or nursing
4. End-stage renal disease or dialysis

Diabetes MTM Intervention

Visit #1 (Baseline)
1) Patient consent form will be completed (appendix 3)
2) Medication review using MTM form (appendix 4)
3) Perform Hemoglobin A1c using GDX Analyzer System
4) Review standards of diabetes care
5) Trained on Blood Glucose meter (if applicable) or given log book

Visit #2 (6 weeks from baseline)
1) Medication review (Evaluate recommendations made to physicians)
2) BG meter will be downloaded or log book will be copied
3) Blood Glucose Assessment
4) Review standards of diabetes care
5) Diabetes Progress report will be sent to physician along with BG log (see appendix 5)
6) Send MTM note or recommendations to physician (if applicable)

Visit #3 (12 weeks from baseline)
1) Medication review (Evaluate recommendations made to physicians)
2) BG meter will be downloaded or log book will be copied
3) Blood Glucose Assessment
4) Perform Hemoglobin A1c using GDX Analyzer System
5) Review standards of diabetes care
6) Diabetes Progress report will be sent to physician along with BG log (see appendix 5)

7) Send MTM note or recommendations to physician (if applicable)
8) Complete Patient Satisfaction Survey (see appendix 6)

Hypertension MTM Intervention

Visit #1 (Baseline)
1) Patient consent form will be completed (see appendix 3)
2) Medication review using MTM form (see appendix 4)
3) Blood pressure measured
4) Patient trained on blood pressure monitor

Visit #2 (6 weeks from baseline)
1) Medication review (Evaluate recommendation made to physicians)
2) Blood pressure measured
3) Blood pressure monitor downloaded (if applicable)
4) Blood pressure log sent to physician
5) Send MTM note with recommendations to physician (if applicable)

Visit #3 (12 weeks from baseline)
1) Medication review (Evaluate recommendations made to physicians)
2) Blood pressure measured
3) Blood pressure monitor downloaded (if applicable)
4) Blood pressure log sent to physician
5) Complete Satisfaction Survey (appendix 6)
6) Send MTM note with recommendations to physician (if applicable)

Timeline

Timeline	Baseline	Week 6	Week 12
Visit	Visit 1*	Visit 2	Visit 3*

* Hemoglobin A1c

Results

The reduction in hemoglobin A1c was greater in the Med*i*compass group compared to the Control group (-1.3% vs -0.98% respectively). The reduction in systolic blood pressure was greater in the Med*i*compass group compared to the Control group (-8.1mmHg vs 0.14mmHg respectively) and the reduction in diastolic blood pressure was greater in the Med*i*compass group compared to the Control group (-1.4mmHg vs 0.86mmHg respectively). Table 1 contains the number of participants in each group along with the results for the Med*i*compass group compared to control group. The majority of the diabetes patients from each group would pay $20-35 per visit with the pharmacist compared to the majority of the hypertension patients would pay $5-15 per visit with the pharmacist.

Table 1

	Med*i*compass Group		Control Group	
	HTN Arm	**DM Arm**	**HTN Arm**	**DM Arm**
No. patients enrolled	21	11	13	19

No. patients lost to follow-up	11	8	6	11
No. patients completed all 3 visits	**10**	**3**	**7**	**8**
Average change in A1c		-1.3%		-0.98%
% of patients with A1c <7% at visit 3		67%		37.5%
Average change in systolic BP readings	-8.1mmHg		0.14mmHg	
Average change in diastolic BP readings	-1.4mmHg		0.86mmHg	
% of patients with BP <140/90 at visit 3	80%		42.9%	
% of patients with BP <130/80 at visit 3		33%		62.5%
% of recommendations accepted	57%	25%	100%	33%
% of recommendations not accepted	43%	75%	0%	67%
Patient Satisfaction Survey				
Patients strongly agreed or agreed meeting with the pharmacist has helped them understand their medications better	100%	100%	100%	100%
Patients strongly agreed or agreed meeting with the pharmacist has helped them manage their diabetes and/or blood pressure better	100%	100%	100%	100%
Patients strongly agreed or agreed they were satisfied with the service and education they received from the pharmacist	100%	100%	100%	100%
Patients stated they would pay out of pocket to meet with a pharmacist	100%	100%	71%	100%
Patients stated they would pay $5-15 per visit with a pharmacist	62.5%	33%	71%	50%
Patients stated they would pay $20-35 per visit with a pharmacist	25%	67%	0%	50%
Patients stated they would pay $5 for downloading their glucometer or blood pressure monitor per download	87.5%	100%	N/A	N/A
Patients stated they would	N/A	N/A	57%	50%

pay to have their glucometer or blood pressure monitor downloaded per download				
Patients stated they would family or friends for this service	100%	100%	71%	100%

Conclusion

This study had a few limitations to the design, which included a small sample size due to enrollment issues and patient's lost to follow-up. Also the initial proposal for the study was to enroll 5 hypertension and 5 diabetes patients for each of the 10 sites resulting in 50 hypertension patients and 50 diabetes patients, which is a small sample size.

Even with these limitations, the results revealed that the Med*i*compass group had a larger percentage of patients meeting recommended goals (BP<140/90 and hemoglobin A1c <7%; a larger reduction in hemoglobin A1c, systolic BP, and diastolic BP; and more overall satisfaction by patients. The Control group had a larger percentage of patients meeting recommended goals for BP <130/80 if they had diabetes, a reduction in hemoglobin A1c, and a small increase in systolic and diastolic BP. Overall the Control group's patient satisfaction was less compared to the Med*i*compass group. In both groups, physicians were more likely to accept recommendations related to blood pressure medications but less likely to accept recommendations related to diabetes medications.

Based on the patient survey, pharmacists have a very important role to play with helping patients understand their medications, managing patients' disease states, educating patients about their disease states, and patients are willing to pay pharmacists for their service. This shows that patients value the service of the pharmacists and recognize that pharmacists should be reimbursed for their service. This is another large step towards pharmacists being recognized as providers for third-party payers and being compensated for providing patient education, MTMS, and disease state management.

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