Final Report to Community Pharmacy Foundation
Pharmacist Care for Diabetes Program

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Introduction

Pharmacist care services (PCS) have evolved over the past 20 years, with medication therapy management (MTM) now sharing center stage as an effective approach to help address the escalating health care costs of chronic disease, which is expected to reach $4.1 trillion in the U.S. by 2023.[1]

The medical literature supports the view that PCS for direct patient care has favorable clinical outcomes across a variety of health care settings and disease states, including diabetes, asthma, hypertension, and conditions requiring anticoagulation therapy, among others.[2 3 4 5 6 7 8 9] In a comprehensive review of PCS program assessments, the return on investment (ROI) was reported to be over 4 to 1.[10] Perhaps most prominently, the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) recognizes pharmacist-driven MTM as a core component of the Medicare Part D benefit for seniors and more notably, through regional MTM innovators (e.g., California, North Carolina, Wisconsin, Minnesota, others).[11 12 13 14]

The UCSF Center for Self Care has developed its model of MTM care for type II diabetes (hereafter diabetes) and associated co-morbidities such as hypertension and hyperlipidemia through the *Northern California Pharmacist Care Services Collaborative*, which is an umbrella group for partners and collaborators of the Center in its multi-setting MTM programs. The Center's model of MTM care has been successfully applied in a pilot diabetes MTM program with Raley's community pharmacists as MTM practitioners, a reimbursed contract services via televideo-counseling between the Center and union headquarters of UA447 Pipefitters-Sacramento, and funded televideo-counseling services between the Center and St. Anthony's Medical Clinic of San Francisco. Clinical, humanistic and economic outcomes from these programs are at least comparable or better than those from the Asheville program.

Based on the successful pilot diabetes MTM program mentioned above, Raley's expressed interest to the Center in collaborating with the California Public Employee Retirement System (CalPERS). CalPERS has 1.5 million members overall and an estimated 100,000 members with diabetes with 60% of those also having hypertension. Blue Shield of Northern California provides health coverage for a large number of CalPERS members, and was therefore was also approached for purposes of providing patient identification, enrollment, claims data, and associated medical and legal oversight to the program. The resulting program was called *The CalPERS/BlueShield/Raley's/UCSF Pharmacist Care for Diabetes Program,* and it was designed to cover about 39,000 square miles in Northern California.

Funding for the program was also a collaborative effort and spanned over 3 years of preparation and deployment, including soliciting agreement from collaborators, obtaining funding, completing the pilot Raley's diabetes MTM program, protocol development, creation of patient education materials, refining the Center's Field Operations Manual for MTM services, program approval by collaborators, training, and implementation. The collaborators included: The Community Pharmacy Foundation, NACDS Foundation, Raley's

Pharmacies, Sanofi-Aventis, and Novartis, as well as in kind contributions from Blue Shield and the UCSF Center for Self Care.

Research Questions

These considerations prompted the following research questions:

1. Do MTM counseling services for persons with diabetes by community pharmacists improve clinical, humanistic and economic outcomes?
2. What is the level of patient satisfaction with the MTM program by patients?
3. What are the major obstacles and facilitators for an effective MTM program involving a larger payer delivered by community pharmacists?

Methods

A. Model of Care

The model of MTM care used in *The Pharmacist Care for Diabetes Program* was one developed by the UCSF Center for self-care. The model of care involved up five visits in a 12 month period (e.g., initial, 30 day, 4-to-6-month, 9-month and 12-month), lasting about 40 minutes (initial) or 20-25 minutes (follow-up). Pharmacist counseling was based on the national standards of care for diabetes as published annually by the American Diabetes Association, through use of the Center's structured Subjective-Objective-Assessment-Plan (SOAP) note (see below). The program was supported by a Field Operations Manager, Field Operations Manual, an extensive list of essential protocols, external physician audits and other quality assurance activities, and standardized patient education materials (see below).

The one difference between the Center's other MTM programs and *The Pharmacist Care for Diabetes Program* was that physician referral was not the main driver for patient enrollment.

B. Pharmacist Recruitment and CE Training

Participating Raley's pharmacists were recruited by Raley's corporate pharmacy services department and trained by UCSF pharmacists who are experts in diabetes MTM and field operations aspects of our programs. CE was offered for the training

C. Patient Selection and Enrollment

The Pharmacist Care for Diabetes Program was an opt-out program, meaning CalPERS members who had Blue Shield health insurance were automatically enrolled if they fit certain criteria (see below). The Blue Shield member had the opportunity to opt-out of the program at any time without prejudice or loss of claims coverage. As noted above, physician referral, which is typically used in the Center's other MTM programs, was not a component of this program.

Patient selection for enrollment was made based on the following criteria:

- CalPERS member

- >18 years old
- Physician diagnosis of type 2 diabetes
- Member of a Blue Shield health plan
- First prescription from a Raley's pharmacy for a diabetes medicine (NOTE: if first diabetes medicine prescription was from another pharmacy even if they member frequented a Raley's pharmacy, patient was excluded)
- Within 5 miles of a participating Raley's pharmacy
- Signed contract to agree to see the pharmacist over the course of 12 months
- Agreement to share personal health information

Patient registration was initially handled by Blue Shield and involved standard mail outreach. However, the response was less 1%. Subsequent to the poor response to the initial enrollment plan, enrollment was taken over by Raley's Pharmacies Corporate Pharmacy Services Department. Two Raley's employees who were well versed in customer service made telephone calls to prospective patients, talking from a script and using procedures in the program's Registration Protocol. If the patient who was contacted by phone decided at that time to participate in the program, then the Raley's employee making the registration call obtained certain basic information (e.g., name, address, telephone number etc.) and assigned the patient to a store location within 5 miles of their home. Once a patient was enrolled and registered, the pharmacist who was assigned to that patient made a follow-up call to schedule the appointment and make the reminder call for the appointment.

D. Quality Assurance

A number of different activities were pursued during the program to help ensure quality implementation and outcomes of the program for those patients entered for MTM services. Main drivers for these activities were principles of consistency, predictability, accountability, and transparency. A Steering Committee led by Blue Shield with representation from Blue Shield, Raley's and UCSF met regularly during the program, especially in the implementation phase. Blue Shield provided a program manager to support the Steering Committee.

1. Field Operations Manual and Protocols

A detailed Field Operations Manual was derived from a similar manual used by the Center for its other MTM programs and tailored to *The Pharmacist Care for Diabetes Program.* This Manual covered all aspects of the program from context, scope of practice, training, operational flow charts, and all protocols and patient and pharmacist educational materials. The Table of Contents of the Field Operations Manual, the list of Protocols and the list of Forms are found in Appendix A , Appendix B and Appendix C, respectively.

2. Field Operations Manager

The Field Operations Manager (FOM) was a California licensed pharmacist with training in MTM and experience in managing and implementing MTM telepharmacy services for the Center for Self Care. Functional responsibilities for the FOM were:

- Support in creating protocols and forms;
- Support in creating the Field Operations Manual;
- Clinical Training;
- Clinical consultation via telephone, prn;
- Site visits;
- Best practices Update;
- Data collection and storage;
- Field support and troubleshooting;
- Member of the Steering Committee.

3. Training

A three-person team from UCSF School of Pharmacy provided CE training to Raley's pharmacists, who volunteered to participate in the program. Two of the trainers were licensed pharmacists and very experienced in diabetes MTM; the third person was the UCSF principal investigator who had responsibility for training operational and documentation aspects of the program. CE was provided by the Pharmacy Foundation of California.

Training occurred in three parts: (a) pre-study program prior to in-person training; (b) 6-hour refresher training in diabetes MTM; and (c) 4-hour training in operations and documentation. For a small group of pharmacists who volunteered later in the implementation period, the training was collapsed to pre-study and 8-hours split between diabetes MTM and operations/documentation.

4. Physician Audit

The Physician Auditor for Clinical Compliance (hereafter, "physician auditor") was a licensed physician who conducted quarterly clinical audits on a random sample of 30 pharmacist consultation visits. The overall purpose of the clinical audit of the pilot program was to help ensure that the clinical standards and requirements established by *Blue Shield of California's Pharmacist Care for Diabetes* Program.

The physician auditor determined through the review of the documentation made available to him/her as represented by the SOAP note, Medication Action Plan and Personal Medication Record Initial Intake Forms, Labs, and Diabetes Foot Screen Form, that:

- Clinical interventions, consultations and recommendations meet current best evidence in treatment of members with type II diabetes enrolled in the pilot program.
- Pharmacist interventions are within professional scope of pharmacy practice.

- Provide assurances that members in the program are receiving evidence-based best practices in the medication management of type II diabetes.

Flexibility in interpretation of the pharmacist documentation was a guiding principle, to allow clarifying follow-up discussions between pharmacist and reviewing physician. For example, an audit was for one visit, while certain information the physician was seeking may have been contained in prior visits.

Raley's used a random number generator to identify 30 unique patient visits from 30 unique patients each quarter. The physician auditor had access to copies of the patient visit documents from the pharmacies. These documents were scanned into PDF format, redacted of patient identifiers, protected by password and sent by secure email or FAX to UCSF.

Each audit was reviewed by the Field Operations Manager, and as needed corrective action was taken to clarify ambiguous findings, correct mistakes, make process improvements, and create Best Practices updates to the field.

5. Best Practices Updates

Best Practices used by the participating pharmacists were routinely collected by the Field Operations Manager either directly via email from MTM community pharmacists and/or through site visits, the medical literature and/or physician audits. Best Practice alerts were issued to the field by the Field Operations Manager on a quarterly basis throughout the program, and on a monthly basis during the first six months of the program. Examples of Best Practices included:

- Clinical updates from the medical literature;
- Identification of common errors in using the documentation approach of the study;
- Inconsistent values from one visit to another, despite no new lab values
- Among others.

6. Documentation of Outcomes

Documentation was based mainly on the SOAP Note (see below) which was completed during the MTM counseling session. Data in the SOAP Note were transferred to an electronic patient record, used to complete the Personal Medication Record and the Medication Action Plan. In addition, patient flow charts and checklists for visit preparation and visit close-out, which are found in the Field Operations Manual, were used to help the pharmacist organize their workflow and prepare for the MTM counseling visit.

7. Standardized SOAP Note

The Subjective Objective Assessment and Plan (SOAP) Note has been modified for all of the Center's MTM programs, including *The Pharmacist Care for Diabetes Program*, so that it contains a standardized format with heading for collection of specific information related to the standards of care for diabetes, hypertension and

hyperlipidemia. The revised format limits the amount of open-field entry which is typical of most SOAP Notes and instead uses specific questions and data fields to facilitate a standard quality assurance approach to MTM counseling across different MTM pharmacists and different care settings (i.e., different pharmacies). A copy of the Center's SOAP Note, which is copyrighted by the University of California Reagents, is found in Appendix D. In effect, the revised SOAP Note represents a structured survey, and once practitioners are used to its format (e.g., the patient's physician) a very quick snapshot of the patient's progress can be made. The structured format of the SOAP NOTE also helped in physician audits. The SOAP Note and the Medication Action Plan and Personal Medication Record were sent by the pharmacist to the patient's physician after each MTM visit.

8. Personal Medication Record and Medication Action Plan

Examples of the Personal Medication Record and Medication Action Plan are found in Appendix E and Appendix F, respectively. As noted, these forms when competed at the MTM visit were sent along with the SOAP Note to the patient's physician.

9. Patient Education and Pharmacist Supplement Materials

Patient Education Materials for use during MTM counseling covered essential medication and disease content to help patients take a central role in their own self-care. A list of the Patient Education materials can be found in Appendix G. Patient education materials were co-branded by the innovator (UCSF) and the partner (Blue Shield).

In addition, Pharmacist Supplement Materials were developed to help in the pharmacists MTM assessments and decision making. These focused on treatment algorithms and other medication related matters. A list of the Pharmacist Supplement Materials is found in Appendix H.

10. Pharmacy, Medical and Legal Review

All protocols, forms, patient education materials, pharmacist supplement materials received review and sign-off by pharmacists, physicians, and lawyers in Blue Shield and Raley's and by UCSF pharmacists.

E. No Incentives for Participation

Unlike the pilot program that helped form the basis for *The Pharmacist Care for Diabetes Program*, this program did not provide patient incentives.

F. Data Analysis

Standard descriptive statistics were used for demographic data. Pre-post analysis of clinical outcomes used a paired t-test. Likert scale responses were analyzed using a z-test for proportions.

Results

A. Patient Enrollment and Pharmacist Participation

While enrollment by mail alone through Blue Shield had a response rate of 1%, the in-person telephone approach by skilled consumer service representatives yielded about a 50% registration rate and a cohort of 57 patients making a first visit to participating MTM community pharmacists. Significant drop-out occurred during the 12 month follow-up period, such that by the second visit 39 patients remained in the program (i.e., 68%); by the third visit, 51%; by the fourth visit, 39%: and by the fifth visit, 22%.

Reasons for drop-out were not systematically assessed by the Raley's Enrollment Team. However, there were certain reasons noted by the customer service employees at Raley's who managed enrollment. These included: change in RPh employment or store; difficulty in the patient's schedule fitting the pharmacist's schedule; patients moved so that the participating pharmacy locations were not convenient; disinterest in the program because the patients thought they were meeting standards of care; lack of support from the physicians of enrolled patients, among other reasons.

B. Clinical Outcomes

We observed clinically and statistically significant reductions in A1c for patients who entered at baseline with A1c values >7%. The drop in mean A1c for this group was 1.5 absolute percentage points ($p<0.03$), which translates into a 23% reduction in myocardial infarction, 9% reduction in deaths from diabetes, and 23% reduction in microvascular

Table 1: Clinical Outcomes: Baseline v 6-month Visit

	n	Baseline	6-month Visit	Difference	p
Mean A1c: All Patients*	21	7.3	7.0	-0.3	0.14
Mean A1c: Out of goal, baseline	7	8.5	7.1	**-1.5**	**0.03**
Systolic Blood Pressure	27	142	130	**-13**	**0.00**
Diastolic Blood Pressure	27	76	71	**-5**	**0.01**
LDL	17	84	88	4	0.55
HDL	15	51	53	2	0.06
TG	15	152	146	6	0.52
TC	16	170	171	1	0.87
BMI	11	35	35	<-1	0.60

*** All patient with a baseline and 6-month visit**

disease, among other adverse risks. [15] (Table 1) By the 6-month visit, both systolic and diastolic blood pressure dropped by 13 mm Hg and 5 mm Hg, respectively (I.e., p<0.001 and 0.01). The mean SBP/DBP at baseline was 142/76 mm Hg. (Table 1) LDL values were in range at baseline and maintained as such.

These findings conform closely with historical case and comparator data from other UCSF Center for Self Care diabetes programs. Typically, patients in the Center's MTM programs who are not meeting goals of therapy for A1c, BP and/or LDL, achieve statistically and clinically significant reductions of the magnitude shown in Table 1 for a subgroup of patients not meeting goals of therapy at baseline.

For example, Table 2 provides clinical outcomes for patients with diabetes who engaged in UCSF pharmacist MTM consultations through a telepharmacy (tele-video) remote counseling program. Patients were members of a Sacramento union. Patients were selected and referred by their physicians to the telepharmacy diabetes clinic. A subset of these patients had diabetes and their clinical outcomes are shown below.

The model of diabetes MTM care used in this program was the same as that for which the community pharmacists were trained in the program funded by the Community Pharmacy Foundation. As can be seen, patients with higher A1c values at baseline than the preferred value of 7% can achieve as a group statistically and clinical significant reductions in mean A1c within a 6 month timeframe. The group of patients with mean A1c > 7.5% at baseline had a greater absolute reduction in A1c values than the total diabetes population (-1.3, vs. -0.9).

Table 2: Historical Clinical Outcomes Data from Other Diabetes MTM Programs of the Center for Self Care
All Patients vs. Those not Meeting Goals of Therapy at Baseline

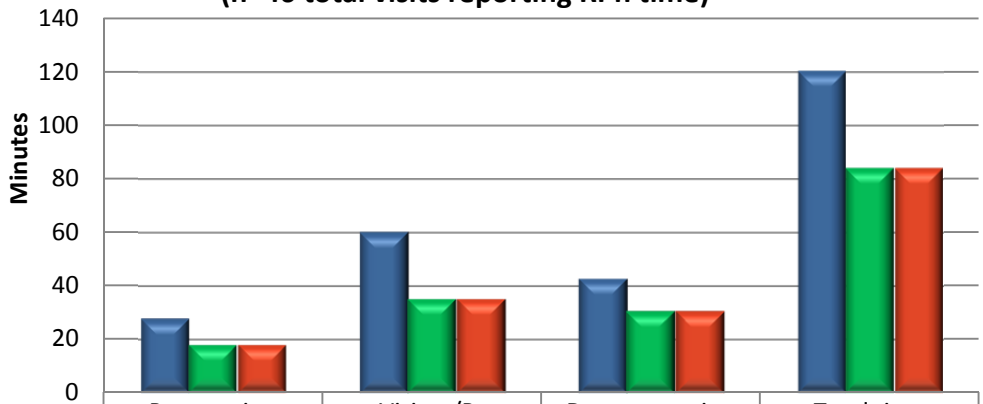
Parameter	N	Clinic Site	Baseline	Post*	P
A1C All	61	CSC	8.80%	7.9	<0.003
A1c >7.5%	38	CSC	9.50%	8.2	<0.005
SBP All	61	CSC	122	122.1	Ns
SBP >130 mmHg	38	CSC	140.5	123.5	<0.005
DBP All	61	CSC	78.9	78.8	Ns
DBP >80 mmHg	38	CSC	87.9	78.1	<0.005
LDL All	61	CSC	108.5	92.5	Ns
	38	CSC	139.5	100.5	<0.005
Legend:					
* Post follow-up was at 4-6 months after the initial visit.					

C. Economic and Workforce Outcomes

Evaluations of the economic outcomes will be made when Blue Shield provides the needed information. Nevertheless, with other programs that the Center for Self Care has undertaken for Raley's (pilot project preceding this program) and for UA447 Pipefitters – Sacramento Benefit Trust, the Center has observed similar absolute drops in mean A1c and blood pressure values with associated reductions in medical claims of about 26% over the first year. Both the Raley's and UA447 populations are similar to the CalPERS population, and we would project cost savings in reduced medical claims of the same magnitude for those not at goal of therapy at baseline. A supplement to this Final Report will be given to the Foundation, when the economic data are released by Blue Shield and analyzed by UCSF. Irrespective of Blue Shield's delay, this in no way detracts from the many important learnings from this project.

Mean time for pharmacist preparation, counseling and documentation was 121 minutes, 84 minutes and 84 minutes for the initial, 6-month and 12-month visits, respectively. (Figure 1) The length of time spent on these operational functions was a function of: (a) The amount of information that needed to be inputted at the initial visit, despite some pre-population of forms; (b) the newness DM MTM counseling to a number of the participating pharmacists; (c) the nature of the design of this study in terms of data collection activities associated with a research study which would not necessarily be associated with a clinical service; and (d) the complexities of one of the documentation systems which was dropped after the initial visit for most patients.

Figure 1
Mean Time (Minutes) Per Visit Type
(n=46 total visits reporting RPh time)



	Preparation	Visit w/Pt	Documentation	Total time
Initial Visit	27.81	60.19	42.89	120.68
6m Visit	18.21	35.36	30.71	84.29
12m Visit	18.21	35.36	30.71	84.29

D. Satisfaction with the MTM Program by Patients and Pharmacists

Overall patient satisfaction for the quality of the counseling by MTM community pharmacists was 100% for patients remaining in the program for 6 months and 12 months. (Figure 2)

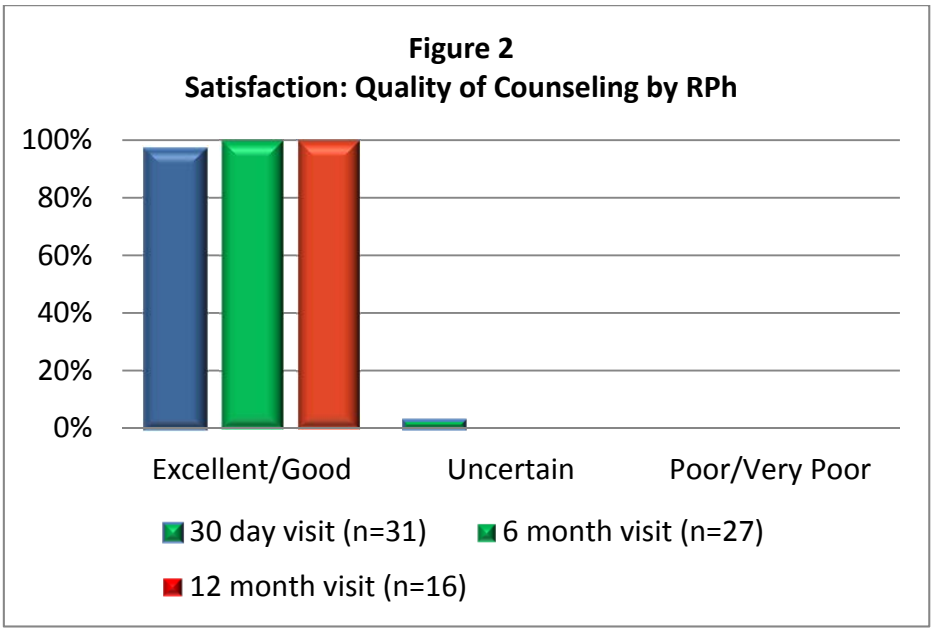


Table 3 (next page) shows the mean Scores for all parameters related to Patient Satisfaction, each of which was scored on a 5-point Likert scale in response to the stem question, "how do you rate the following." The Likert rankings were: Very Poor (5); Not So Good (4); Uncertain (3);Pretty Good (2); and Excellent (1). Mean scores less than 1.5 are ranked on the high side of "pretty good" to "excellent." Patient satisfaction with difference aspects of the community pharmacy MTM experience described in Table 3 was overall very high. Lower scores were reported for patients' understanding of their physician's interest in the program (mean value of 1.77 $\pm$ 0.89), which correlates with anecdotal reports from some participating pharmacists about their own difficulties interfacing with physician offices.

Discussion

A. Barriers

Several key and unexpected issues affected the final patient "n" and therefore the ability of this program to impact more patients in need of MTM services. These issues include: (a.) pharmacist-physician interactions; (b) health plan policies concerning the enrollment process; (c) limited interest by mid-career pharmacists to participate in the program; (d) limitations in data-sharing imposed by an open health plan system.

Table 3: Patient Satisfaction				
Parameters	**Visit**	**N**	**Mean**	**SD**
Overall (Global) Satisfaction	**30 day**	31	1.26	0.77
	6 month	27	1.11	0.32
	12 month	16	1.00	0.00
	Subtotal	**74**	**1.15**	**0.54**
Satisfaction with the Quality of Counseling	**30 day**	30	1.03	0.18
	6 month	27	1.07	0.27
	12 month	16	1.00	0.00
	Subtotal	**73**	**1.04**	**0.20**
The Program Helped Me Better Manage My Diabetes	**30 day**	31	1.32	0.48
	6 month	27	1.22	0.42
	12 month	16	1.13	0.34
	Subtotal	**74**	**1.24**	**0.43**
My Perspective of My Physician's Interest in the Program	**30 day**	31	1.81	0.88
	6 month	27	1.85	0.97
	12 month	16	1.56	0.81
	Subtotal	**74**	**1.77**	**0.89**
My Community Pharmacist Listens to Me	**30 day**	31	1.03	0.18
	6 month	27	1.07	0.27
	12 month	16	1.00	0.00
	Subtotal	**74**	**1.04**	**0.20**
My Community Pharmacist Answers My Questions	**30 day**	31	1.03	0.18
	6 month	27	1.04	0.19
	12 month	16	1.00	0.00
	Subtotal	**74**	**1.03**	**0.16**
Value of the Medication Action Plan (MAP)	**30 day**	38	1.23	0.50
	6 month	39	1.44	0.70
	12 month	18	1.13	0.34
	Subtotal	**95**	**1.28**	**0.56**
Value of the Personal Medication Record (PMR)	**30 day**	31	1.19	0.48
	6 month	27	1.33	0.62
	12 month	16	1.13	0.34
	Subtotal	**74**	**1.23**	**0.51**

Pharmacist-physician interactions

Pharmacist-physician interactions in the open system of health benefits coverage of the CalPERS-Blue Shield system did not permit a physician-referral component as a part of the enrollment and registration process. Such referral mechanisms have been used, for example in the Center's MTM program with a San Francisco community clinic, or in a

closed system like Kaiser Permanente. As a result, it was not typical for the participating MTM community pharmacists to have a clinical counseling tie with the patients' community based physicians, although some reported to have close professional relationships with local physicians. As a result, there were limitations imposed by the weaker nature of the pharmacist-physician interaction of this program. These limitations included:

- Uncertainty on the part of the patients in relation to their physician's perspective of *The Pharmacist Care for Diabetes Program*;
- No physician referral of patients, which is in the experience of the UCSF Center for Self Care one of the most important drivers for patient participation in MTM programs, even in closed systems;
- Certain instances when physicians told potential registrants that the program was not needed;
- Time delays and even barriers to getting lab information from the physician's office, notwithstanding the fact that a release was signed by the patient and sent to the physician for this purpose;

Recommendation: Given the recent advances in Accountable Care Organizations and structuring of physician networks, as well as government stimulus to advancing a seamless collaborative healthcare framework, future programs should be designed with physician referral as a component of the enrollment and registration process. Not only would the non-opt out rate of MTM programs be higher, but pharmacist-physician relations and collaborations in patient care during the program would be facilitated.

Health Plan Policies Concerning the Enrollment Process

Enrollment was hampered by the policy of the health plan that stipulated no outreach to individuals with diabetes in the general community who were not customers of Raley's. That is, one of the inclusion criteria for enrollment was that the prospective enrollee had to have received a first script for a diabetes medicine from Raley's. As a result, the patient pool in the areas serviced by the pharmacies that participate was significantly limited. This was not predicted at the start of the program

In addition, the health plan decided at the outset to do the solicitation for potential registrants. The response to this initial enrollment outreach was by mail with a less than 1% response. As a result, telephone-based enrollment was taken over by a small team in the Raley's corporate pharmacy services. This was a time-consuming effort, and although successful in relation to enrollment per attempted call, could only be done on a relatively small scale.

Recommendation: Use of health plans to recruit patients seems to have little return, in part because the legal and marketing perspective placed into the communication is not conducive to self-selection into an MTM program. On the other hand, direct outreach by a community pharmacy to its customers has a high positive response rate, and this should be leveraged in an efficient manner in future studies. Emerging science shows how to engage

patients in meaningful behavioral changes, and this ground approach should be applied to outreach by plans and pharmacies.

Limited Interest by Mid-career Raley's pharmacists to Participate in the Program

It was not an easy matter to get Raley's community pharmacists to volunteer to participate in the study even with C-suite support, or to sustain their involvement. This also was not expected and was determined to be as a result of a combination of factors, including: the complex nature of the index disease and the associated clinical demands of MTM services for a complex disease; some mid-career pharmacists not being comfortable with time needed to come up to speed with a new form of practice; Raley's downsizing at the start of the program (after training) thus leading to a sudden and expected escalation of demands on participating pharmacists' time for dispensing functions. As a result, some pharmacists opted-out after the start of the program leading to a break in the initial patient-pharmacist relationship.

Recommendation: This suggests that there should be a dialogue on how to address the readiness of mid-career pharmacists to provide MTM services in chronic disease and whether there should be a board certification or certificate process that would identify suitable candidates for programs such as ours.

Limitations of Data-sharing in an Open Health Plan System

In our experience from our other diabetes MTM programs, there is a smaller subset of diabetes patients with a desire to participate in on-going MTM programs as a matter of ensuring they are doing all they can in their own self-care of their diabetes. However, these patients are often already meeting goals of therapy, and from a population standpoint will demonstrate little benefit if defined purely by clinical outcomes (i.e., A1c, BP and LDL being already in the range of the goal of therapy). As a result, the populations for which greatest clinical and economic benefits will be seen are those with key clinical markers of disease which are not within the goals of therapies established by their physicians. This was pointed out above re historical experience of the Center with other successful MTM programs. (See Table 2 above.)

However, large payers in an open system are typically not able to identify members who are not meeting goals of therapy (e.g., A1c's > 8.5%) since specific lab values are not available to them. As a result, they are unable to risk stratify their patients for MTM programs. In addition, patients are traditionally of little help in obtaining lab values from their physicians, and this was reflected in this program as well. Point of care testing was considered, but was deemed, not an option because of questions surrounding the comparison of point of care vs. testing by established and validated laboratories, cost, and difficulties with the board of pharmacy in meeting requirements per Clinical Laboratory Improvements Amendment (CLIA) for on-site (which post our program has been improved statewide in California.)

Recommendation: Future MTM programs should be designed in health plan or physician office networks where critical lab values are able to be obtained for risk

stratification of patients. In every patient group, it has been our experience that patients with disease risk factors that are in control will still want to be in the program. Blue Shield did not want to deny them access to the program. In the end patients with A1c, BP and LDL values that are stable and within goal will statistically dilute the apparent magnitude of the MTM impact, which is shown in Tables 1 and 2.

B. Facilitators

There were a number of design features to this program that we highly recommend to other programs to insure consistency, transparency, and documentation. These include the following, which contributed to our being able to show statistically and clinically significant outcomes in the enrolled population that stayed with the program for12 months.

- Detailed Field Operations Manual, with all necessary materials and information including protocols, forms, patient education materials, pharmacist supplement materials, philosophy and goals of the program, etc.
- Field Operations Manager;
- An integrated quality assurance program, which is outlined in the Methods section;
- Use of patient education materials to facilitate counseling, as well as training of pharmacists in core concepts relating to disease self-management re diet, exercise, emergency preparedness, etc.
- Quarterly physician audits to ensure accountability and help define specific feedback as needed, including remedial training.

Conclusion

1. This program created useful insights into barriers and facilitators of MTM programs at the community pharmacy level which helped to frame specific recommendation that we make in this paper.
2. The model of care used by UCSF Center for Self Care and applied in this program for MTM by community pharmacists is an effective approach to helping patients with diabetes achieve better glycemic and blood pressure control in those not meeting goals of therapy at baseline.
3. For programs defined by the parameters of this project, large payers face significant barriers to registration and risk stratification of patients in MTM programs at the community level. The open nature of the system works against data-sharing among the health team and plan. No access to label data by the plan is a barrier to risk stratification of plan members into an MTM program so higher risk patients are not able to be targeted for MTM service. Recommendations are offered on these and other issues.
4. Patients with diabetes express overall high patient satisfaction with the program and MTM community pharmacists.

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Appendix A: Table of Contents - Center for Self Care MTM Field Operations Manual

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Appendix B: List of Protocols for *The Pharmacist Care for Diabetes* Program

	SOURCE: Center for Self Care Field Operations Manual
No.	**List of Protocols for the Pharmacist Care for Diabetes Program**
1.	Registration
2.	Central File & Audit
2a.	Physician Audit of Pharmacist Files
3.	Raley's Patient Numbering System
4.	Patient Transfer
5.	Pharmacist First Call
6.	Pharmacist Reminder Call
6a.	Referral to Urgent Care, or Emergency Care, or Physician
7.	Form Amendment
8a.	Inventory of Self Care Practices
8b.	Key Findings of the Patient Inventory of Self Care Report
9.	*Not for CalPERS Program* - Medication/Supply Benefit Changes (*For Raley's DM Self Management Program*)
10.	MTMPath
11.	Best Practices Update
12.	*Not included in this program*
13.	Master ID List and UCSF ID Patient Numbering System
14.	Grievance and Appeal Protocol for CalPERS Members participating in the Pharmacist Care for Diabetes Program
15.	Scope of Pharmacist Services Protocol
15a.	Pharmacist Care Services Protocol - Initial (Required)
15b.	Pharmacist Care Services Protocol - Month 1 Visit (Required)
15c.	Pharmacist Care Services Protocol - Month 6 Visit (Required)
15d.	Pharmacist Care Services Protocol - Month 9 Visit (Required)
15e.	Pharmacist Care Services Protocol - Month 12 Visit (Required)
15f.	Pharmacist Care Services Protocol – Any Month Interim Visit (Optional)
16	Reports to Blue Shield Protocol

Appendix C: List of Forms for *The Pharmacist Care for Diabetes* Program

SOURCE: Center for Self Care Field Operations Manual

No.	List of Forms for the Pharmacist Care for Diabetes Program
F1	Pre-Visit Checklist
F2a	Agreement to Participate
F2b	Agreement to Participate for CalPERS
F3	Authorization to Obtain and Release PHI
F3b	Authorization to Obtain Lab Values
F4	Not included in this edition of the program
F5	Patient Inventory of Self-Care for Diabetes
F6	Initial Intake Form
F7	Not included in this edition of the program
F8	SOAP Note
F9	Foot Screen Form
F10	Physician Introduction Letter
F11a	Memorandum of Patient Assessment
F12	Diabetes Medication Action Plan (MAP)
F12A	Personal Medication Record (PMR)
F13	Not used in this program
F14	Patient Satisfaction Survey
F15	Pharmacist Satisfaction Survey (online)
F16	Post-Visit Checklist
F17	Summary of findings from Physician Patient File Audit

Appendix D: UCSF Center for Self Care SOAP Note

SOAP NOTE *Pharmacist Care for Diabetes Program*

Patient Name	**Raley's Pt. No.**
Pharmacist **Store No.**	**Date: / / Start Time:**
Complete for CalPERS patients: Visit No. ❒ Initial ❒ ≤30 days ❒ Mo 4 ❒ Mo 6 ❒ Mo 9 ❒ Mo 12 ❒ Interim	

SUBJECTIVE

GLUCOSE MANAGEMENT

1. How often do you check your blood glucose (BG)?
   ☐ Qday ☐ BID ☐ TID ☐ Other:_____

2. When do you check your BG levels and what are the values?
   - When fasting _____
   - 1-2hr after breakfast _____
   - Before lunch _____
   - 1-2hr after lunch _____
   - Before dinner _____
   - 1-2hr after dinner _____
   - At bedtime _____
   - When hypoglycemic _____
   - When hyperglycemic _____
   - Other _____

3. **Over the past 2 to 4 weeks, how often have you had hypoglycemia?**
   (*probe severity and cause*) ____ times/2-4wks

4. **Over the past 2 to 4 weeks, how often have you had hyperglycemia?**
   (*probe severity and cause*) ____ times/2-4wks

NOTES

Have patient describe his/her meds – **what**, **how**, **when**, **how much**, **how frequent** he/she takes meds (and supplements).

If responded other than 'No' to questions 5-9, please explain why.

MEDICATIONS (meds & supplements)	**Check "No" if "no" for all meds. Check other choices as needed**				
	"No"	DM	HTN	LDL	Other
5. Over the past 2 to 4 wks, have you missed any doses or stopped taking your meds on your own?	❒	❒	❒	❒	❒
6. Over the last 3 months, were you ever without a supply of your meds (ran out; forgot to pick-up; not delivered; other)?	❒	❒	❒	❒	❒
7. Have you had any changes in your meds recently?	❒	❒	❒	❒	❒
8. Do you have trouble taking any of your meds?	❒	❒	❒	❒	❒
9. Have you had any side effects from your meds?	❒	❒	❒	❒	❒

F8 Modified: 3/24/10

Raley's Pt No: _____ **SOAP NOTE *Pharmacist Care for Diabetes Program***

MUST COMPLETE THIS SECTION (QUESTIONS 10-18) FOR THE FOLLOWING VISITS: INITIAL, 6-MO, AND 12-MO VISITS Otherwise Ask As Needed (RELATED STANDARDS OF CARE)	
10. Have you been keeping up with your scheduled doctor's appointments a. Annual physical exam b. Dilated eye exam c. Pneumococcal immunizations d. Flu vaccine e. Dental exam f. Foot screen	If NO, please explain. a. ☐Yes ☐ No b. ☐Yes ☐ No c. ☐Yes ☐ No d. ☐Yes ☐ No e. ☐ Yes ☐ No f. ☐ Yes ☐ No
11. About how much exercise do you get per week? If patient gives time in min/day, convert to min/week.	_____min/week (*goal: mod-intensity = 150 min/wk; vigorous-intensity = 75 min/wk*)
12. How do you monitor your carbohydrate (CHO) intake?	☐ Does not monitor CHO intake ☐ CHO count ☐ CHO Exchange ☐Check food label ☐ Portion control ☐ Plate method ☐ Other_____
13. Do you know your A1C goal *(A1c < 7%, or <8%)*?	☐ Yes ☐ No Pt's stated A1C goal _____%
14. Do you know your blood pressure goal *(<130/80)*?	☐ Yes ☐ No Pt's stated BP goal _____/_____mgHg
15. Do you know your LDL cholesterol goal *(<100, or <70)*?	☐ Yes ☐ No Pt's stated LDL-C goal _____mg/dL
16. Do you have an emergency preparedness kit? *(TK_Pt#12 Handout, prn)*	☐ Yes ☐ No
17. Are you using a blood pressure monitor at home?	☐ Yes ☐ No If yes, how often do you measure your BP? ☐ BID ☐ Qday ☐ Qweek ☐ Other:____ times/mo
18. How do you currently limit your salt intake *(<1,500mg Na/day)*?	☐ Do not limit salt intake ☐ Check food label ☐ Avoid/reduce salty foods ☐ Other:

OBJECTIVE

1. ☐ Check box if blood pressure measured at visit
2. ☐ Check box only if emergency referral (BP > 180/120 w/ acute onset)
3. ☐ Check box if attaching lab sheet to SOAP. Otherwise complete below

Parameter	Value	Date
4. Blood Pressure	_____/_____ mmHg	*today's visit*
5. Weight	_____lbs	*today's visit*
6. BMI	_____	*today's visit*
7. A1c	_____ %	
8. eAG (est. avg. glucose)	_____mg/dl	
9. Fasting BG	_____mg/dl	
10. Random BG	_____mg/dl	
11. Total Cholesterol	_____mg/dl	
12. LDL-C	_____mg/dl	
13. HDL-C	_____mg/dl	
14. Triglycerides	_____mg/dl	
15. Urine albumin /creatinine ratio)	_____µg/mg Cr (or mg/g Cr)	
16. Serum Creatinine	_____mg/dl	
17. ALT	_____U/L	
18. AST	_____U/L	
19. K^+ (Potassium)	_____mmol/L	
20. CK (creatine kinase)	_____U/L	
21. TSH (thyroid stim horm)	_____µU/ml	
22. Insulin Antibody		

Raley's Pt No: _____ **SOAP NOTE *Pharmacist Care for Diabetes Program***

ASSESSMENT

Assess whether patient has diabetes & co-morbidities in control & is meeting standards of care. Add notes as needed. Does patient have……..

1. A1C and blood glucose in control? ☐ Yes ☐ No
2. Blood pressure in control? ☐ Yes ☐ No
3. LDL-C in control? ☐ Yes ☐ No
4. Any medication issue? ☐ Yes ☐ No
5. Any other issue (standard of care, other)? ☐ Yes ☐ No

PLAN

Create Diabetes Medication Action Plan

To Patient: **(List Recommendations to Patient in Order of Priority)**

1. **☐ PCP Referral**

2.

3.

4.

Next Visit: _____ date _____time

To Physician: **(List Recommendations to PCP in Order of Priority)**

1. **☐ Lab Test(s) Referral**

2.

3.

4.

TIME SPENT **Preparation:** _____(min) **Counseling:** _____(min) **Documentation**: _____(min)

Target: 10 min. preparation; 30-45 min initial counseling; 20-30 min other visits; 15 min documentation

Raley's Pt No: _____ **SOAP NOTE *Pharmacist Care for Diabetes Program***

ALERT! Pharmacist completes after appointment and entered into the MTM Path Complete this page only if MTM Path® is NOT ACCESSIBLE. Otherwise, if MTMPath® is ACCESSIBLE, entry of SOAP note within MTMPath® auto-populates this page.

Is Your Patient Meeting Standards of Care at this Visit?					
Lab Measure		**Yes**	**No**	**Uncertain (if NA, write NA)**	**REFERENCE** *Selected Notes from ADA Standards of Care Published in Diabetes Care, 2010*
1	**A1c** <7.0% <8.0% **per MD only**				A1c goal (<7% for most) A1c goal <8% **per MD only** if patient has limited life expectancy, advanced microvascular (e.g., CKD/ESRD) or macrovascular complications (e.g., CAD, peripheral vascular disease, MI), history of severe hypoglycemia or hypoglycemia unawareness
2	**LDL-C** <100mg/dl, OR <70mg/dl **with overt CVD**				
3	**HDL-C** Men >40mg/dl Women>50mg/dl				
4	**TG** <150mg/dl				
5	**BP** <130/80mmHg				
6	**Microalbumin** <30mcg/mg Cr				
Lab Frequency					
7	**A1c**			Indicate date of next A1c due:	yes= HbA1c within last 6 months IF patient is meeting glycemic goal OR yes = HbA1c in last 3 months IF patient is NOT meeting glycemic goal or IF patient's diabetes med therapy has changed
8	**Lipids**				yes = visit date is within 12 months since lab date
9	**Microalbumin**				yes = visit date is within 12 months since lab date.
10	**Serum Creatinine**				yes = visit date is within 12 months since lab date
Other Standards of Care					
11	BP Measured at Visit				Pharmacist took blood pressure measurement during patient visit
12	Self-Monitoring BG				NOTE: BG monitoring ≥ tid for pts using multiple insulin injections OR insulin pump
13	Self-monitoring CHO intake				yes = see SOAP re: self-report of CHO counting or plate method or other method
14	Exercise (150 min/wk)				Goal is: 150 min/wk mod-intense exercise (50-70% max HR); (about 15-20 min/day on average)
15	Pt is non smoker at current visit				yes = patient never smoked or has quit within last 2 weeks
16	Aspirin daily				yes = the following: - Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). - Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. - For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. - NOTE: There is not sufficient evidence to recommend aspirin for primary prevention in lower risk individuals, such as men <50 years of age or women <60 years of age without other major risk factors. In patients in these age-groups with multiple other risk factors, clinical judgment is required.
17	Annual Physical Exam				
18	Flu Vaccine: annual				yes = pt is up-to-date for flu shot at time of visit
19	Pneumococcal Vaccine				yes = pt up-to-date at time of visit. NOTE: A one-time revaccination for individuals >64 yrs who were previously immunized when they were <65 yrs, if vaccine was administered >5 years ago.
20	Comprehensive Foot Exam				yes = visit date is within 12 months since comprehensive foot exam by physician
21	Dental Exam				yes = pt is up-to-date at time of visit for annual dental exam
22	Dilated Eye Exam				* In newly diagnosed DM, check "yes" if patient has had initial dilated and comprehensive eye exam. * Subsequent examinations for type 1and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less frequent exams (every 2–3 years) may be considered following one or more normal eye exams. Examinations will be required more frequently if retinopathy is progressing.
23	Personal Preparedness Kit				yes = pt self reports having Kit; Advise that Kit should be replenished twice a year
24	PCP referral				
25	Lab test referral				

F8 Modified: 3/24/10

Appendix E: UCSF Center for Self Care Personal Medication Record

blue of california

Pharmacist Care for Diabetes Program

Your Personal Medication Record (PMR)
Patient Receives Original, and Pharmacist Retains Copy

Patient Name: _____
Patient Number: _____
Dated as of: _____
Med Allergies: _____
Other Med Issue: _____

	Medications *(Take Daily)*	Med Strength	Purpose	Notes	Morning	Afternoon	Evening	Bedtime	Daily Total
1									0
2									0
3									0
4									0
5									0
6									0
7									0
8									0
9									0
10									0
11									0
12									0
13									0
14									0
15									0
16									0
17									0
18									0
19									0
20									0
				Daily Total	0	0	0	0	0

TAKE DAILY

	Medications *(Take As Needed)*	Med Strength	Purpose	Notes	Instructions To Take Medication
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

TAKE AS NEEDED

Please carry this Personal Medication Record with you so that you can show your med list to your healthcare providers.

Blue Shield of California is an Independent Member of the Blue Shield Association

F12a last updated 1/11/2010

UCSF University of California San Francisco

Raley's BelAir Nob Hill Foods

Appendix F: UCSF Center for Self Care Medication Action Plan

Pharmacist Care for Diabetes

Your Diabetes Medication Action Plan

Patient Receives Original, and Pharmacist Retains Copy

Patient's Name:_____
Patient Number:_____
Doctor:_____

Next Appointment
Date: _____/_____/_____
Time:

Visit Number: ❒ **Initial** ❒ ≤ **30d** ❒ **Mo.4** ❒ **Mo. 6** ❒**Mo. 9** ❒ **Mo. 12** ❒ **Interim**

Assessment:

Medications:

	Use	Dosage
1.		
2.		
3.		
4.		
5.		
6.		

Information Needed from Physician or Laboratory:

1. **HbA1c** ❒ **Copy of Results, if done in last 3 months** Or ❒ **Request for lab work**
2. **Lipid Panel** ❒ **Copy of Results, if done in last 3 months** Or ❒ **Request for lab work**
3. **OTHER** ❒ **Copy of Results, if done in last 3 months** Or ❒ **Request for lab work**

_____

Short-term Plan

Longer-term Plan

1) Help you reach/maintain HgBA1C goal and blood sugar control.
2) Improve knowledge of diabetes management.
3) Safe and effective medication use.

Attending Pharmacist	**Time Spent with Patient**
	❒ ¼ hour ❒ ½ hour ❒1 hour ❒ Other: ____Hrs

►**Original to Patient.** ►**Fax to Central Support (916) 372-6226** ►**Copies to Store File**
As Needed, Attach Copy to Assessment Memorandum

UCSF#_____ Last Modified F12:9.12.2009

Appendix G: List of UCSF Center for Self Care Patient Education Materials for *The Pharmacist Care for Diabetes Program*

Patient Handouts

1. 7 Steps for Highly Effective Diabetes Self Care (TK_Pt#1)
2. Type 2 Diabetes Medicines (TK_Pt#2)
3. Hyperglycemia (High Blood Glucose) (TK_Pt#3)
4. Hypoglycemia (Low Blood Glucose) (TK_Pt#4)
5. Over-The-Counter Products for Treating Low Blood Glucose (TK_Pt#5)
6. Diabetes and High Blood Pressure (TK_Pt#6)
7. Diabetes and High Cholesterol (TK_Pt#7)
8. 5 Steps to Eating Healthy (TK_Pt#8)
9. Be Active & Stay Active: A 5 Step Plan (TK_Pt#9)

Appendix H: List of UCSF Center for Self Care Pharmacist Supplement Materials for *The Pharmacist Care for Diabetes Program*

Pharmacist Supplements

1. Medication Algorithms for Treatment of Diabetes and Co-Morbidities (TK_Rph#1)
2. Medication Therapy Management of Type 2 Diabetes (TK_Rph#2)
3. Diabetes and High Blood Pressure (TK_Rph#3)
4. Diabetes and High Cholesterol (TK_Rph_#4)

REFERENCES

[1] DeVol R, Bedroussian A. An unhealthy America: the economic burden of chronic disease. Santa Monica, CA: Milken Institute; 2007

[2] Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service, December 2011. Available at www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf. Accessed February 1, 2012.

[3] Cranor CW et al. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc. 2003;43:173–84.

[4] Bunting BA, Cranor CW. The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. J Am Pharm Assoc. 2006;46:133–47.

[5] Bunting B et al. The Asheville Project: Clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. J Am Pharm Assoc. 2008;48:23–31.

[6] Soller RW and Vogt E. DIA Annual Meeting program Workshop: Improving Clinical, Economic and Quality of Life Outcomes in Chronic Disease through Pharmacist Care Services, San Diego, 2009.

[7] Soller RW, and Vogt E. Deriving Value in Benefit Design through Community Pharmacists: a New Path for Managing Chronic Disease Cost and Care. Benefits and Compensation Digest. February, 2009.

[8] Chisholm-Burns, M et al. Economic effects of pharmacists on health outcomes in the United States: A systematic review. Am J Health-Syst Pharm. 2010;76.

[9] Chisholm-Burns, M et al. US Pharmacists' Effect as Team Members on Patient Care Systematic Review and Meta-Analysis. Med Care 2010;48: 923–93.

[10] Perez A. Economic Evaluations of Clinical Pharmacy Services:2001–2005. Pharmacotherapy 2008:28(11);285e-323c).

[11] Center for Medicare & Medicaid Services. Medication Therapy Management. Available at: https://www.cms.gov/PrescriptionDrugCovContra/082_MTM.asp

[12] North Carolina Association of Pharmacists. Outcomes Launches North Carolina MTM Program. Press Release. October 25, 2007. Available at: http://www.ncpharmacists.org/displaycommon.cfm?an=1&subarticlenbr=69

[13] Isetts B. Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program. December 14, 2007. Available at: http://www.dhs.state.mn.us/main/groups/business_partners/documents/pub/dhs16_140283.pdf

[14] Pharmacy Society of Wisconsin. Wisconsin Quality Collaborative: medication therapy management program. March 2011. Available at: http://ww.pswi.org/professional/WPQC%20Program%20Description.pdf

[15] Stratton I et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35: Prospective observational study. BMJ. 2000;405-412.