Patient Safety–Focused Medication Therapy Management: Challenges Affecting Future Implementation

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Objectives/Background: Lessons learned from the implementation of a pharmacist-delivered medication therapy management (MTM) intervention in primary care (PC) can inform future MTM studies and be adopted into real-world clinical settings. We sought to describe the variations and challenges of patient recruitment, enrollment, MTM pharmacist visits, and telephone follow-up in a 3-arm randomized trial of MTM interventions conducted at 3 health centers.

Study Design/Methods: Using a post-study structured interview, we interviewed study personnel, clinical pharmacists, and investigators about 5 study domains: recruitment, enrollment visits, MTM pharmacist visits, telephone follow-up, and data collection.

Results: All centers screened clinic schedules and conducted queries of administrative databases to identify eligible participants. Patients were recruited either during existing primary care visits or by mailing letters with telephone follow-up. Patients with many medical problems, with transportation difficulties, or who were unaccompanied by a family member were less likely to enroll. MTM visits scheduled separately from other clinic appointments had higher cancellation or no-show rates. Provider response to pharmacist recommendations was low overall but better when the provider was acquainted with the pharmacist who was making contact.

Conclusions: Off-site implementation of MTM services results in lower participation by patients and providers. Future MTM studies should consider integrating MTM services within the clinic during existing appointments by a pharmacist familiar to the primary care provider.

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For author information and disclosures, see end of text.

The Medication Evaluation and Drug Use Problem Identification to Improve Safety in High Risk Medicare Beneficiaries (MEDIS-MB) study was a randomized, multisite trial of different medication therapy management (MTM) strategies conducted at the University of Illinois at Chicago (UIC), the Baylor Health Care System in Dallas, Texas, and the Duke Primary Care Research Consortium (PCRC) in Durham, North Carolina. Patients 65 years or older with 3 or more chronic illnesses, 6 or more medications, and 1 or more risk factors for development of a drug-related problem (DRP) (eg, recent hospitalization or multiple providers) were randomly assigned to 1 of 3 treatment arms: usual care; basic MTM by patient interview only; or enhanced MTM with access to a clinical synopsis of medical history, laboratory data, and medications from the patient's medical record.[1] The overall results showed that MTM reduced DRPs and increased patient satisfaction. Access to the clinical synopsis in the enhanced MTM arm resulted in fewer medication list discrepancies.[1] Touchette and colleagues discussed the potential benefits of expanding MTM services to include platforms for clinical record data sharing for community pharmacist access, thus potentially improving patient outcomes by reducing adverse drug events (ADEs).[2]

Communicating the study implementation issues that we experienced can inform clinicians, administrators, researchers, and payers who may be interested in 1) clinical adoption of the intervention, or 2) conducting future MTM studies. In this paper, we intend to describe the variations and challenges of patient recruitment, enrollment, MTM pharmacist visits, and telephone follow-up within this comparative effectiveness trial.

METHODS

The detailed MEDIS-MB study design has been previously described.[1] Institutional review boards at participating health systems approved the study; written informed consent was obtained from all patients. During the enrollment phase, weekly screening and enrollment reports, including reasons for ineligibility and patient refusal, were sent from Duke and Baylor to the UIC coordinating center and reported to the study sponsor. At the end of study, the investigators developed a questionnaire of 5 study domains—

recruitment, enrollment visits, MTM pharmacist visits, telephone follow-up, and data collection issues—to understand the challenges of study implementation and gather feedback on how to improve future studies.

Take-Away Points

This paper describes the lessons learned from implementing a pharmacist-delivered medication therapy management (MTM) intervention.

- Patients with many medical problems, transportation difficulties, or who were unaccompanied by a family member were less likely to enroll. MTM visits scheduled separately from other clinic appointments had higher cancellation or no-show rates. Provider response to pharmacist recommendations was better when the provider was acquainted with the pharmacist who was making contact.
- Off-site implementation of MTM services resulted in lower participation by patients and providers. Usual care implementation can be improved by integrating these services within the clinic during existing appointments by a pharmacist familiar to the primary care provider.

Under the recruitment domain we asked questions about the recruitment method (mail, phone, or in person), time spent on recruitment, previous MTM program enrollment, differences in patient participation, whether incentives were adequate, consent form problems, and how the various study team members approached the clinics and providers. Under the enrollment visit domain we asked questions about the length of visit and space available. Under the MTM pharmacist visit domain we asked about scheduling the visit and the number of visits needed/required, work flow issues, contacting or faxing the provider with recommendations, access to pill bottles, and completing the clinical synopsis, medication lists, and drug-related problem surveys. Under the telephone follow-up domain we asked about the length of the phone call and issues with filling out the symptom survey scale, resource utilization survey, and pharmacist satisfaction form. Finally, under the data collection domain, we asked questions about the methods of data collection (ie, filling out, making copies of, and mailing paper forms to the coordinating center), monthly study calls, and overall clinic participation. An initial conference call with the study personnel, clinical pharmacists, and investigators was held to gather initial responses to the questionnaire items; a second call confirmed their responses and gathered additional feedback. Personnel who were unable to attend the calls submitted written responses to the questionnaire.

Table 1. Screening and Enrollment Numbers by Site

		UIC	Duke	Baylor	Total
Patients Screened		442	1903	739	3084
Ineligibility Reasons[a]	Low number of doctor visits	0	51	84	135 (11%)
	>65 years old	0	0	66	66 (5%)
	Non-English speaking	110	3	38	151 (12%)
	<3 comorbidities	5	38	26	69 (6%)
	<6 chronic medications	19	104	398	521 (42%)
	No telephone	92	1	0	93 (8%)
	No DRP	29	124	14	167 (14%)
	Other ineligibility	25	5	0	30 (2%)
	Total ineligible	280	326	626	1232
Refusal Reasons[a]	Too busy	10	129	24	163 (9.5%)
	Not interested	293	861	91	1189 (69.5%)
	Too sick	13	91	15	119 (7%)
	Need more information	1	33	5	39 (2.3%)
	Bad research experience	1	2	0	3 (0.1%)
	Enrolled in too many studies	0	11	0	11 (0.6%)
	Other	20	153	15	188 (11%)
	Total refusals	338	1280	94	1712
Patients Eligible		258	322	252	832
Patients Enrolled		156	254	227	637

DRP indicates drug-related problem; UIC, University of Illinois-Chicago.
[a]Participants may have more than 1 reason for ineligibility or refusal; percentages calculated based on total number of ineligible or refusal reasons.

Table 2. Study Personnel Feedback by Study Domain

Study Domain		Feedback
Recruitment	Method	• Recruitment letters with phone calls used at Duke exclusively; UIC and Baylor tried this initially with limited success, then switched to in-clinic recruitment • Informational brochure given to patients prior to PC visit was useful to introduce study and facilitate discussion
	Time spent	• More perceived staff time spent on mailings and screening phone calls. Less perceived staff time from in-clinic recruitment, though this does not account for the time the study coordinator waited to approach the patient after the patient came to his or her appointment and saw the provider
	Previous MTM	• Few (<5) patients had previously received or were actively receiving an MTM intervention
	Participation differences	• Patient's mood affected enrollment; less likely to enroll if not feeling well • Patients with family members were more likely to enroll and see benefit of participation • Patients with lots of medical appointments were less likely to enroll
	Incentives	• Free MTM services and gift cards were helpful; reimbursement amount ($30) was perceived as low for time spent at clinic visits and telephone follow-up • Some participants asked for medication discounts • Control group wanted MTM intervention at the end of the study follow-up
	Problems	• Consent form language concerned approximately 20 patients and was cited as the reason for declining participation • Shorter consent would have been helpful • Consent form was read aloud to low-literacy population • Weather, transportation, and cost of gasoline affected participation
	Approach clinic/ providers	• Duke prepared a study synopsis and presented this at provider meeting at 6 practices • UIC approached 3 PC clinics and had buy-in from 2 • Baylor worked with 2 practices and provided lunch for study meetings
Enrollment Visit	Length	• Enrollment visit ranged from 20 to 45 minutes
	Space	• Space to conduct study visits was available in the academic clinics but limited at the UIC outpatient pharmacy • Baylor used clinic room space prior to the provider entering the room; timing was key • Duke held all study visits at 1 central location that had unoccupied clinic rooms available depending on the day of the week
MTM Pharmacist Visit	Scheduling	• Placing study pharmacist visits in the clinic scheduling system was helpful because the listing included existing clinic appointments • To meet with patients, pharmacists had to adjust their schedules when they had existing appointments • Reminder phone calls the day before reduced no-shows • Patients were more likely to cancel pharmacist visits when they were scheduled on a separate day from their clinic visits
	Work flow	• First MTM visit lasted 45 to 60 minutes; second MTM visit lasted 15 to 30 minutes
	Provider contact	• Notes or faxes sent to the provider were often not acknowledged or not returned to the study pharmacist • Patients were given medication recommendation information to discuss with their provider at their next visit, but would often forget to do so
	Clinical synopsis	• The research assistant spent about 10 to 15 minutes filling out this form • Synopsis of clinical information was useful to the MTM pharmacist; next version should have larger font or more space to write • The start date for medications was often left blank because patients and/or their charts did not include this

(Continued)

RESULTS

The MEDIS-MB study was conducted at 3 institutions to reach the enrollment goal of 600 participants (approximately 200 participants per site). UIC worked with 1 family medicine (FM) and 1 internal medicine (IM) clinic, Baylor enrolled patients from 2 senior health centers, and Duke recruited participants from 6 primary care clinics (1 FM, 5 IM) within its practice-based research network (PBRN). Enrolling at 3 institutions resulted in ethnic diversity among participants (51% black, 48% white, 1% Asian/American Indian).[2] Table 1 outlines the number of patients that were screened, contacted, and enrolled. Of the 3084 patients who were screened, we enrolled 637 (21%) participants. Patients were most often deemed ineligible for participation because they did not meet the inclusion criteria of taking at least 6 chronic medications (42%); patients most commonly refused to participate due to lack of interest (69.5%). Enroll-

Table 2. Study Personnel Feedback by Study Domain *(Continued)*

Study Domain		Feedback
MTM Pharmacist Visit *(Continued)*	Medication list	• The medication list took 10 minutes to complete; handwriting had to be neat so patients could read the list • Baylor used a computerized medication list that required extra time at the first MTM visit but less time at the second MTM visit; this list could only be accessed if the interview room had a computer
	Fax forms	• Form needed more space to write observations and recommendations • Many providers signed the forms without indicating whether they accepted the recommendation • Some providers relied on the pharmacist to take care of the recommendation • Many providers did not send faxes back to the pharmacist (estimated 50% response rate) • In-person or telephone communication may be preferable
	DRP forms	• The DRP form provided a way to identify the cause of medication problems; sometimes it was difficult to determine the cause of the DRPs • Form may not be useful in routine clinical practice
	Number of visits	• Many patients did not require the second MTM visit; in those instances, the second visit was used for reinforcement and education and could have been done by phone
	Pill bottles	• Pill bottles were very helpful for the first MTM visit and for any medication changes at the second visit • Patients had difficulty remembering the dose and prescriber name; some could not pronounce the medication name
Telephone Follow-up	Length	• Time ranged from 10 to 60 minutes (average 20 minutes), depending on the number of side effects discussed
	Symptom survey scale	• This survey was difficult to administer by phone; the interviewer had to keep the patient focused on whether the symptom was medication related • Patients also did not refer to the paper copy of the survey given to them at the enrollment visit
	Utilization survey	• Patients had difficulty recalling the dates of their clinic visits, but having access to the scheduling system allowed the coordinator to find the information • Patients were either fully compliant or noncompliant with the visit log; patients with higher socioeconomic status were more likely to fill out the form
	Satisfaction survey	• Survey administration was fine overall, but the negatively worded questions would often confuse patients
Data Collection/ Other Study Issues	Method	• Paper forms had to be copied and mailed to the coordinating center; future studies should have the sites enter their own data into an online database • Computer-assisted telephone interview system would be useful for the patient telephone follow-up
	Copying forms	• Use of carbonless forms (1 copy for site, 1 copy for data entry) would be preferred to copying
	Monthly study calls	• Monthly calls were helpful for standardizing procedures at the sites
	Clinic participation	• The presence of a provider champion and a motivated clinic staff was useful for recruitment

DRP indicates drug-related problem; MTM, medication therapy management; PC, primary care; UIC, University of Illinois at Chicago.

ment lasted 9 months at Duke, 12 months at Baylor, and 13 months at UIC. Both Duke and Baylor enrolled more than 200 participants to help reach the total enrollment goal. Additional subjects (more than 600) were enrolled to replace patients who were lost to follow-up.

Feedback about the 5 study domains from investigators, coordinators, and pharmacists is shown in Table 2. Under the recruitment domain, study staff reported that administrative and pharmacy databases were useful for identifying eligible patients. All 3 sites initially used recruitment letters and phone calls to mimic real-world pharmacy implementation; however, Baylor and UIC switched to in-person clinic recruitment because response rates were low with the mail approach. Duke was able to continue the letter/telephone recruitment strategy given the larger patient population from 6 participating clinics. The differences in recruitment approach translated into the differences in the proportion of participants enrolled to the patients screened for this study (35.3% at UIC, 30.7% at Baylor, and 13.3% at Duke). Patients who were approached at the clinic visit and accompanied by a caregiver were more likely to participate. These caregivers viewed the MTM intervention as a benefit. The presence of a provider champion and a motivated clinic staff was felt to be useful for enhancing recruitment.

For the enrollment visit domain, patients with more chronic illnesses and multiple clinic appointments were more likely to decline participation due to perceived study visit burden. Patients who were concerned about the consent form

language, cost of gas, or transportation difficulties were also less likely to participate. The free MTM intervention was perceived as a benefit; however, the study payment ($10 per completed visit, or $30 total) was perceived as too low by the patients. In addition, some patients in the control group inquired whether the MTM intervention could be offered to them after all study follow-up was completed. The amount of space available to conduct the enrollment and MTM visits varied at the 3 sites. UIC had ample space in the academic clinics, but limited space in the outpatient pharmacy. Baylor used the clinic room space prior to the provider entering the room to see the patient, so timing was essential to limit interference with clinic work flow. Duke held all study visits at a central location that had available rooms depending on the day of the week.

In the MTM pharmacist domain, MTM visits occurring separate from an existing clinical visit had higher no-show or cancellation rates. Reminder phone calls helped reduce missed visits. A total of 186 study participants (88.6%) in the basic MTM group attended the first MTM visit, and 155 (73.8%) participants completed their second MTM visit. A similar proportion of participants in the enhanced MTM group completed their first (n = 196, 89.9%) and second (n = 165, 75.7%) visits. The first MTM visit lasted 45 to 60 minutes, and the second MTM visit lasted 15 to 30 minutes. Access to pill bottles was essential for delivering the MTM intervention because patients had trouble recalling medication names and dosages. The second visit was often unnecessary because most drug-related problems were identified during the first visit. Therefore, the second visit was often used to reinforce or educate patients on the previous medication recommendations. The DRP and ADE forms were straightforward but perceived as impractical for real-world (non-study) settings. DRP form was based on the Modified Pharmaceutical Care Network Europe (PCNE) Drug Assessment Form V 5.01 (see **Appendix A**) and served as both a checklist and as a documentation tool for this study.[3] The ADE form was used to assess symptoms potentially related to medications and contained questions from parts 2 and 3 of a validated research tool developed by Jarernsiripornkul and colleagues.[4] Part 2 (**Appendix B**) of this questionnaire assesses potential side effects of medications through a system-by-system approach. Part 3 (**Appendix C**) of the questionnaire assesses the status of the side effect if the drug was stopped. Non-study MTM providers are unlikely to be able to use these surveys for assessing DRPs and ADEs in routine clinical practice, given the length and detail of questions contained in these documents. After the MTM visit, pharmacists sent medication recommendations via facsimile to patients' primary care providers (PCPs). Providers often returned the study facsimiles without indicating whether they accepted the pharmacist's recommendation, or they failed to return the form. Response to e-mail, phone, or face-to-face communication better ensured receipt of the recommendation and implementation of a plan of action.

Within the telephone follow-up domain, study coordinators reported that these calls ranged from 10 to 60 minutes (average, 20 minutes); the length depended on the number of symptoms discussed. Research coordinators asked patients questions from the symptom, utilization, and patient satisfaction surveys at 90 and 180 days. The ADE symptom survey (19 survey items with multiple potential responses to each item, followed by a 10-item survey for each symptom identified by the participant; see Appendix B) was difficult to administer by phone because the interviewer had to maintain a patient's focus on whether the symptom was related to medication. Also, patients did not refer to the paper copy of the ADE symptom surveys while they were being asked the questions by the interviewer on the telephone. A study folder with a copy of the ADE symptom survey, patient satisfaction survey, patient visit log, consent form, medication list, and contact information of study personnel was given to each patient at the enrollment visit. For the visit (clinic/emergency department/inpatient) utilization form, patients had difficulty recalling the dates of these visits, but having access to the scheduling system allowed the coordinator to find the information. Patients were given a visit log to write down their visit dates, and patients were either fully compliant or noncompliant with the visit log. Patients with higher socioeconomic status were more likely to complete the visit log.

Finally, under the data collection domain, the coordinators noted that paper case report forms (CRFs) required them to copy and send forms to the coordinating center, which took a lot of time and effort. Suggestions included 1) using carbonless (no carbon required [NCR]) paper to keep 1 copy of the CRF at the site and send the other to the coordinating center for data entry, or 2) creating a web-based data entry system for electronic data capture (EDC). The EDC system could be complemented by telephone follow-up surveys housed in a computer-assisted telephone interview system, which would allow immediate data entry at the time of the call.

DISCUSSION

We describe our experience implementing a prospective, randomized study to inform clinicians, researchers, and funders about the challenges and successes of community-based MTM trials. As noted above, successes included identifying potentially eligible patients via medication and billing databases, participation of 10 community clinics resulting

in enrollment of a diverse patient population, and monthly study calls that helped standardize operational issues. Challenges included the need to contact numerous patients (5 screened for every 1 enrolled), identifying space to conduct and schedule the MTM visit, contacting PCPs with medication recommendations, telephone follow-up using lengthy symptom questionnaires with variability in patients' recall of clinic/emergency department visits or hospitalizations, and a paper-based data collection system. A description of the MTM intervention and tool kit with copies of the study forms is available on the Agency for Healthcare Research and Quality website.[5]

Our enrollment challenges are similar to those experienced by pharmacy benefit managers (PBMs) in contacting a population at high risk for a medication-related adverse event due to multiple chronic conditions and medications. MTM interventions by PBMs who contact eligible patients by phone or mail also experience low participation by highly motivated patients and even lower participation by patients who would most benefit from pharmacy coaching.[6,7] A medication review survey packet mailed to 4000 US Department of Defense beneficiaries resulted in 1469 responses (38.1%) to the consent letter, 606 consents (15.7%) to participate, and 373 (9.3%) completed surveys.[8] In this study, mailed letter and telephone contact resulted in less participation (13%) than recruitment from within the clinic during existing appointments (30%-35%). Interestingly, about 70% of eligible patients stated that they were not interested in study participation. Non-participation is likely due to the presence of a consent form, required study visits, and telephone follow-up. Participation rates in a real-world community MTM intervention will hopefully be higher if conducted outside the context of a clinical research project.

These findings provide specific opportunities to improve the design of future MTM studies and disseminate and implement MTM within the community setting. Under study design considerations, recruiting at-risk patients during an existing clinical appointment and delivering the MTM intervention on the same day can reduce participant burden (removes the need for a visit on a separate day or location) and allow the pharmacist to contact the prescriber onsite (not via facsimile) with any newly identified problems related to medication. Flexibility for the MTM pharmacist to decide whether a second MTM visit (or additional visits for complex cases) is required and whether it is done in person or by phone can optimize the effectiveness and efficiency of visits. Lengthy patient-reported outcome surveys (drug-related adverse event reporting, satisfaction, etc) should be shortened to facilitate administration by phone or at a follow-up clinic visit. Healthcare utilization (clinic or emergency department visits, hospitalizations) is better obtained from review of an electronic health record than from patient recall. Finally, the use of a web-based data entry system is preferred to transmitting paper forms to a central location.

For the dissemination and implementation of this MTM intervention within a usual care setting, the ideal situation would be the colocation of a clinical pharmacist within the primary care clinic to deliver the intervention at the point of care. Incorporating this pharmacist as a team member within the patient-centered medical home may be feasible in integrated health systems. Smaller independent practices without the resources required for a dedicated pharmacist may consider collaboration with the MTM clinicians from PBMs, as long as this includes communication from the PCP to the patient about the importance of participation to reduce ADEs. In a usual care setting, the barriers of patient consent and lengthy study-related forms would be removed; therefore, we expect that patient buy-in would be greater than within a trial. Creation of a quality improvement strategy to reduce drug-related problems by implementing MTM would allow prospective measurement of the intervention over time.

In summary, we found that implementation of MTM services not directly linked to a primary care visit (either geographically or temporally) resulted in lower participation by patients and providers. Therefore, participation in future MTM studies or usual care implementation can be improved by integrating these MTM services within the clinic during existing appointments by a pharmacist familiar to the primary care provider.

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Appendix A. Modified PCNE Drug Assessment Form

Form Approved
OMB No. 0935-0136
Exp. Date 11/30/2010

For every drug the patient is receiving, assess each of the following DRPs. *Mark all that apply* .

STUDY ID:_____ DATE: _____ □ Visit #1 □ Visit #2
Patient Name: Date:

General Drug Related Problem: check box if "yes"	Specific Drug Related Problem (Modified PCNE Problem Code)	Yes? (circle)	Cause Code/comments
☐ **1. The patient is having an adverse drug event (ADE) as a result of the drug.**	a. Is the ADE an allergy? (1.1) b. Is the ADE a non-allergic reaction? (1.2) c. Is the ADE a toxic reaction to the drug? (1.3)	A B C	

Medication	Problem Identified	Action/plan/recommendation	RPH	Date Resolved	RPH
1.					
2.					
3.					

☐ **2. There is a problem with the choice of the drug for the indication in this patient.**	a. Is the drug not appropriate for the indication given this patient's specific characteristics? (2.1)	A	
	b. Is the drug dose form not appropriate for the indication? (2.2)	B	
	c. Is the drug an inappropriate therapeutic duplication of another drug taken by the patient? (2.3)	C	
	d. Does the patient have a contraindication for the drug? (2.4)	D	
	e. Is there no clear indication for use of the drug in this patient? (2.5)	E	
	f. Is there an untreated indication for which drug therapy is available? (2.6)	F	

Medication	Problem Identified	Action/plan/recommendation	RPh	Date Resolved	RPH
1.					
2.					
3.					

☐ **3. There is a problem with the drug dose being taken by the patient.**	a. Is the dose too low or prescribed at too low of a frequency? (3.1) b. Is the dose too high or prescribed at too high of a frequency? (3.2) c. Is the duration of treatment too short? (3.3) d. Is the duration of treatment too long? (3.4)	A B C D	

Medication	**Problem Identified**	**Action/plan/recommendation**	**RPh**	**Date Resolved**	**RPH**
1.					
2.					
3.					

☐ **4. The patient is having difficulties with taking the drug.**	a. Is the patient not taking the drug enough or at all? (4.1) b. Is the patient receiving the incorrect drug (dispensing error)? (4.2)	A B	

Medication	**Problem Identified**	**Action/plan/recommendation**	**RPH**	**Date Resolved**	**RPh**
1.					
2.					
3.					

☐ **5. The patient is having or at risk for a significant drug interaction.**	a. Is the patient at risk for a potential drug interaction? (5.1) b. Is the patient suffering from an actual drug interaction? (5.2)	A B	

Medication	**Problem Identified**	**Action/plan/recommendation**	**RPh**	**Date Resolved**	**RPh**
1.					
2.					
3.					

☐ **6. There are other problems the patient is having with their drug therapy.**	a. Is the patient dissatisfied with the drug, despite taking it correctly? (6.1) b. Does the patient have knowledge deficits that are affecting the drug therapy? (6.2) c. Does the patient have unclear complaints requiring further investigation? (6.3) d. Is the therapy found to be ineffective in this patient? (6.4)	A B C D	

Medication	**Problem Identified**	**Action/plan/recommendation**	**RPh**	**Date Resolved RPh**
1.				
2.				
3.				

☐ **7. The patient is at risk for a potential ADE.**	a. Does the patient have an allergy to the drug or similar drug? (7.1) b. Has the patient had an ADE to a similar drug? (7.2)	A B	

Medication	**Problem Identified**	**Action/plan/recommendation**	**Rph**	**Date Resolved RPh**
1.				
2.				
3.				

- Insert 1 or more Cause Code for every affirmative DRP using the PCNE DRP Causes List (attached)

Pharmacist initials

_____ _____

_____ _____

_____ _____

Appendix B. Telephone Interview Questions for Assessing Adverse Drug Events

Form Approved
OMB No. 0935-0136
Exp. Date 11/30/2010

STUDY ID:_____ DATE: _____ □ Visit #1 □ Visit #2

Part A

During the last 3 months, have you had any of the following symptoms which you think may be side effects caused by one of your medications?

1. Have you had any of the following symptoms which you think may be due to side effects from a medication related to your skin?

   a bleeding
   b bruising
   c burning sensation
   d flushing of skin/ hot flush
   e increased sensitivity of skin to light
   f itching of skin
   g pale skin
   h puffy skin
   i pins and needles sensation
   j skin rash
   k yellowing of skin
   l Other (*please indicate)*_____
   m None

2. Have you had any of the following symptoms which you think may be due to side effects from a medication related to your hair or nails?

   a change in fingernails
   b hair loss
   c Other *(please indicate)* _____
   d None

3. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your muscles, bones or joints?

   a bone or joint pain
   b muscle pain
   c muscle weakness
   d trembling & shaking of fingers & hands
   e unsteadiness on feet
   f unusual or uncontrolled body movement
   g Other *(please indicate)* _____
   h None

4. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your head?

   a headache
   b migraine headache
   c Other *(please indicate)* _____
   d None

5. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your vision?

   a blurred vision
   b double vision
   c Other *(please indicate)* _____
   d None

6. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your eyes?

   a itchy or irritated or inflamed eyes or eyelids
   b inability to move eyes
   c unusual movement of the eyes
   d Other (please indicate) _____
   e None

7. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your hearing or ears?

   a change or difficulty in hearing
   b feeling of fullness in the ears
   c ringing, buzzing or noises in ears
   d Other *(please indicate)* _____
   e None

8. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your mouth or gums?

a bleeding from gums
b dry mouth or throat
c Other *(please indicate)* _____
d None

9. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your nose, throat, neck or voice?

a difficulty talking
b slurred speech
c runny or stuffy nose
d sore throat
e Other *(please indicate)* _____
f None

10. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your breathing or lungs?

a cough
b difficulty breathing
c fast breathing
d slow breathing
e Other *(please indicate)* _____
f None

11. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your heart or circulation?

a palpitations/ racing heart
b missed heart beat
c Other *(please indicate)* _____
d None

12. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your stomach or digestive system?

a bloated feeling or gas
b decrease in appetite
c indigestion or heartburn
d increase in appetite
e pain or cramps in lower abdomen
f nausea or vomiting
g vomiting blood or material that looks like coffee grounds
h Other *(please indicate)* _____
i None

13. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your rectum or bowel movements?

a black tarry stool
b constipation
c diarrhoea
d Other *(please indicate)* _____
e None

14. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your kidneys, bladder or urinary system?

a burning, discomfort or pain while passing water
b dark brown urine
c difficulty in passing water
d passing water less often
e passing water more often
f bloody urine
g Other *(please indicate)* _____
h None

15. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your sexual function (ability)?

a decrease in sexual desire
b decrease in sexual ability
c increase in sexual desire
d Other *(please indicate)* _____
e None
f Does not apply

16. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your reproductive (sex) organ?

a abnormal or change in vaginal bleeding
b burning or irritated penis
c Other *(please indicate)* _____
d None

17. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your nervous system?

a confusion or delirium
b light-headed when getting up from a lying or sitting position or feeling faint
c dizziness or staggering (vertigo)
d increase in convulsions (seizures)
e Other *(please indicate)* _____
f None

18. Have you had any of the following symptoms which you think may be due to side effects from this medicine related to your mental health?

a anxiety (nervousness) or agitation
b change in mood
c difficulty concentrating or learning
d hallucinations (seeing, hearing or feeling things that are not there)
e nightmares
f anger or aggression
g loss of memory
h thought of suicide
i reduction in sleeping
j increase sleep or drowsiness
k Other *(please indicate)* _____
l None

19. Have you had any of the following symptoms which you think may be due to side effects from this medicine?

a increased sensitivity to cold
b excessive thirst
c fever
d flu-like symptoms
e increase sweating
f unusual tiredness or weakness
g weight gain
h weight loss
i Other *(please indicate)* _____
j None

Total Number of Symptoms Identified in Part A: _____ (fill in this number of Part B forms).

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Part B

For each symptom reported, ask the following questions (complete one Part B form for each symptom reported in Part A):

1. What is the symptom being reported on this form? _____

2. Where is the symptom located (from form A)?

a skin
b hair, nails
c muscles, bones, joints
d head
e vision
f eyes
g hearing, ears
h mouth or gums
i nose, throat or voice
j breathing or lungs
k heart or circulation
l stomach or digestive system
m rectum or bowel movements
n kidneys, bladder, urinary
o sexual function
p reproductive organ
q nervous system
r mental health
s general/constitutional

3. What medication(s) do you believe is causing the problem?

_____

_____

_____

4. How much has this symptom(s) bothered you at its worst ?
a minimally
b mildly
c moderately
d severely
e very severely
f does not apply

5. Have you told your doctor about this symptom?
a yes (go to question 6)
b no (go to question 7)
c does not apply

If the patient told the doctor about the symptom:

6. In response to your symptom, did the doctor recommend any of the following actions?
a The doctor did laboratory tests.
b The doctor recommended continuing taking medication exactly as before.
c The doctor recommended stopping the medication.
d The doctor prescribed another medication.
e The doctor changed the prescription in some other way.
f The doctor prescribed another drug to treat the side effect.
g The doctor told you to do something else to treat the side effect.

7. In response to your symptom, did what action did you take?
a Continued to take medication as before. (End of survey; go to next symptom)
b Changed the dosage. (End of survey; go to next symptom)

c Stopped taking the drug. (Go to question 8)

If patient has stopped taking medication:

8. When did you stop this medication? (__ __ / __ __) month / year

9. Why did you stop?
   a I felt I didn't need it any longer
   b The doctor said I didn't need it any longer
   c The doctor told me to stop because I was having problems with it
   d I decided to stop because I was having problems with it
   e I felt it wasn't helping me
   f Other (please explain)

10. Has the symptom you have described gone away?
    a yes b no c does not apply

(End of survey; fill out another Part B for each reported Part A symptom)

Appendix C STUDY ID:_____ DATE:_____ ☐ Visit #1 ☐ Visit #2

Form Approved
OMB No. 0935-0136
Exp. Date 11/30/2010

Medication Therapy Management Study – Clinical Records for Clinician Pharmacist

Date: / /

Name: _____
Last *First* *Middle*

Site: ☐ Baylor ☐ Duke ☐ UIC

Primary Care Physician: _____

Patient ID: _____

PCP Phone Number: ( ) -

DOB: / /

PCP Fax Number ( ) -

Height: _____ ☐ inch ☐ cm **Weight**: _____ ☐ lbs ☐ kg

Pharmacy Name:

Pharmacy Phone: ( ) -

Allergies

Drug: ☐ PCN ☐ Sulfa Other: _____ **Food:** ☐ Sulfite ☐ Shell Fish Other: _____

Medical History (check where applicable):

☐	Anemia	☐	Dermatophytosis	☐	Hypertension	Other(s):	
☐	Asthma	☐	Diabetes Mellitus	☐	Hypokalemia		
☐	Atrial Fib/Atrial Flutter	☐	DVT/PE	☐	Kidney Transplant		
☐	Chronic Renal Failure	☐	Gastric Ulcer	☐	Myocardial Infarction		
☐	Constipation	☐	GERD	☐	Obesity		
☐	COPD	☐	Heart Failure	☐	Osteoarthritis		
☐	Coronary Artery Disease	☐	Hepatitis	☐	Osteoporosis		
☐	Depression	☐	Hyperlipidemia	☐	Stroke/CVA		

Most Recent Laboratory Values:

Chemistries

Date Lab Drawn: / /
Na (mEq/L)
K (mEq/L)
Glucose (mg/dL)
Creatinine (mg/dL)
BUN (mg/dL)

Liver Function Tests

Date Lab Drawn: / /
AST (U/l)
ALT (U/l)

Coagulation

Date Lab Drawn: / /
INR:
Goal INR:

Complete Blood Count

Date Lab Drawn: / /
Hemoglobin (g/dL)
Hematocrit (%)
WBC (/ul)
Platelets (/mcl)

Lipid Panel

Date Lab Drawn: / /
TC (mg/dL)
LDL (mg/dL)
HDL (mg/dL)
TG (mg/dL)

Thyroid Panel

Date Lab Drawn / /
TSH (µIU/ml)

Vitals

BP: _____/____ HR ___ Date / /
BP: _____/____ HR ___ Date / /

Diabetes

Date Lab Drawn: / /
HbA1C (%)

Drug Levels: (name)

Date Lab Drawn / /
Level:
Goal:

MTM Clinic Only:

CrCl (ml/min)

Specialist Name:
Phone #: ( ) -

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NOTES:

	Medication Name *Generic (trade)*	**Strength** ***Dosage Form and #*** ***tabs*** *(Ex: 25 mg x2)*	**Frequency** *(Ex: qday, bid, tid, qid, qod)*	**Indication** *(Ex: DM,HTN, etc.)*	**Initiation of Drug** *≤ 30 days, 1-6 months, > 6 months*	**Last Titration Date**	**Prescriber Name**	**Source** *Medical Record (MR), Patient (Pt),Caregiver (Cg), or Other (Oth)*	**Is pt. taking the drug?** *(reported by pt)*	**How is pt taking the drug?** **(Ex: am/pm) (reported by pt.)**
1					□ ≤30d □1-6m □ >6m	mm/dd/yy		□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
2					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
3					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
4					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
5					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
6					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
7					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
8					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
9					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
10					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	

Note: Use another form if additional medications need to be entered.

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	Medication Name *Generic (trade)*	**Strength** ***Dosage Form and #*** ***tabs*** *(Ex: 25 mg x2)*	**Frequency** *(Ex: qday, bid,* *tid, qid, qod)*	**Indication** *(Ex: DM,HTN, etc.)*	**Initiation of Drug** *≤ 30 days, 1-6 months, > 6 months*	**Last Titration Date**	**Prescriber Name**	**Source** *Medical Record (MR), Patient (Pt),Caregiver (Cg), or Other (Oth)*	**Is pt. taking the drug?** *(reported by pt)*	**How is pt taking the drug?** **(Ex: am/pm) (reported by pt.)**
_1					□ ≤30d □1-6m □ >6m	mm/dd/yy		□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_2					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_3					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_4					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_5					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_6					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_7					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_8					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_9					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_0					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_1					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_2					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_3					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_4					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_5					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_6					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_7					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_8					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_9					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	
_0					□ ≤30d □1-6m □ >6m			□ MR □ Pt □ Cg □ Other	□ 0-30% □ 30-80% □>80%	

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