Who is at Risk: Identifying Patients in Need of Medication Therapy Management

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Introduction

Medication therapy management (MTM) services, introduced in Medicare Part D in 2006, are designed to address medication-related problems.[1] These services have since been provided to a growing number of patients nationally in both Medicare and non-Medicare populations. Part D MTM plans are required to target beneficiaries using multiple Part D drugs, having multiple chronic diseases, and having Part D drug costs exceeding approximately $3,000 annually. In 2013, "multiple drugs" is defined as no fewer than two but no more than eight Part D drugs. No more than three comorbid chronic conditions can be required for MTM eligibility and plans that choose to target specific disease states must target at least five of nine specific chronic conditions.[2] Various risk factors for medication problems have been identified, including those available in a medical chart (e.g., number of medications) and incorporated into risk assessment tools.[3-9] However, some patients with these risk factors may be managing their medications well and not be in need of MTM while some of those without may still benefit from MTM. Furthermore, including the patient's perspective (e.g., through the use of self-administered questionnaires) on how their medications are working for them may provide additional insights into risk for problems.

Some such tools have previously been described but have limited published evaluations of their psychometric properties as medication-related problem (MRP) predictors or have only been studied in patient populations limited by age or specific disease state[10-15] Therefore, further evaluation of self-administered MRP risk assessment tools is warranted. To this end, the objective of this study was to examine the utility of a self-administered questionnaire assessing patient perceptions related to all MRP types as an indicator of MRPs in a general, ambulatory patient population.

Methods

We selected Blalock's Drug Therapy Concerns Questionnaire (DTC) for further evaluation as a self-administered medication risk assessment tool.[16] This instrument was selected because its item domains included those from a well-accepted taxonomy for MRPs,[17] it was discovered during our early literature searches, and its developer was willing to discuss and share information with our team.

Phase 1: Modification of Drug Therapy Concerns Scale

Data Collection

We administered the original 78-item DTC (Appendix A) to a sample of adults (aged 18 years and older) using at least one prescription medication daily. All data were collected anonymously and the study protocol received exempt approval status by the University of Pittsburgh Institutional Review Board. Using quota sampling techniques,[18] potential respondents were recruited at community pharmacies (n=8) and community health centers (n=2) located within two counties in Pennsylvania over a period of approximately four months. At each location, a member of the research team was seated at a table with a sign indicating that interested persons could approach to inquire about participation. Patients were screened for participation by completing an 8-question demographics survey. Patients were eligible for inclusion if they were 18 years of age or older, taking at least one regularly scheduled prescription medication, and were within an age/sex category necessary to fill the quotas determined a priori. Age/sex quotas were developed using 2006 United States census data as a guide.[19] Recruitment procedures and completion of the scale required approximately 10-20 minutes, with a few

participants needing more time. Respondents completing at least part of the DTC received a $5 gift card to compensate them for their time.

Data were coded and entered into a Microsoft Excel file (v. 2007) by a research assistant. The dataset was then reviewed for accuracy and "cleaned" by the principal investigator (MES) by examination of the data set for out-of-range or impossible responses, data entry errors, and appropriateness of missing data labels. Subsequent analyses were then performed using SPSS.

Data Analysis

Three investigators (MES, KSP, KSH) reviewed the original item pool and narrowed it down to 15 items (Appendix B) that maximized clinical utility (i.e., applicable to most chronic medications) and reduced redundancy among items (one of our critiques of the published 25-item DTC). Notes made by patients on their surveys were also taken into consideration. Exploratory factor analyses (principal components analysis) examining both one- and two-component solutions were then computed for this item set and used to remove poor items based on item loadings. The final 9-item modified version of the DTC considered in subsequent analyses is in Appendix C. Descriptive statistics were also computed to characterize the study population.

Phase 2: Estimating the Utility of the Modified DTC for use as MRP Predictor

Data Collection

Patients were recruited from two community pharmacy locations in Lancaster County, PA. Eligible patients were those 18 years of age and older taking at least one scheduled prescription medication for a chronic condition, able to complete all study procedures, and were not pregnant. Initial contact with patients was made by an approach by a member of the pharmacy staff; only patients believed to meet all study eligibility criteria were approached. Interested patients were then asked to provide authorization for their laboratory records to be provided to the pharmacist for the purposes of the study and were scheduled to meet with their pharmacist. After providing informed consent, patients completed a demographics questionnaire (Appendix D) and the modified 9-item version of the DTC and placed their completed documents in a sealed envelope. They were then engaged in a comprehensive medication review by their pharmacist (who was blinded to the patients' scores on the DTC), in a private area, who documented the presence and type of any MRPs identified. (Appendix E.) Laboratory data, if available, were used by the pharmacist during the medication assessment. For completing the questionnaires and participating in the medication review, patients received a $25 gift certificate. Pharmacists forwarded all study documents to the Principal Investigator; no protected health information or other identifiable data were shared. Upon receipt, study documents were reviewed for completeness and data were entered into SPSS v 19.0 for analysis.

A total of three community pharmacists (who routinely practice together at the community pharmacy) participated in data collection. To promote consistency across MRP documentation, prior to commencement of data collection each pharmacist independently completed five fictitious patient cases and documented identified problems in the same manner as required for study patients. We then reviewed their responses and discussed specific discrepancies in a conference call between the pharmacists and the principal investigator. This training was

treated as a separate study protocol and pharmacists provided informed consent. The protocol was approved by the University of Pittsburgh and Purdue University Institutional Review Boards.

Data Analysis

Descriptive statistics were computed to characterize the study population. We also computed item statistics (i.e., means, medians, frequencies of endorsement of each response option, item-total correlations, item-criterion correlations) and a reliability estimate (Cronbach's alpha) for the modified DTC. The construct validity of the modified scale was also evaluated through exploratory factor analyses. To examine the relationship between scores on the DTC and the presence of medication-related problems, we computed a Spearman's correlation coefficient.

We also assessed relationships between potential predictors of MRPs (determined a priori) and the presence of MRPs. These variables included: age, sex, race, education level, marital status, number of prescription, non-prescription, and vitamin/herbal medications, total number of medication doses per day, description of household income, and self-reported ability to pay for medications. These associations were evaluated using correlations and t-tests as appropriate. Variables with significant or borderline significant (i.e., $p < 0.2$) associations with MRPs were then entered into a multivariate regression model to model associations between the variables and the number of MRPs detected. Insignificant predictor variables in the model were then removed manually until the simplest model explaining the most variability in MRPs was determined. This model was then evaluated sequentially to determine the change in R^2 when scores on the DTC were entered into the model, after controlling for other significant predictors.

Additionally, predictors of MRPs within each broad category of problem (i.e., indication, effectiveness, safety, adherence) were also evaluated first through bivariate statistics (t-tests, Wilcoxon rank sum tests, and chi-squared tests as appropriate) and then by constructing logistic regression models where the presence of one or more problems within the specified category was the dependent variable. Finally, we constructed a receiver-operator characteristic (ROC) curve to examine the sensitivity and specificity of various cutpoints (i.e., scores) on the modified DTC (with items reverse scored as appropriate) for use as a "positive screen" for MRP risk. For all analyses except when noted, a $p < 0.05$ was considered statistically significant.

Results

Phase 1

Sample characteristics for Phase 1 (n=394) are summarized in Table 1. Participants were generally Caucasian females, using approximately 4 medications, with at least a high school education, with an average age of approximately 51 years. In evaluating the structure of the modified DTC using exploratory factor analyses, a one-component solution was found that was clinically logical and exhibited reasonable communalities and factor loadings (Table 2.) This item set was then utilized in Phase 2.

Phase 2

Sample characteristics for Phase 2 (n=200) are summarized in Table 3. Participants were generally married Caucasian females, with at least a high school education, using approximately 6 prescription medications. The majority (n=187, 93.5%) had at least one MRP

identified by the pharmacist and the most prevalent type of MRP was indication-related problems, which were detected in 78% of participants. All types of MRPs documented are defined in Appendix E. Item statistics are reported in Table 4. The "best" performing items were 3 and 4 as these items had means closest to 3.0 and statistically significant correlations between these item scores and total scores on the DTC and the number of MRPs detected.

The reliability estimate for the scale was sufficient, with a computed Cronbach's alpha of 0.823 (Table 4.) In examining both one- and two-component factor solutions for the items, a one-component solution represented the most appropriate fit when examining the items for clinical meaning and their communalities and factor loadings (Table 5.)

Scores on the DTC were significantly correlated with the number of MRPs detected, with higher scores correlating with more problems ($r = 0.24$, $p < 0.01$). In addition to DTC scores, variables significantly associated ($p < 0.2$) with number of MRPs detected on bivariate tests included: marital status, education level, income, ability to pay for medications, total number of prescription medications, total number of vitamins/supplements/herbals, and total number of daily medication doses. After removing "ability to pay" and total number of prescription medications from the multivariate regression model due to significant correlations with income and daily medication doses, respectively, and lower R^2 values when these variables were included, we constructed a statistically significant multivariate regression model that modeled associations among predictor variables and number of MRPs detected (Table 6.)

Scores on the DTC were associated with whether the patient had one or more safety problems ($p < 0.1$.) Other significant associations on bivariate tests were found for: total number of prescription medications, income, and total number of daily medication doses. These predictor variables were used to construct a logistic regression model with one or more safety problems as the dependent variable. Scores on the DTC did not remain a significant predictor of safety problems when controlling for other predictor variables in the regression (data not shown.)

Scores on the DTC were associated with whether the patient had one or more adherence problems ($p < 0.01$.) Other significant associations on bivariate tests were found for: age, sex, marital status, total number of prescription medications, income, ability to pay for medications, and total number of daily medication doses. These predictor variables were used to construct a logistic regression model with one or more adherence problems as the dependent variable. Scores on the DTC did not remain a significant predictor of adherence problems when controlling for other predictor variables in the regression (data not shown.)

DTC scores were not associated with indication- or effectiveness-related problems on bivariate tests.

The ROC curve (Figure 1) produced a significant area under the curve (area= 0.782, p= 0.001; 95% CI: 0.661-0.903.) Coordinates of the curve are presented in Table 7. Scores presented are those with items 1-8 on the modified scale reverse-scored so that higher scores on the scale are associated with more MRPs.

Discussion & Limitations

Our findings suggest that the use of the modified DTC serves as a statistically significant, although fairly modest, predictor of MRPs when controlling for other significant predictors of problems. There is a potential for clinical utility; highlighting that patient-reported data (i.e., information not routinely available in a medical chart) may offer some benefit in identifying

patients' risk for MRPs beyond MTM eligibility criteria used routinely, such as number of medications. However, the role of DTC scores might be limited and further study of the instrument is warranted. This is especially the case if the goal of the user is to ultimately predict indication- or effectiveness-related problems as DTC scores were not associated with these problem types in particular. Furthermore, as some of the items on the DTC "performed" poorly more work is needed to examine the psychometric properties of this scale in other samples. In addition, more research is needed in general with regards to identifying predictors of MRPs as our regression model only explained approximately 20% of the variability in numbers of MRPs in this sample. Individuals choosing to utilize the DTC in practice as a potential screen for MRPs could consider a score of 15 as a reasonable starting place for a definition of a "positive screen", i.e., an individual with higher risk of MRPs. Using this score, the DTC exhibits an approximate sensitivity and specificity of identifying patients with at least one MRP of between 81-86% and 61%, respectively.

There were several limitations to this study. First, the sampling approach for Phase 1 was quota sampling. Although this improved on the heterogeneity of the sample as reported in previous assessments of the DTC,[16] it was not without problems. Due to the concurrent collection of data at multiple sites, quotas were not precisely met and we struggled to enroll younger males in particular. Furthermore, Phase 2 enrolled a convenience sample. In addition, as data for Phases 1 and 2 were collected at some of the same sites, it is possible that some patients participated in both phases of the research. Finally, although pharmacists completed fictitious patient cases for practice and discussion prior to data collection to maximize consistency among the group, it is important to note that our outcome measure (i.e., number and type of MRPs detected) could be dependent on the pharmacists participating and it is possible that different results could have been found in a study with other pharmacists conducting the medication assessments.

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Table 1. Phase 1 Participant Characteristics

Characteristic		Result
Age, mean (range)		50.9 (18-90)
Male sex, n (%)		174 (44.2)
Number of Medications Used Daily, median (range)		4 (1-22)
Race/Ethnicity, n (%)	White/Caucasian	313 (80.1)
	Black/African-American	65 (16.6)
	Hispanic	7 (1.8)
	Asian	3 (0.8)
	Other	3 (0.8)
Highest Education Received, n (%)	Grade School	10 (2.6)
	High School	156 (40.8)
	College	139 (36.4)
	Graduate/Professional School	77 (20.2)
Annual Income, n (%)	0-$20,000	125 (35.4)
	$20,001-$40,000	91 (25.8)
	$40,001-$60,000	58 (16.4)
	$60,001+	79 (22.4)
Language spoken at home, n (%)	English	384 (97.5)
	Bilingual	7 (1.8)
	Other	3 (0.8)

Table 2. 1-Component Solution of Reduced Item Set, Accounting for 38% Variance[a]

Item	Mean (SD)[b]	Communality	Factor Loadings
My medication is helping improve my condition	2.02 (0.778)	0.23	0.48
My medication does not seem to help that much[c]	1.84 (0.94)	0.32	0.56
Sometimes I think I take too many medications[c]	2.58 (1.3)	0.37	0.61
Sometimes I think I may not be taking the right medication for my condition[c]	2.32 (1.06)	0.39	0.63
Sometimes my medication has effects I do not like[c]	2.99 (1.32)	0.41	0.64
Sometimes I feel worse after I take my medication[c]	2.18 (1.09)	0.50	0.71
I worry about drug interactions between the medications I take[c]	2.80 (1.25)	0.35	0.59
My medication interferes with my routine daily activities[c]	1.99 (1.03)	0.54	0.74
I have trouble taking my medication the way I am supposed to[c]	2.09 (1.04)	0.31	0.56

a: Total n= 394, however not every respondent answered each question. For this analysis, n=358.
b: 1= Strongly agree, 2= Agree, 3= Not Sure, 4= Disagree, 5= Strongly Disagree
c: Reverse-scored so that higher scores on scale are associated with more MRPs.

Table 3. Characteristics of Phase 2 Participants

Characteristic	Result	
Age, mean (range)	64.8 (19-93)	
Sex, n (%) male	69 (34.5)	
Race, n (%)	Caucasian	192 (96.5)
	African-American	3 (1.5)
	More than one race	4 (2)
Marital status, n (%)	Single, living alone	19 (9.5)
	Single, living with partner	6 (3)
	Single, living with friend/relative	4 (2)
	Married	123 (61.5)
	Separated/divorced	14 (7)
	Widowed	34 (17)
Highest education received, n (%)	Grade/middle school	18 (9.1)
	High School or GED	96 (48.7)
	Some college or community college/trade school	53 (26.9)
	Bachelor's	19 (9.6)
	Graduate or professional school	11 (5.6)
Income, n (%)[a]	Comfortable	108 (54.5)
	Just enough to make ends meet	74 (37.4)
	Do not have enough to make ends meet	16 (8.1)
Difficulty paying for medications, n (%)[b]	Strongly agree	21 (10.7)
	Agree	46 (23.4)
	Not sure	19 (9.6)
	Disagree	77 (39.1)
	Strongly disagree	34 (17.3)
Number of prescription medications, median (range)	6 (1-19)	
Number of non-prescription medications, median (range)	1 (0-7)	
Number of vitamins, herbals, supplements, median (range)	1 (0-23)	
Total number of daily doses of medication, median (range)	9 (1-32)	
Number of medication-related problems, median (range)	2 (0-8)	
One or more indication problems, n (%)	156 (78)	
One or more effectiveness problems, n (%)	61 (30.5)	
One or more safety problems, n (%)	60 (30)	
One or more adherence problems, n (%)	68 (34)	

a: Item: "How would you describe your household income?"
b: Item: "It is difficult to pay for my medication."

Table 4. Item Statistics[a]

Item	Mean (SD)	Alternatives (n, % Endorsing)[c]	Item-total correlation (corrected)	Item-Criterion (Number of MRPs) Correlation
1[d]	2.69 (1.33)	1 (48, 24.1) 2 (55, 27.6) 3 (23, 11.6) 4 (57, 28.6) 5 (16, 8.0)	0.507[b]	0.108
2[d]	2.12 (1.05)	1 (64, 32.2) 2 (78, 39.2) 3 (31, 15.6) 4 (22, 11.1) 5 (4, 2.0)	0.500[b]	0.020
3[d]	2.89 (1.35)	1 (36, 18.1) 2 (52, 26.1) 3 (30, 15.1) 4 (59, 29.6) 5 (22, 11.1)	0.496[b]	0.258[b]
4[d]	2.73 (1.35)	1 (46, 23.1) 2 (56, 28.1) 3 (23, 11.6) 4 (53, 26.6) 5 (21, 10.6)	0.537[b]	0.230[b]
5[d]	1.93 (1.02)	1 (76, 38.2) 2 (89, 44.7) 3 (9, 4.5) 4 (21, 10.6) 5 (4, 2.0)	0.450[b]	0.134
6[d]	1.98 (0.98)	1 (70, 35.2) 2 (89, 44.7) 3 (15, 7.5) 4 (24, 12.1) 5 (1, 0.5)	0.671[b]	0.094
7[d]	2.17 (1.04)	1 (60, 30.2)	0.669[b]	0.174[b]

		2 (76, 38.2) 3 (37, 18.6) 4 (22, 11.1) 5 (4, 2.0)		
8[d]	1.93 (0.92)	1 (68, 34.2) 2 (98, 49.2) 3 (14, 7.0) 4 (17, 8.5) 5 (2, 1.0)	0.649[b]	0.077
9	2.11 (0.90)	1 (49, 24.6) 2 (98, 49.2) 3 (38, 19.1) 4 (10, 5.0) 5 (4, 2.0)	0.321[b]	0.189[b]
Total Score on DTC, median (range)[e]			20.5 (9-40)	

a: Cronbach's alpha: 0.823

b: $p < 0.01$

c: Measured on scale where 1= strongly agree, 2= agree, 3= not sure, 4= disagree, 5= strongly disagree

d: Reverse-scored so that higher scores are associated with more MRPs

e: Possible scores range from 9-45

Table 5. 1-Component Solution of Modified DTC, Accounting for 43% Variance[a,]

Item	Communality	Factor Loadings
My medication is helping improve my condition	0.179	0.423
My medication does not seem to help that much[b]	0.387	0.622
Sometimes I think I take too many medications[b]	0.350	0.592
Sometimes I think I may not be taking the right medication for my condition[b]	0.602	0.776
Sometimes my medication has effects I do not like[b]	0.411	0.641
Sometimes I feel worse after I take my medication[b]	0.626	0.791
I worry about drug interactions between the medications I take[b]	0.416	0.645
My medication interferes with my routine daily activities[b]	0.596	0.772
I have trouble taking my medication the way I am supposed to	0.329	0.573

a: 1= Strongly agree, 2= Agree, 3= Not Sure, 4= Disagree, 5= Strongly Disagree
b: Reverse-scored so that higher scores on scale are associated with more MRPs.

Table 6. Predictors of Medication-Related Problems

Dependent Variable	Significant Predictors (P-value)	Exp(B)
Total number of MRPs	Total number of vitamins, herbals, supplements (0.024)	-0.168
	Household income[b] (0.003)	3.023
	Total daily medication doses (< 0.001)	4.118
	Score on DTC (0.043)[c]	2.038

a: Overall model, $p < 0.001$, $R^2 = 0.203$ Also evaluated but removed from model: total number of non-prescription medications, marital status, and education level.

b: Item asked, "How would you describe your household income?; 1= comfortable, 2= just enough to make ends meet, 3= do not have enough to make ends meet."

c: Change in R^2 when adding DTC scores after controlling for other significant predictors: 0.019, p= 0.043

Table 7. Coordinates of the Curve

DTC Score	Sensitivity	1-Specificity
8.00	1.000	1.000
9.50	.935	.692
10.50	.919	.692
11.50	.914	.615
12.50	.903	.538
13.50	.876	.462
14.50	.855	.385
15.50	.812	.385
16.50	.763	.385
17.50	.720	.385
18.50	.651	.231
19.50	.586	.154
20.50	.522	.154
21.50	.473	.154
22.50	.414	.154
23.50	.366	.077
24.50	.306	.000
25.50	.237	.000
26.50	.172	.000
27.50	.145	.000
28.50	.097	.000
29.50	.081	.000
30.50	.059	.000
32.00	.048	.000
33.50	.022	.000
34.50	.016	.000
35.50	.011	.000
38.00	.005	.000
41.00	.000	.000

Figure 1. ROC Curve of Scores on Modified DTC as MRP Indicator
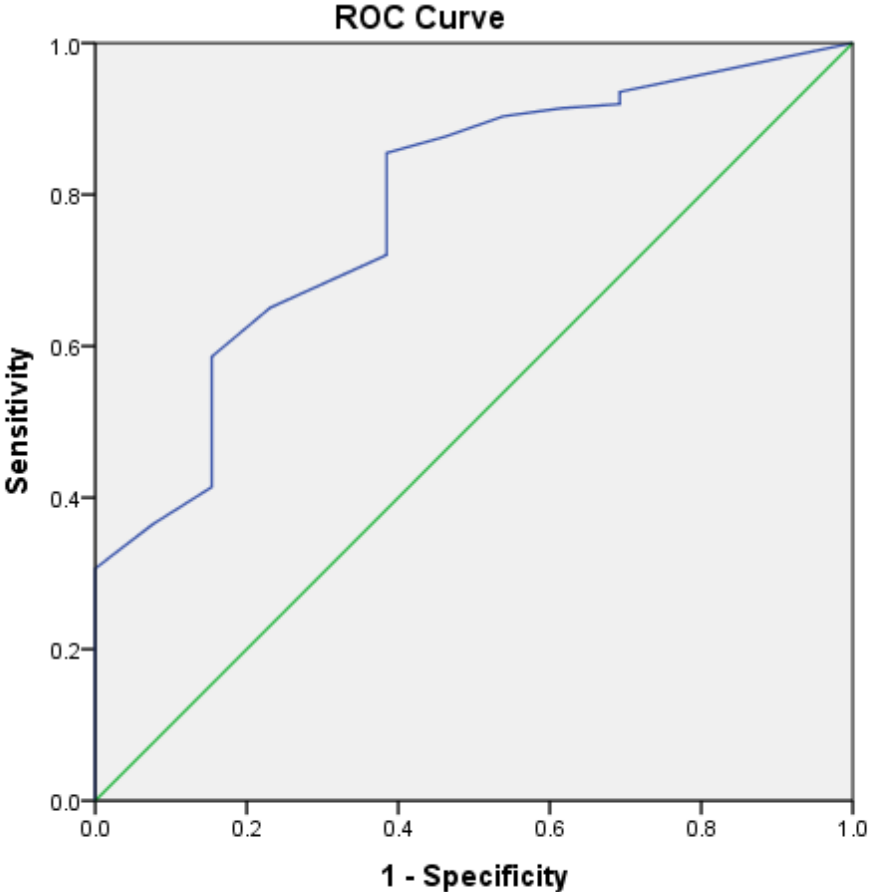
Diagonal segments are produced by ties.

Pharmaceutical Care Concerns Scale

Instructions: Please Read Carefully

We would like to learn more about the kinds of concerns people have about the medication(s) they take. Please take a minute and think about the medication(s) that you are **currently taking.**

In addition to prescription medications, think about any over-the-counter medications, vitamins or herbal medications you may be taking.

Be sure to think about all the different types of medications you are using. For example, this might include tablets, capsules, liquids, nasal sprays, eye or eardrops, oral inhalers, injections, suppositories, patches, creams, or ointments.

If you use more than one medication, please think about all of the medications you use as a group.

This questionnaire consists of a list of statements. For each statement, please circle the number that best describes how much you agree or disagree with the statement. **There are no right or wrong answers. We just want to know what you think.**

For each statement below, please indicate the extent to which you either agree or disagree with the statement by circling the appropriate number.

1. My medication does **not** seem to help that much that much…………………………………………

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

2. I do **not** need all the medication I take……………

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

3. Sometimes my medication has effects I do **not** like…………………………………………………

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

4. My medication interferes with my routine daily activities………..……………………………………

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

5. It is hard for me to get my prescriptions filled…………………………………………………

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

6. It is hard to remember to take my medication………………………………………………

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

7. I would like to know more about my medication…

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

8. My medication makes me feel better………………

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

9. Sometimes I think I take too many medications…

   | 1 | 2 | 3 | 4 | 5 |
   | Strongly Agree | Agree | Not Sure | Disagree | Strongly Disagree |

		1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
10.	I know all I want to about the medication I take…	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
11.	I worry about the long-term side effects that my medication may have………………………………	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
12.	I am uncomfortable taking my medication around other people……………………………………	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
13.	I dislike the paperwork involved in filling and refilling my prescriptions………………………	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
14.	I have trouble taking my medication the way I am supposed to……………………………………	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
15.	My medication helps me do the things that are important to me………………………………………	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
16.	I would like to take fewer medications……………	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
17.	Sometimes I feel worse after I take my medication	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
18.	Sometimes people seem uncomfortable when I take my medication…………………………………	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
19.	I dislike the way my medication tastes or smells….	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
20.	It would be easier to take my medication if I could get more at one time…………………………………	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree

		1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
21.	It is difficult to pay for my medication………………					
22.	I sometimes forget to take my medication……….					
23.	I understand why I am taking my medication……					
24.	I know everything about my medication that I need to……………………………………………………					
25.	My pharmacist has answered all my questions about my medication…………………………………					
26.	I wish that there were better medications for my condition……………………………………………					
27.	I wish that I did **not** have to take so much medication………………………………………………					
28.	My medication has **no** bad side effects……………					
29.	I have difficulty swallowing my medication………					
30.	Paying for my medication is not a problem………					
31.	I am **not** able to take my medication the way I am supposed to………………………………………					

		1	2	3	4	5
32.	I do **not** know how to tell if my medication is working……………………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
33.	I have difficulty taking my medication…………….	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
34.	My medication is helping improve my condition…	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
35.	My medication is absolutely essential……………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
36.	I worry that certain foods may interact with my medication…………………………………………….	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
37.	It is easy to remember when to take my medication…………………………………………….	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
38.	I am **not** sure how to tell if I am taking my medication correctly…………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
39.	I have noticed an improvement in my health since taking my medication………………………………..	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
40.	I would not take my medication unless I was certain that I needed it…………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
41.	I have no difficulty taking my medication…………..	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
42.	I worry about the short-term side effects of the medication I take……………………………………...	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree

		1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
43.	I do **not** like taking my medication………………….	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
44.	It is hard to follow the instructions about when to take my medication……………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
45.	I do **not** know what my medication is for…………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
46.	It is embarrassing to pick up my medication from the pharmacy………………………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
47.	It is easy to get my medication……..……………….	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
48.	My health has **not** improved since I started taking my medication………………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
49.	I do **not** feel that I need any of the medication I take…………………………………………………..	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
50.	I am **not** worried about the potential side effects of the medication I take…………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
51.	I rarely forget to take my medication………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
52.	Sometimes I do **not** get my medication because I do **not** have enough money………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
53.	I do **not** understand how my medication will help make me better…………………………………………..	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree

		1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
54.	It is convenient to take my medication…………….					
55.	My insurance does **not** cover my medication…….					
56.	I think the medication I am taking will improve my health………………………………………………..					
57.	I think I take too much medication………………….					
58.	Sometimes I do **not** get my medication because I have no way to get to a pharmacy………………….					
59.	The potential side effects of my medication worry me…………………………………………………..					
60.	I do **not** know what side effects my medications cause………………………………………………					
61.	I am worried that I will have to take my medication for the rest of my life……………………………..					
62.	It is hard to get to a pharmacy to get my medication…………………………………………					
63.	I believe that I am taking the best medication available for my condition…………………………….					
64.	I do not take my medication because I am worried about the side effects………………………………					

		1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
65.	I think that my medication is necessary……………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
66.	The potential side effects of my medication do **not** bother me at all…………………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
67.	I am **not** sure how to take my medication…………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
68.	I think my medication limits my ability to do certain things……………………………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
69.	I have no problems getting my medication………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
70.	I am **not** sure how much medication to take………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
71.	I worry about drug interactions between the medications I take……………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
72.	Sometimes I think I may **not** be taking the right medication for my condition…………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
73.	I could **not** live without my medication……………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
74.	My pharmacist has talked to me about my medication……………………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree
75.	My medication does **not** interfere with any of my normal daily activities…………………………………	Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree

		1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
76.	My medication helps me stay healthy…………….					
77.	I am **not** sure when to take my medication………..					
78.	I do **not** like the dosage form (e.g. pill, capsule, injection, etc.) of the medication I take…………....					
79.	Overall, I am satisfied with my medication(s)……					
80.	There is nothing that I would change about my medication(s)………………………………………					
81.	I am unhappy with my medication(s)………………					
82.	My medication(s) are excellent……………………					
83.	My medication(s) could be improved………………					

Finally, just a few questions about yourself:

1.   What is your age? _____

2.   Are you a male or a female (Circle one)?   MALE   FEMALE

3.   How many medications do you use? _____

4.   Which of the following types of medications do you use? (Please circle all that you use.)

A) Oral tablets or capsules   F) Nasal sprays

B) Eye drops   G) Ear drops

C) Oral inhalers   H) Injections

D) Suppositories   I) Skin patches

E) Creams or ointments   J) Other (Please specify type: _____)

5.   Do you usually get all of your medications from one specific pharmacy?

YES   NO

Appendix B. Original Items Selected for Inclusion in Phase 1 Analyses[a]

My medication does not seem to help that much that much
Sometimes my medication has effects I do not like
My medication interferes with my routine daily activities
I have trouble taking my medication the way I am supposed to
My medication helps me do the things that are important to me
Sometimes I feel worse after I take my medication
I sometimes forget to take my medication
I have difficulty taking my medication
My medication is helping improve my condition
My medication is absolutely essential
I know everything about my medication that I need to
I do not like taking my medication
I worry about drug interactions between the medications I take
Sometimes I think I may not be taking the right medication for my condition

a: All items have the following response options: 1= strongly agree, 2= agree, 3= not sure, 4= disagree, 5= strongly disagree

Appendix C. Modified DTC Scale

*A 25-item DTC was published in 2005: Blalock SJ, Patel RA. Drug therapy concerns questionnaire: initial development and refinement. *J Am Pharm Assoc.* 2005;45:160-169.

With the cooperation of Dr. Blalock, our project team used additional psychometric testing and clinical judgment to create a modified version of the DTC. This modified version will be used in the current protocol and will be limited for use in individuals using at least one prescription medication for a chronic condition.

Drug Therapy
Concerns Scale
(Modified Version- 4/10)

Instructions^: Please Read Carefully

We would like to learn more about the kinds of concerns people have about the medication(s) they take. Please take a minute and think about the medication(s) that you are **currently taking.**

In addition to prescription medications, think about any over-the-counter medications, vitamins or herbal medications you may be taking.

Be sure to think about all the different types of medications you are using. For example, this might include tablets, capsules, liquids, nasal sprays, eye or eardrops, oral inhalers, injections, suppositories, patches, creams, or ointments.

If you use more than one medication, please think about all of the medications you use as a group.

This questionnaire consists of a list of statements. For each statement, please circle the number that best describes how much you agree or disagree with the statement. **There are no right or wrong answers. We just want to know what you think.**

For each statement below, please indicate the extent to which you either agree or disagree with the statement by circling the appropriate number.

1. Sometimes my medication has effects I do not like.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
2. My medication does not seem to help that much.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
3. Sometimes I think I take too many medications.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
4. I worry about drug interactions between the medications I take.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
5. I have trouble taking my medication the way I am supposed to.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
6. Sometimes I feel worse after I take my medication.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
7. Sometimes I think I may not be taking the right medication for my condition.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
8. My medication interferes with my routine daily activities.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree
9. My medication is helping improve my condition.	1 Strongly Agree	2 Agree	3 Not Sure	4 Disagree	5 Strongly Disagree

^Instructions taken from original Drug Therapy Concerns Scale developed by Drs. Blalock and Patel. Please see above citation for published version of DTC.

Appendix D. Demographics

1. Age_____ years

2. Sex:
□₁ Male
□₂ Female

3. Are you Hispanic or Latino?
□₁ Yes
□₂ No

4. What is your race?
□₁ Caucasian/White
□₂ African-American/Black
□₃ Asian
□₄ American Indian/Alaska Native
□₅ Native Hawaiian/Other Pacific Islander
□₆ More than one race

5. Marital Status
□₁ Single, living alone
□₂ Single, living with partner
□₃ Married
□₄ Separated/Divorced
□₅ Widowed

6. Language spoken at home:
□₁ English
□₂ Spanish
□₃ Other_____

7. **Highest** level of education completed. **Please choose just one answer.**

□₁ Grade/Middle School   □₂ High School (12th grade) or G.E.D.

$\square_3$ Some College/Community College/Technical/Trade School

$\square_4$ College (Bachelor's) $\square_5$ Graduate (e.g., M.S., PhD)/Professional School (e.g., MD, DDS)

8. How would you describe your household income?

$\square_1$ Comfortable

$\square_2$ Just enough to make ends meet

$\square_3$ Do not have enough to make ends meet

9. It is difficult to pay for my medication.

$\square_1$ Strongly Agree

$\square_2$ Agree

$\square_3$ Not Sure

$\square_4$ Disagree

$\square_5$ Strongly Disagree

Appendix E. Pharmacist Assessment Form

INSTRUCTIONS: Please indicate the medication related problems (as defined below) that you identified during your MTM assessment. Please document each individual medication related problem separately in the spaces provided.

1. Total Number of **PRESCRIPTION** medications being used: _____

Of these total medications, how many was the patient instructed to take…

ONCE DAILY?_____

TWICE DAILY?_____

THREE OR MORE TIMES DAILY?_____

AS NEEDED (this means only when you feel you need it or have symptoms)?_____

2. Total Number of **NON-PRESCRIPTION** medications (items that are purchased without a doctor's prescription, examples are aspirin, ibuprofen, and acetaminophen) being used: _____

Of these total medications, how many does the patient take…

ONCE DAILY (regularly)?_____

TWICE DAILY (regularly)?_____

THREE OR MORE TIMES DAILY (regularly)?_____

AS NEEDED (this means only when you feel you need it or have symptoms)?_____

3. Total Number of **VITAMINS, SUPPLEMENTS, AND HERBAL MEDICATIONS** being used (non-prescription, examples are calcium/vitamin D, multivitamins, garlic, etc): _____

Of these total medications, how many does the patient take…

ONCE DAILY (regularly)?_____

TWICE DAILY (regularly)?_____

THREE OR MORE TIMES DAILY (regularly)?_____

AS NEEDED (this means only when you feel you need it or have symptoms)?_____

4. TOTAL number of medication-related problems identified _____

5. Types of medication-related problems identified:

Problem #	Type of Medication-Related Problem (e.g., A.4)
1	
2	
3	
4	
5	
6	
7	
8	

Problem Definitions

Medication Need	Category	Specific Type
Indication	Unnecessary drug therapy	**A.1** No valid medical indication for the drug therapy at this time **A.2** Multiple drug therapies are being used for a condition that requires single drug therapy **A.3** Medical condition is more appropriately treated with nondrug therapy **A.4** Drug therapy is being taken to treat an avoidable adverse reaction associated with another medication **A.5** Drug abuse, alcohol use, or smoking is causing the medical problem
Indication	Needs additional drug therapy	**B.1** Medical condition requires the initiation of drug therapy **B.2** Preventive drug therapy is required to reduce the risk of developing a new condition **B.3** Medical condition requires additional drug therapy to attain synergistic or additive effects
Effectiveness	Ineffective drug therapy	**C.1** Drug product is not the most effective product for the indication being treated **C.2** Medical condition is refractory to the drug product **C.3** Dosage form of the drug product is inappropriate **C.4** Drug is not effective for the medical problem
Effectiveness	Dosage too low	**D.1** Dose is too low to produce the desired response **D.2** Dosage interval is too

		infrequent to produce the desired response **D.3** Drug interaction reduces the amount of active drug available **D.4** Duration of drug therapy is too short to produce the desired response
Safety	Adverse drug reaction	**E.1** Drug product causes an undesirable reaction that is not dose-related **E.2** Safer drug product is required due to risk factors **E.3** Drug interaction causes an undesirable reaction that is not dose-related **E.4** Dosage regimen was administered or changed too rapidly **E.5** Drug product causes an allergic reaction **E.6** Drug product is contraindicated due to risk factors.
Safety	Dosage too high	**F.1** Dose is too high **F.2** Dosing frequency is too short **F.3** Duration of drug therapy is too long **F.4** Drug interaction occurs resulting in a toxic reaction to the drug product **F.5** Dose of the drug was administered too rapidly
Adherence	Noncompliance	**G.1** Patient did not understand instructions **G.2** Patient prefers not to take medication **G.3** Patient forgets to take medication **G.4** Drug product is too expensive for the patient **G.5** Patient cannot swallow or self-administer the drug product appropriately **G.6** Drug product is not available for the patient