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# Analysis of Drug Therapy Problems Identified by Community Pharmacists in Non-English Speaking Patients

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## Introduction

In 2008, pharmacy organizations established the five core elements of a medication therapy management (MTM) service model: medication therapy review, a personal medication record, medication action plan, intervention and/or referral, and documentation and follow-up.<sup>1</sup> These services solve problems related to polypharmacy, preventable adverse drug events, medication adherence, and medication misuse.<sup>2</sup> A plethora of literature exists demonstrating the positive patient outcomes from pharmacist-lead MTM services. A 2010, meta-analysis analyzed 298 randomized controlled trials where patients received direct patient care from pharmacists. The analysis demonstrated improvements in patient's HbA1c in patients with diabetes, blood pressure in patients with hypertension, medication adherence, quality of life, and patient satisfaction. The study also saw a reduction in the number of patients' sick days taken and hospitalization. Upon economic analysis, the range of return on investments for these services ranges from 2:1 to 12:1 in favor of MTM services provided by pharmacists.<sup>3</sup>

Though there is an abundance of data concerning the benefits of pharmacists-lead MTM services in the United States, few look at if these benefits are seen equally between English and non-English speaking patients. There is also little data that analyzes if there is a difference in the volume or categorization of drug therapy problems (DTPs) faced by patients with these language barriers.<sup>4</sup>

The United States' government defines a limited English proficient (LEP) individual as a person who does not "speak English as their primary language and... [has] a limited ability to read, speak, write or understand English."<sup>5</sup> Limited English proficiency is also defined as the ability to speak English less than "very well"; nearly one in eleven individuals meet this criterion in the United States.<sup>6</sup> Under executive order 13166, LEP individuals should have "meaningful access" to language services at federally conducted and federally funded programs and activities.<sup>5</sup> Though

laws requiring access to language services in the healthcare system have been passed,<sup>7</sup> LEP patients still feel the effects of their language barriers.

An Institute of Medicine report indicated that poor comprehension of prescription medication instructions was the cause of many adverse drug events and medication errors.<sup>8</sup> Previous studies conducted in the LEP population have discovered that this higher rate of prescription instruction misunderstandings can lead to a higher rate of adverse drug events, unsafe medication use, and poor drug adherence.<sup>4,9-13</sup> Even when language services are provided, health disparities still exist. One study found children of families with LEP were less likely to have their pain assessed or receive opioids postoperatively than children of English proficient (EP) families with similar pain scores.<sup>14</sup>

A previous study conducted in the Minneapolis-St. Paul area of Minnesota, published in 2005, sought to determine whether the types of DTPs identified during pharmaceutical care assessments differed between English speaking and non-English speaking patients. The primary languages spoken by the 38 non-English speaking patients included: Vietnamese, Hmong, Laotian, Somali, Spanish, and Khmer. During the pharmacist visits for the 91 study participants, a total of 186 DTPs were identified. A higher percentage of patients within the non-English speaking arm had DTPs categorized as non-adherence compared to the English speaking arm (31% vs. 12%).<sup>4</sup> A separate survey of pharmacists and physicians at a Canadian ambulatory care center sought to study how pharmaceutical care was provided to LEP patients. Pharmacists and physicians also noted a higher rate of DTPs related to non-adherence in the LEP patients.<sup>15</sup>

The objective of this study is to determine if there is a difference between the volume and categorization of drug therapy problems, and subsequent medication adherence or chronic disease management outcomes in patients with limited English proficiency.

## **Methods**

### *Study Oversight and Funding*

This study is a subset of a grant project funded from the Connecticut Department of Public Health, as the pharmacy initiative component of the comprehensive chronic disease grant from the Centers for Disease Control and Prevention (CDC). The original CDC grant was entitled "State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health." The study protocol and subsequent revisions were reviewed by the University of Connecticut's Institutional Review Board.

### *Study Design*

Community pharmacists that service underserved populations were certified to provide MTM services. The overall study targeted a population of patients with hypertension and/or diabetes to receive these services.

Patient recruitment occurred in one of four ways. First, patients with prescriptions for hypertension and/or diabetes medications were contacted at point-of-service at the pharmacy. When the patient picked up their prescription(s), the dispensing pharmacist would alert the patient that they may be a candidate for the study. At the same time, a flier describing the MTM study would be attached to their prescription bag. Fliers detailing the study were also posted at senior housing complexes surrounding the pharmacies participating in the study. Fliers detailing the study were also given to local physicians who have patients that utilize the community pharmacies where the study took place. Lastly, study investigators also planned to use word of mouth to help recruit family and friends of current study participants.

Over the course of a twelve-month period, patients completed up to four MTM visits. During these visits pharmacists collected a full medication list, performed a comprehensive medication review,

educated patients on self-management techniques, developed a mutually agreed upon action plan, and conducted an assessment of the appropriateness of, the effectiveness of, the safety of, and adherence to therapy.

For this author's analysis, patients were separated into arms based on the language their visits were conducted in. Patients were put into the English Proficiency (EP) arm if their visits were conducted in English and informed consent forms were provided in English. Patients were put into the limited English proficiency (LEP) arm if their visits were conducted in Spanish or their informed consent form was provided in Spanish. Only data from the study participants at Arrow Pharmacy at 500 Farmington Avenue in Hartford, CT was included. The site had three pharmacists that were trained in human subjects research and certified to perform MTM services through the UConn Office of Pharmacy Professional Development. Additionally, three bilingual pharmacy technicians were involved in patient visits to provide Spanish translation services.

### *Study Population*

Patients were eligible for inclusion into the original study if they were 18 years or older and had at least one prescription medication for diabetes and/or hypertension. Additionally, patients had to speak either English or Spanish and sign an informed consent form in either the English or Spanish translation. Patients were excluded from the study if they had a diagnosis of Alzheimer's disease or were receiving any of the following drugs: donepezil, galantamine, memantine, or rivastigmine. An additional inclusion criterion for this author's analysis required that patients complete their visits at Arrow Pharmacy at 500 Farmington Avenue in Hartford, CT.

### *Endpoints*

The primary endpoint of this study was the number of DTPs identified per patient. Secondary outcomes for the study included: change in systolic blood pressure, change in diastolic blood

pressure, change in HbA1c, and change in adherence behavior as measured by the Modified Morisky Adherence Scale (MMAS). Additionally, the number of patients at their blood pressure and HbA1c goals at baseline and final visit were analyzed. The net change of the number of patients at goal in both arms was also compared. For all patients, a blood pressure goal was set at 140/90 mmHg. For patients with diabetes, an HbA1c goal of 9% was utilized.

The MMAS is a self-administered tool that provides patients with a score ranging from 0 to 8. A value less than 6 indicates low adherence. A value of 6 or 7 indicates medium adherence. A value of 8 indicates high adherence.<sup>16</sup> The number of patients within each adherence category were also compared between each arm. The net number of patients within each arm that improved their adherence categorization (i.e. low adherence to medium adherence) were analyzed.

To calculate these values, data related the patient's baseline and final systolic and diastolic blood pressure, HbA1c, and MMAS were collected. Additional secondary endpoints included analysis of DTP categorization. DTPs identified by pharmacists could be categorized into one of seven categories, including Unnecessary Drug Therapy, Needs Additional Drug Therapy, Needs Different Drug Product, Dosage Too Low, Adverse Drug Reaction, Dosage Too High, and Non-Adherence.

Data related to a patient's sex, age, race or ethnicity, social history, comorbidities, and medications were used to analyze patients' baseline characteristics.

### *Statistical Analysis*

During a patient's first visit, baseline data including a patient's sex, age, race or ethnicity, smoking history, use of alcohol, comorbid conditions, MMAS score, and current medication list were collected by pharmacists. The mean data for age, total number of comorbid conditions, total number of medications, and number of medications per morbid conditions was compared.

The baseline characteristics were compared using one of two statistical tests. Age, total number of comorbidities, total number of medications, and medications per comorbid condition were analyzed using a two-tailed unpaired T-test. Comparisons of population proportions for characteristics including, sex, race, ethnicity, tobacco use, alcohol use, and individual comorbidities were made using a two-tailed Z-Test of proportions.

Due to the study's small size, a formal power calculation was not performed. The final analysis would be an intention to treat analysis. A two-tailed unpaired T-test was utilized to compare differences between the arms in terms of the primary endpoint of the number of DTPs identified per patient. A two-tailed unpaired t-test was also utilized to compare differences between the arms for the secondary endpoints of change in medication adherence score as calculated by the MMAS, change in systolic blood pressure, change in diastolic blood pressure, and change in HbA1c. A two-tailed Z-test of proportions was utilized to analyze the secondary outcomes of individual DTP categorization, net adherence category improvement, and change in the number of patients at blood pressure and HbA1c goals. A two-sided alpha of 0.05 would be considered significant. All analysis was performed utilizing Microsoft Excel 2013.

## **Results**

### *Study Participants*

The data analyzed in the study was collected from a total of fifty-eight patients at Arrow Pharmacy in Hartford, CT from May 9, 2014 to May 13, 2016. All fifty-eight patients completed at least two MTM visits. A total of fifty-three patients, eleven patients (100%) within the LEP arm and forty-two patients (89.3%) within the EP arm, completed their third MTM visit. A total of six patients, one patient (9.1%) in the LEP arm and five patients (10.6%) within the EP arm, completed a fourth visit. Overall, 175 patient visits were conducted during the study period.

Of the fifty-eight patients, eleven had limited English proficiency (LEP) and were provided a translator so the visits could be conducted in Spanish. The remaining forty-seven patients made up the English proficiency (EP) arm of the study and had their visits conducted in English without translation services.

As shown in the baseline characteristics table below (Table 1), the majority of patients in both arms were female (63.7% in the LEP arm and 59.6% in the EP arm). The average age of patients was 64.1 years. In the LEP arm, each of the 11 patients (100%) identified as Hispanic or Latino and nine of the patients (81.8%) identified as white. In the EP arm, 32 patients (55.2%) identified as Hispanic or Latino, 28 patients (48.3%) identified as white, 22 patients (37.9%) identified as Black or African American, and one patient (1.7%) identified as Asian. The majority of patients included in the study identified with more than one racial or ethnic group.

In both arms of the study, the majority of patients stated that they were never smokers (54.4% in the LEP arm and 74.5% in the EP arm,  $p=0.190$ ). A greater proportion of patients within the EP arm (21.3%) stated that they were current smokers than those within the LEP arm (9.1%),  $p=0.352$ . A greater proportion of patients in the LEP arm stated that they have a history of smoking tobacco, but are not current users (36.4% vs. 4.3% in the EP arm,  $p=0.002$ ). The majority of patients in both arms of the study denied alcohol use. Thirteen patients (27.7%) in the EP arm and zero patients (0%) in the LEP arm stated rare, social, or occasional alcohol use,  $p=0.048$ .

On average, patients with LEP stated a history of more medical comorbidities (5.2 conditions) than those in the EP arm (3.5 conditions),  $p=0.009$ . The majority of patients in this study had hypertension (100% vs. 95.7% respectively), type 2 diabetes mellitus (100% vs. 61.7%,  $p=0.014$ ), and hyperlipidemia (90.1% vs. 44.7%,  $p=0.006$ ). Other common comorbidities included:

<b>Baseline Characteristics</b> (Chart 1)				
	<b>Patients with Limited English Proficiency (n=11)</b>	<b>Patients with English Proficiency (n=47)</b>	<b>Total (n=58)</b>	<b>P-Value</b>
<b>Demographics</b>				
Male Sex	4 (36.3%)	19 (40.4%)	23 (39.6%)	0.803
Age	67.5 years	63.2 years	64.1 years	0.349
<b>Race/Ethnicity</b>				
White	9 (81.8%)	19 (40.4%)	28 (48.3%)	<b>0.014</b>
Hispanic or Latino	11 (100%)	21 (44.7%)	32 (55.2%)	<b>&gt; 0.001</b>
Black or African American	0 (0%)	22 (46.8%)	22 (37.9%)	<b>0.004</b>
Asian	0 (0%)	1 (2.1%)	1 (1.7%)	0.624
<b>Social History</b>				
Smoking				
Current Smoker	1 (9.1%)	10 (21.3%)	11 (19.0%)	0.352
History of Smoking	4 (36.4%)	2 (4.3%)	6 (10.3%)	<b>0.002</b>
Never-Smoker	6 (54.5%)	35 (74.5%)	41 (70.7%)	0.190
Alcohol Use				
States Alcohol Use	0 (0%)	13 (27.7%)	13 (22.4%)	<b>0.048</b>
Denies Use	11 (100%)	34 (72.3%)	45 (77.6%)	<b>0.048</b>
<b>Comorbidities</b>				
Hypertension	11 (100%)	45 (95.7%)	56 (96.6%)	0.484
Type 2 Diabetes Mellitus	11 (100%)	29 (61.7%)	40 (70.0%)	<b>0.014</b>
Hyperlipidemia	10 (90.1%)	21 (44.7%)	31 (53.4%)	<b>0.006</b>
Asthma	5 (45.5%)	9 (19.1%)	14 (24.1%)	0.066
Ulcers	2 (18.1%)	9 (19.1%)	11 (19.0%)	0.944
Depression	4 (36.4%)	13 (27.7%)	17 (29.3%)	0.569
Total Number of Comorbidities	5.2 conditions	3.5 conditions	3.8 conditions	<b>0.009</b>
<b>Medications</b>				
Total Number of Medications	9.4 medications	6.7 medications	7.2 medications	<b>0.024</b>
Medications per Comorbid Conditions	1.8 medications per conditions	1.9 medications per conditions	1.9 medications per conditions	0.823

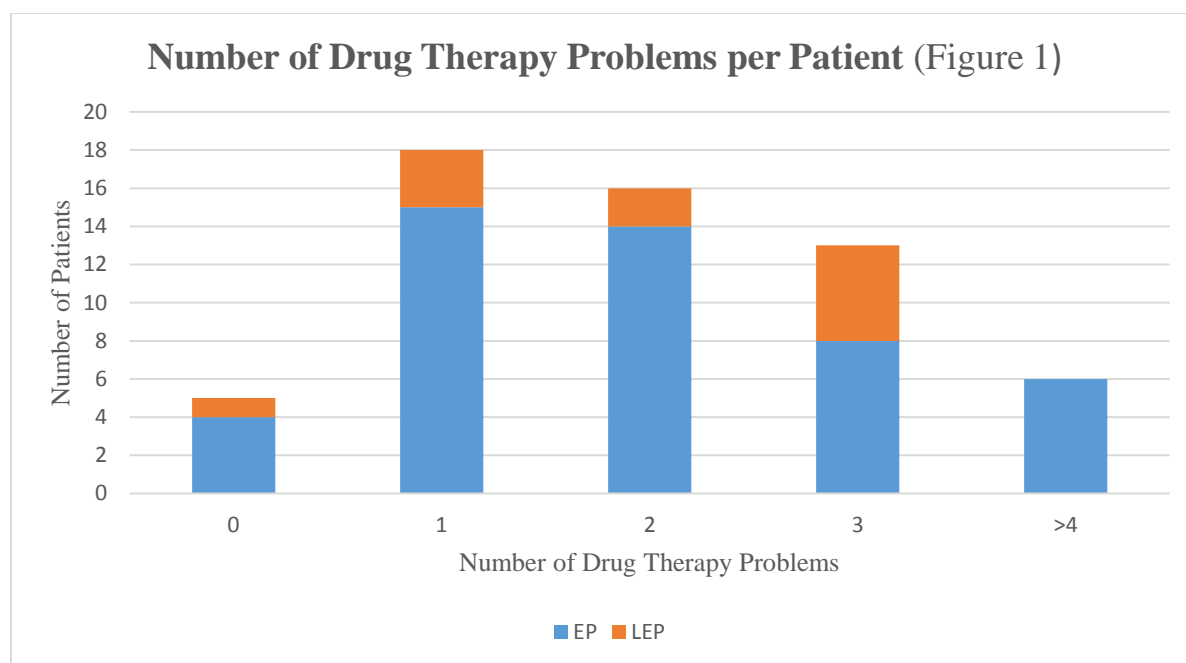
depression (36.4% vs 27.7%), asthma (45.5% vs 19.1%,  $p=0.066$ ), and ulcer disease (18.1% vs 19.1%). Other comorbidities included: arthritis, COPD, gastroesophageal reflux disease, and osteoporosis. Four patients stated they had a previous heart attack.

Patients within the LEP group also took a larger number of medications, 9.4 medications on average, compared to patients with English proficiency at 6.7 medications,  $p=0.024$ . However, the average number of medications per comorbid condition was similar between groups at 1.8 medications per comorbid condition in the LEP group and 1.9 medications per comorbid condition in the EP group,  $p=0.823$ .

### *Primary Endpoint*

Overall, a total of 115 drug therapy problems were identified for the fifty-eight patients involved in the study. Twenty-two drug therapy problems were identified in patients within the LEP arm, while ninety-three drug therapy problems were identified within patients in the EP arm. In terms of the primary endpoint, the number of drug therapy problems identified per patient, a statistically significant difference was not found. A mean of 2.00 DTPs were identified for each patient in the LEP arm and 1.98 DTPs were identified for each patient in the EP arm with a  $p$ -value of 0.959.

As shown in the graph below (Figure 1), the overall mode was one drug therapy problem per patient (18 patients). The mode for LEP patient was three drug therapy problems; for EP patients it was one drug therapy problem. A total of four patients (8.5%) within the EP arm and one patient (9.1%) within the LEP arm had zero DTPs identified. A total of fifteen patients (31.9%) with EP and three patients (27.3%) with LEP had one DTP identified. Fourteen patients (29.8%) with EP and 2 LEP patients (18.2%) had two DTPs identified. A total of eight patients (17.0%) in the EP group and five patients (45.5%) in the LEP group had three DTPs identified. Six patients (12.8%) in the EP group had greater than or equal to four DTPs identified.



### *Secondary Endpoints*

#### *Drug Therapy Problem Categorization*

Similarly to the primary endpoints, the secondary endpoints of DTP categorization did not reach statistical significance. A similar proportion of patients within both arms had the DTPs categorized as Needs Additional Drug Therapy (45.5% vs. 42.6%,  $p = 0.865$ ) and Dosage Too Low (18.2% vs 17.0%,  $p=0.928$ ). Though not statistically significant, the greatest proportional difference occurred in the DTPs of Unnecessary Drug Therapy (18.2% vs. 6.4%,  $p=0.208$ ), Needs Different Drug Product (9.1% vs. 19.1%,  $p= 0.430$ ), Adverse Drug Reaction (18.2% vs. 38.3%,  $p=0.207$ ), and Non-Adherence (81.8% vs 70.2%,  $p=0.435$ ). Lastly, a higher percentage of patients within the LEP arm (9.1%) compared to the EP arm (4.3%) had the DTP of Dosage Too High documented,  $p=0.516$ .

Of the 115 total drug therapy problems that were identified, 42 problems (36.5%) were categorized as Non-Adherence. The second most common category was Needs Additional Drug Therapy, with 25 problems (21.7%) identified. The remaining categories of Adverse Drug Reaction, Dosage Too

<b>DTP and Adherence Outcomes</b> (Chart 2)			
	<b>Patients with Limited English Proficiency (n=11)</b>	<b>Patients with English Proficiency (n=47)</b>	<b>P-Value</b>
<b>Primary Outcome</b>			
Number of DTPs per Patient	2.00	1.98	0.959
<b>Secondary Outcomes</b>			
<b>DTP Categorization</b>			
Unnecessary Drug Therapy	2 (18.2%)	3 (6.4%)	0.208
Needs Additional Drug Therapy	5 (45.5%)	20 (42.6%)	0.865
Needs Different Drug Product	1 (9.1%)	9 (19.1%)	0.430
Dosage Too Low	2 (18.2%)	8 (17.0%)	0.928
Adverse Drug Reaction	2 (18.2%)	18 (38.3%)	0.207
Dosage Too High	1 (9.1%)	2 (4.3%)	0.516
Non-Adherence	9 (81.8%)	33 (70.2%)	0.435
<b>Medication Adherence</b>			
Baseline Morisky Adherence Value	5	4.47	
Morisky Adherence Value at Final Visit	5.91	5.46	
Change in Morisky Adherence Value	0.91	0.98	0.861
Patients with Low Adherence at Baseline	5 (45.5%)	29 (61.7%)	
Patients with Low Adherence at Final Visit	6 (54.5%)	22 (46.8%)	
Patients with Medium Adherence at Baseline	4 (36.4%)	12 (25.5%)	
Patients with Medium Adherence at Final Visit	3 (27.3%)	20 (42.6%)	
Patients with High Adherence at Baseline	2 (18.2%)	6 (12.8%)	
Patients with High Adherence at Final Visit	2 (18.2%)	5 (10.6%)	
Net Adherence Category Improvement	-1	6	<b>0.020</b>

Low, Needs Different Drug Product, Unnecessary Drug Therapy, and Dosage Too High had a respective 20 (17.4%), 10 (8.7%), 10 (8.7%), 5 (4.3%), and 3 (2.6%) problems identified within them.

### Adherence Outcomes

Patients within the LEP arm had an average baseline adherence of 5.00 determined by the MMAS. During their last visit, patients within the LEP arm had an average score of 5.91 on the MMAS, giving them an average change of 0.91. In the EP arm, it was determined that patients had a baseline adherence score of 4.47 with an average score of 5.46 on the MMAS at their final visits. Patients within the EP arm saw a similar average change to the LEP group of 0.98, resulting in a p-value of 0.861.

In the LEP arm, five patients (45.5%) had an MMAS value that placed them at low adherence at baseline. At baseline, four patients (36.4%) had medium adherence and two patients (18.2%) had high adherence in the LEP arm. In the EP arm, twenty-nine patients (61.7%) had low adherence, twelve patients (25.5%) had medium adherence, and six patients had high adherence at baseline. At the final visit, one of the patients in the LEP arm originally calculated to have medium adherence now had low adherence. No other patients within the LEP arm changed adherence category, giving the arm a net adherence category improvement of negative one patient. At the final visit for patients within the EP arm, twenty-two patients (46.8%) were categorized as having low adherence, twenty patients (42.6%) had medium adherence, and five patients (10.6%) had higher adherence. Within the EP arm, seven patients characterized with low adherence at baseline had medium adherence at their final visit; however, an additional patient that was characterized as having high adherence at baseline was calculated to have medium adherence at their final visit. This resulted in a net adherence category improvement of 6 patients for the EP group. The

difference in net adherence category improvement was statistically significant with a p-value of 0.020.

### Health Outcomes

When looking at the secondary outcomes of change in systolic blood pressure, diastolic blood pressure, and HbA1c, no statistical significance was seen.

Patients within the LEP group had an average baseline systolic blood pressure of 141.55 mmHg and a final systolic blood pressure of 139.55 mmHg. An average change of -2 mmHg in LEP patient's systolic blood pressure was seen. Patients within the EP arm had average baseline systolic blood pressure of 143.23 mmHg and final systolic blood pressure of 138.62 mmHg. Overall, a larger change in systolic blood pressure was seen in the EP group at -4.62 mmHg,  $p=0.470$ .

Patients within the LEP group had an average baseline diastolic blood pressure of 85.09 mmHg and a final diastolic blood pressure of 85.55 mmHg. An average increase of 0.45 mmHg in LEP patient's diastolic blood pressure was seen. Patients within the EP arm had average baseline diastolic blood pressure of 86.23 mmHg and final systolic blood pressure of 84.72 mmHg. Unlike the LEP group, the patients within the EP arm saw an average drop of -1.51 mmHg in their diastolic blood pressure,  $p=0.484$ .

This difference in change in systolic and diastolic blood pressure translated to additional patients' abilities within each arm to reach their blood pressure goal. At baseline, five patients (45.5%) within the LEP arm and sixteen patients (34.0%) within the EP arm were at their blood pressure goal. An additional patient (9.1%) within the LEP arm and twelve patients (25.5%) within the EP reached their blood pressure goal of 140/90 mmHg by their final visit,  $p=0.238$ . At their final study visit a total of six patients (54.5%) within the LEP arm and twenty-eight patients (59.6%) within the EP arm were at their blood pressure goal.

<b>Blood Pressure and HbA1c Outcomes (Chart 3)</b>			
<b>Blood Pressure</b>			
Baseline Systolic Blood Pressure	141.55 mmHg	143.23 mmHg	
Final Systolic Blood Pressure	139.55 mmHg	138.62 mmHg	
Change in Systolic Blood Pressure	-2 mmHg	-4.62 mmHg	0.470
Baseline Diastolic Blood Pressure	85.09 mmHg	86.23 mmHg	
Final Diastolic Blood Pressure	85.55 mmHg	84.72 mmHg	
Change in Diastolic Blood Pressure	0.45 mmHg	-1.51 mmHg	0.484
Baseline Patients at Blood Pressure Goal	5 (45.5%)	16 (34.0%)	
Final Patients at Blood Pressure Goal	6 (54.5%)	28 (59.6%)	
Change in Number of Patients at Goal	1 (9.1%)	12 (25.5%)	0.238
<b>HbA1c Outcomes</b>			
Baseline HbA1c	8.45%	9.26%	
Final HbA1c	8.22%	8.97%	
Change in HbA1c	-0.23%	-0.29%	0.792
Baseline Patients at HbA1c Goal	6 (54.5%)	9 (19.1%)	
Final Patients at HbA1c Goal	6 (54.5%)	10 (21.3%)	
Change in Number of Patients at HbA1c Goal	0 (0%)	1 (2.1%)	0.624

Patients within the LEP group had an average HbA1c of 8.45% and a final HbA1c of 8.22%. An average change of -0.23% in LEP patient's HbA1c was seen. Patients within the EP arm had an average HbA1c of 9.26% and final HbA1c of 8.97%. A similar drop, -0.29%, was seen in the EP group.

At baseline, six patients (54.5%) within the LEP arm and nine patients (19.1%) within the EP arm were at their HbA1c goal. An additional patient (2.1%) within the EP reached their HbA1c

goal of 9% by their final visit,  $p=0.624$ . At their final study visit a total of six patients (54.5%) within the LEP arm and ten patients (21.3%) within the EP arm were at their HbA1c goal.

## **Discussion**

This article details a small, unpowered, prospective study looking at the difference in volume and categorization of drug therapy problems as well as the subsequent changes in patient adherence, blood pressure, and HbA1c between patients who speak English or have limited English proficiency. As was expected with the unpowered nature of this substudy of a larger project, a statistically significant difference was identified for none of the primary and few of the secondary outcomes. For the remainder of this section, how the results suggest further directions for research in this area will be discussed.

Both arms of the study were predominantly female and had a similar overall age. Based on the inclusion criteria of the study requiring patients to speak either Spanish or English, the less diverse racial and ethnic breakdown of the LEP arm is understandable. Overall, patients within the English proficiency arm had a higher rate of tobacco and alcohol use than those within the limited English proficiency arm. The difference in alcohol use was statistically significant between arms. This difference may be one factor that explains the higher baseline systolic and diastolic blood pressure values in the EP arm.<sup>17</sup> Though patients could be counseled on their alcohol and tobacco use as part of the MTM appointments, it was not documented if any change in a patient's alcohol or tobacco use was made during the course of their visits.

Upon analysis of the patient's comorbidities, patients within the LEP group had a higher rate of five of the top six most common comorbidities. A statistically significant higher rate of diabetes and hyperlipidemia was seen in the LEP population as well as a trend towards a higher rate of asthma. Though patients within the EP arm had a slightly higher rate of ulcers than those within

the LEP arm, on average, they had approximately two fewer comorbidities. The difference in the number of comorbidities contributes to the difference in the total number of medications patients taken within the two study arms. This belief is strengthened by the similar number of medications per comorbidity seen in the two groups.

One factor, however, that has not been accounted for within the analysis of drug therapy problem volume and categorization in this study is the higher number of overall medication use in the LEP population. On average, the LEP population used 2.7 more medications per patient, a statistically significant 40% increase from the EP arm. Results from the primary outcome of this study show nearly identical numbers of drug therapy problems identified per patient, though the distribution differed between the arms. Future studies may want to study this outcome in a population with a similar number of medications used in both arms. The difference in the number of DTPs may falsely appear to be similar on analysis within this study due to this confounder.

A small 2010 study also conducted in Connecticut analyzed the rate and types of medication discrepancies and DTPs identified in Medicaid patients. The patients included in this study had an average of 9.5 medical conditions and 15.7 prescription and non-prescription medications per patient. Pharmacists identified an average of 10.4 DTPs per patient, over a five-fold increase from the number of DTPs identified per patient in this author's analysis. It's important to note that patients within the 2010 study had over two-fold the number of medications than the patients within this study.<sup>18</sup> However, the average number of DTPs identified in this study closely resembles the average of 2.04 found in the Minnesota study published in 2005 that also compared the LEP and EP populations.<sup>4</sup>

Upon analysis of drug therapy problem categorization, similarities were seen between the two studies, supporting this study's drug therapy problem categorization results. Similar rates of DTPs

were noted in Needs Additional Drug Therapy (21.7% vs 22.7%), Adverse Drug Reaction (17.4% vs 15.7%), Needs Different Drug Product (8.7% vs 6.8%), Unnecessary Drug Therapy (4.3% vs 7.4%), and Dosage Too High (2.6% vs 4.9%). A higher rate of problems categorized as Non-Adherence (36.5% vs. 26.2%) and a lower rate of problems categorized as Dosage Too Low (8.7% vs. 16.3%) was seen in this author's analysis compared to the 2010 study.<sup>18</sup>

The results of this study suggest that there may be a higher rate of patients who have Unnecessary Drug Therapy with limited English proficiency, which may account for some of the additional medications seen in the LEP arm. This study also suggested that a larger proportion of patients may have drug therapy problems categorized as Adverse Drug Reaction and Needs a Different Drug Product in the EP arm, and a larger proportion of patients may have drug therapy problems categorized as non-adherence in the limited English proficiency arm. In the 2005 study, there was also a higher rate of DTPs categorized as non-adherence in the LEP population compared to patients who spoke English as their primary language.<sup>4</sup> Even with the provision of a bilingual pharmacy technician to provide translation services, it appears that drug DTPs that require the patient to communicate the problem to the healthcare provider, i.e., having an adverse reaction, requiring another drug product, are still less likely to be identified in patients with limited English proficiency. If these problems are not communicated, these problems may be inadvertently coded as non-adherence in the LEP population, accounting for the higher rate seen in that arm. It is possible that a smaller percentage of patients within the LEP arm were experiencing these problems. However, this possibility is less likely due to the higher number of medications utilized within the LEP arm. These results suggest that although adequate language services were provided to patients, additional social determinants that pharmacists and other healthcare providers have not

yet accounted for in their care of patients with limited English proficiency may be impacting the appropriateness of, efficacy of, safety of, and adherence to drug therapy.

The difference in drug therapy problem categorization was not universal between all categories. The rate of identification of Needs Additional Drug Therapy and Dosage Too Low were similar between the two arms. To contrast the problems previously discussed, identification of these problems would not require communication with the patient. Rather, pharmacists are able to categorize these problems based off of their clinical knowledge and the patients' comorbidities.

Patients within the EP arm had a lower baseline MMAS value, indicating worse baseline adherence.<sup>16</sup> It is important to note, that this result conflicts with the higher rate of non-adherence DTPs identified in the LEP population, which strengthens the theory that problems may be incorrectly identified as non-adherence in this population. Because communication between health care provider and LEP patients may be challenging and time-consuming, categorizing patients as non-adherent may prevent the ability to identify the true cause of non-adherence. This may inadvertently attribute the DTP to a patient cause, rather than a health-system cause. The accuracy of identifying the appropriate DTP is critical to the eventual resolution of the DTP, and therefore may affect health outcomes.

Though a similar numerical improvement in the MMAS value was seen within both arms, a statistically significant difference was noted in how patients changed among the adherence categories throughout the course of their visits. Though one patient in both arms fell into a lower adherence category, zero patients within the LEP arm and six patients within the EP moved into a higher adherence category throughout the course of their visits. Though a higher proportion of patients within the LEP arm were categorized as having high adherence and had a higher average MMAS value, the lack of upward movement between categories is noteworthy. This may be an

indicator that additional strategies to improve adherence rates should be implemented for LEP patients that are truly non-adherent in order to see the same clinically meaningful outcomes that were observed in the EP population.

Patients within the EP had double the decrease in their systolic pressure compared to patients within the LEP arm. Patients within the LEP had a slight increase in their diastolic pressure, while patients within the EP group had an average 1.51 mmHg decrease in diastolic pressure. Though these difference in values may not be statistically significant, the disparity should be noted for future research with larger populations.

This disparity becomes more concerning when looking at individual patient's ability to reach their blood pressure goal. Though a higher proportion of patients within the LEP arm had reached their blood pressure goal at baseline, only one additional patient was able to reach the goal in this arm. However, over a quarter of patients within the EP arm reached their blood pressure goal during the course of their MTM visits, leading to a higher proportion of patients at goal at their final visit in the EP arm.

As described above, this difference in the outcomes related to blood pressure may be due to the increased rates of smoking and alcohol use in patients with English proficiency and subsequent counseling they received as part of this study. However, this disparity may be further evidence that even when language services are provided to LEP patients; there may be additional socioeconomic or cultural barriers in place that prevent them from reaching the same health outcomes as English proficient patients given the same resources.

Patients within the EP arm had a higher baseline HbA1c. Though no additional patients within the LEP population reached their A1c goal during the study period, this is likely due to the large percentage of patients that were already at goal at baseline. In contrast to outcomes related to blood

pressure, it is reassuring that a similar drop in HbA1c was seen in both study arms, and their final visit a greater proportion of patients within the LEP arm were at goal. Unlike the outcomes related adherence and blood pressure, it does not appear that a patient's lack of English proficiency provided a significant barrier to their ability to lower their HbA1c or reach the HbA1c goal. It is important to note, however, that the high proportion of LEP patients already at their HbA1c goal may have prevented this small analysis from discerning a difference in these outcomes.

This study was designed as a small, unpowered, prospective trial. Further investigation of these outcomes in a powered study is required to either support or refute the results of this study in terms of differences of drug therapy problems seen in both populations and outcomes related to adherence and blood pressure and diabetes control.

There were a number of limitations to this study, many of which have been previously discussed. The first and largest limitation of the study is its small size and unpowered nature. Though our results can suggest potential differences in these populations, further studies should be conducted before the results of this study can be interpreted. On a similar note, the results of this study stem from a single site limiting the external validity of the results. Due to the single-site and small nature of this study, interventionist bias in patient selection and visit conduction cannot be excluded. As previously stated, the difference in the number of medications taken by patients within the LEP population and the EP population likely confounded this study's analysis in the difference in the number of drug therapy problems identified. The last limitation of this study concerns the collection of patient medication data. The number of medications a patient is taking was calculated through the number of medications recently filled at Arrow Pharmacy in Hartford, CT and any over-the-counter or herbal medications that may be listed on the patient's visit sheet. This method of data collection fails to account for any over-the-counter or herbal medication not reported by

the patient or documented by the pharmacist, any medications that are filled at another site, or medications taken periodically by the patient.

In summation, the results of this small prospective study suggest that there may be a difference in how drug therapy problems are categorized and the subsequent control of chronic health conditions in patients with limited English proficiency even when language services are provided.

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