

University of the Sciences in Philadelphia

Annual Progress Report: 2012 Formula Grant

Reporting Period

July 1, 2013 – June 30, 2014

Formula Grant Overview

The University of the Sciences in Philadelphia received \$29,488 in formula funds for the grant award period January 1, 2013 through June 30, 2015. Accomplishments for the reporting period are described below.

Research Project 1: Project Title and Purpose

Health Literacy Interventions to Improve Medication Adherence – Our goal is to collect preliminary data leading to an efficacy trial of whether public health center patients with limited literacy (LL) or limited English proficiency (LEP) report (1) better comprehension of their illness and their medication regime (i.e. have better health literacy/HL), and (2) have better medication adherence (MA), following receipt of medication instructions written at a reduced reading level and/or in a foreign language of their choosing. Our purpose is to assess the effectiveness of this intervention in a busy, urban public health care setting.

Anticipated Duration of Project

1/1/2013 – 6/30/2015

Project Overview

Objectives: We will test whether pharmacy medication information written in simplified English and/or a foreign language makes it easier for public health center patients with limited literacy (LL) or limited English proficiency (LEP) to understand their medication regime (a measure of HL), skip fewer doses of their medication and refill their prescriptions on time (measures of medication adherence, MA).

Specific Aims: In a two-year period we plan to: (1) Test the efficacy of language-tailored written medication information in improving patient health literacy; (2) Test the efficacy of these same materials on adherence to the patient's prescribed medication regime; and (3) Identify logistical issues in integrating assessment and dispensing procedures into the public health center workflow.

Research Design and Methods: Aims 1 & 2 involve conducting a controlled, randomized experiment in which patients who receive simplified English or foreign language instructions in addition to the standard medication instruction (intervention group) are compared to patients who

receive only standard medication instructions generated by the pharmacy (control group). Aim 3 involves a qualitative, interactive assessment of patient flow, staff training needs, logistics, equipment and other needs in the six centers participating in the study. The study will be done in health care centers chosen by the Philadelphia Department of Public Health (PDPH) as well as the Health Federation of Philadelphia, which oversees the Federally Qualified Health Centers (FQHC). Sites will be selected based on the census of LL/LEP clients as well as availability of in-center pharmacies or dispensaries. Following the visit with their health care provider, patients who grant consent will be given the baseline assessment and assigned randomly to intervention and comparison groups. Baseline HL will be measured by asking a patient to review a 'standard' pharmacy leaflet and a pill bottle prepared for a mock patient. Two weeks later we will call both groups of patients and ask similar questions, this time pertaining to their own prescription. We will measure the patient's reported adherence at 2 weeks time as well as collect pharmacy refill data as a proxy of actual adherence though 4 months post enrollment. The study will compare data from the two groups.

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Expected Research Outcomes and Benefits

- 1) Use health information technology, the Meducation® computer application, developed with funding from NIH (R44MD001212-NCMHD) in an urban public health setting. While culturally and linguistically appropriate services (CLAS) are required in FQHC and PDPH facilities, limited human resources make this difficult to deliver consistently. If the procedure tested in our research is effective at improving patient understanding of prescription medication, it will facilitate the delivery of CLAS in public health care delivery throughout the city, and serve as a model for the state.
- 2) Reduced medication errors and deleterious consequences for patients receiving prescription medications but heretofore, unable to read or understand instructions. If we can demonstrate that patients receiving tailored information are more adherent to their medication regimen, this will be of enormous consequence not only to patients, who will suffer less illness and even death, but enhance results for health care providers, and reduce costs to insurers and payers.
- 3) Sensitize public health center staff to needs of LL and LEP clients, while demonstrating a low burden method to deliver linguistically appropriate medication information.
- 4) Train a cohort of doctor of pharmacy graduates with experience in cross-cultural patient

communication and health literacy. The cross-cultural and health literacy training of pharmacy students will benefit the city, the state, and eventually, anyone encountering a pharmacist trained in this manner.

5) We will make our validated multilingual pharmacy communication materials available as a national/international resource for pharmacy communication and serve as a model for development of similar resources in other languages and for other health applications.

Summary of Research Completed

Subject Enrollment

During the time period, we completed enrollment of subjects from Health Care Center 2 (September-December 2013) and Health Care Center 3 (January-May, 2014). We initiated the study in Health Care Center 6 on June 9th, 2014, and plan to collect data in that center through the fall. Enrollment figures appear in Table 1 below.

Research Design and Methods

The overall protocol remains unchanged from what has been submitted. We refer to an ‘active’ and a ‘passive’ portion of the study. The active portions include enrollment and baseline questions as well as the follow-up phone call concerning patient health, medication literacy, and reported adherence. This ends the active portion of the study for the participating patients. The passive portion involves collection of refill data from the health center pharmacies for 3 months. These components contribute to Specific Aims 1 and 2. Specific Aim 3 involves only the health center staff and administration, and it is interwoven into our regular interactions with each health center and will continue after patient data analysis is completed.

Outcomes to Date

Here we report on findings from HC 2, for which activities were completed during this period. We presented this information to the leadership and staff of the health center in May, and received their feedback to include in Specific Aim 3.

Enrollment and likely confounders

We enrolled 109 patients from the HC 2 site. Of these, 85 completed all portions of the study protocol (both active and passive components) giving us sufficient data for analysis. Forty- three had been randomly assigned to standard care (Group=S), in which they received only standard instructions generated by the pharmacy, and 42 were in the intervention group in which they received both the standard instructions and the Meducation® instructions (Group=M).

Demographics, Education and language use: Our analysis shows that the two groups (M, S) are non-distinguishable in terms of sex, age range, first language, second language, or education level. As demographic factors are known to contribute to health literacy, it is important to examine them for confounding in our study.

Prescribed medication: The form of a medication as well as the total number of drugs taken by a patient are known to affect medication adherence. Our analysis shows that there are no significant differences between the M and S group with respect to medication characteristics.

Study intervention

Our only study intervention is the information flyer generated using Meducation®. We found that overall, 68.4% of the Meducation® flyer group used their flyer compared to only 34.2% of the standard group using the standard information. This difference was significant ($p=.0029$). Table 2 breaks this down further and shows the statistical tests used.

Specific Aim 1 –Health literacy (HL) outcomes

We assessed baseline HL by asking patients questions in reference to a pill bottle prepared for a mock patient together with a standard drug leaflet. Patients who could not read English at all, or identify the information with the help of an interpreter translating the questions, scored a 0 on this section. Patients who answered all questions correctly scored a 5. The median score in both the M and S groups was 4. On follow-up, there were a few significant differences between the M and the S group: 79.07% of patients in M group knew what time of day to take their medications compared to 54.76% in S group, $p=0.0171$. Patients in M group were also less likely to miss a dose of their medication (21.62%) compared to S group (44.74%), $p=0.0337$. M group patients who reported using their leaflets had higher ML scores (4; 4-5) than S group patients who reported using their information (3; 3-4), $p=0.1270$. (See Table 3 below, Health Literacy.)

We used a Kruskal-Wallis test to assess if Meducation® flyer use was associated with health literacy score at follow-up. We compared both the condition (M or S) as well as reported use of the flyer (Yes or No) producing 4 groups for comparison. While there is no significant difference among the 4 groups, the scores of individuals in the M group reporting use of the flyer tend to be higher than the scores in the other groups. This is shown in Table and Figure 4 below.

Specific Aim 2 – Effects on patient’s medication adherence (MA)

We examine medication adherence in two ways: Reported adherence and pharmacy refill data.

Reported Adherence

There is a significant difference between the M group and the S group with respect to the MA outcome, “Missing any doses” with 21.6% of the M group and 44.7% of the standard group saying “yes” to this question ($p=.0337$). All other questions concerning medication adherence, including difficulty taking the medicine or discomfort, were statistically very similar.

Pharmacy Refill Data

We collected one round of pharmacy refill data for analysis at this time. Overall, 57% of the patients in the M and 59% of patients in the standard group refilled their prescription in a timely manner, (i.e. no difference). We used a logistic regression model to estimate and test the effect of Meducation® on the chance of successful refill, controlling for language (English, Non English).

In the *English first language group*: The Odds Ratio of Successful Refill for M vs S is 0.389 (95% CI: 0.116-1.302); i.e. the odds of successful refill are actually 2.57 times higher for standard compared to intervention, however the effect is not statistically significant ($p\text{-value}>0.05$) In the *Non English group*: The Odds Ratio of successful refill for M vs Standard is 15.995 (95% CI: 1.315-194.519); i.e. the odds of successful refill are roughly 16 times higher for

Meducation® compared to Standard. The effect of Meducation® is statistically significant (p-value<0.05). The results are shown graphically in Figure 5.

We interpret this to mean that the intervention is more effective for non-native speakers of English. The alternative interpretation is that other factors associated with not speaking English confound the effects of the main effect. We will use more statistical analyses to tease this apart when we have completed data collection and analysis on the full sample.

Discussion

Based on the experience reported here, we made some refinements to improve our ability to control for confounding effects as well as strengthen our ability to test our hypotheses. The key changes are: (1) We added questions about race/ethnicity to the data entry form, (2) We revised the wording of the baseline and follow-up health literacy questions so that we could compare items individually as well as by total score, (3) we added questions to both the baseline and follow-up health literacy assessment so that a patient may get a total score of 9 on either scale (the original total was 4 on the baseline and 5 on the follow-up), (4) we added a question to the baseline concerning counseling by their physician or nurse and a question to the follow-up concerning counseling by the pharmacist. We plan to examine these for their effects separately and as confounding.

Finally, we made a change in the drug used in the baseline health literacy assessment from Glucophage (*Generic: metformin*) used for diabetes, to Ampyra (*Generic: dalfampridine*), used for multiple sclerosis. We found that many patients were familiar with metformin, (whereas no one, to date, has been familiar with Ampyra), and their baseline score was therefore artificially high.

Conclusion

We are encouraged by these findings and are continuing the project in the other sites, as proposed. Because of the refinements made in the protocol, we will analyze data from each health center separately, and then use appropriate norming statistics to combine data sets where possible.

Table 1 Subject Enrollment by Healthcare Center

Health Center	HC 2	HC 3	HC6	Total
Enrolled/Accrued	109	60	20	189
Ongoing Active (Phone follow-up interview)	0	0	20	20
Ongoing Passive (refill monitoring from pharmacy + 3 months)	85	59	0	144
Completed study procedures	85	0	0	0

Table 2 Flyer Use

	Overall	Medication (n=38)	Standard (n=38)	p-value
Flyer usage				
Did not use it	36 (47.37%)	11 (28.95%)	25 (65.79%)	
Did not received it	1 (1.32%)	1 (2.63%)	0 (0.00%)	
Used it once	30 (39.47%)	19 (50.00%)	11 (28.95%)	
Used it more than once	9 (11.84%)	7 (18.42%)	2 (5.26%)	0.0065#
Flyer usage				
Yes	39 (51.32%)	26 (68.42%)	13 (34.21%)	
No	37 (48.68%)	12 (31.58%)	25 (65.79%)	0.0029*

*p-value from chi-squared test #p-value from Fisher's exact test

Table 3 Health Literacy Scores at Baseline and Post Intervention (Follow-Up)

	Overall	Medication	Standard	p-value
Baseline (Correct answers)				
Who is medicine for (n=84)	76 (90.48%)	39 (90.70%)	37 (90.24%)	1.0000#
Name of medication (n=84)	69 (82.14%)	34 (79.07%)	35 (85.37%)	0.4514*
How take medic (n=83)	68 (81.93%)	35 (83.33%)	33 (80.49%)	0.7362*
How long (n=84)	30 (35.71%)	12 (27.91%)	18 (43.90%)	0.1262*
Miss a dose (n=84)	25 (29.76%)	11 (25.58%)	14 (34.15%)	0.3908*
Side effects (n=84)	35 (41.67%)	14 (32.56%)	21 (48.78%)	0.0829*
Baseline HL score (0-6)				
Median (IQR)	4 (3-4)	4 (3-4)	4 (3-5)	0.3907@
Follow-up (Correct answers)				
How many times (n=85)	61 (71.76%)	32 (74.42%)	29 (69.05%)	0.5823*
When in the day (n=85)	57 (67.06%)	34 (79.07%)	23 (54.76%)	0.0171*
How take medic (n=85)	71 (83.53%)	36 (83.72%)	35 (83.33%)	0.9616*
How long (n=85)	51 (60.00%)	26 (60.47%)	25 (59.52%)	0.9294*
Side effects (n=85)	28 (32.94%)	17 (39.53%)	11 (26.19%)	0.1906*
Follow-up HL score (0-5)				
Median (IQR)	4 (2-4)	4 (3-4)	3 (2-4)	0.0853@

*p-value from chi-squared test #p-value from Fisher's exact test @p-value from Wilcoxon test

TABLE 4 | Health Literacy score by flyer usage (n=76)

	Medication Flyer used (n=26)	Medication Flyer not used (n=12)	Standard Flyer used (n=13)	Standard Flyer not used (n=25)	p-value
Baseline HL score (0-6)					
Median (IQR)	4 (3-4)	3.5 (1-4.5)	5 (4-6)	4 (3-4)	0.2013 @
Follow-up HL score (0-5)					
Median (IQR)	4 (4-5)	4 (3-4)	3 (3-4)	3 (2-4)	0.1270 @

@p-value from Kruskal-Wallis test

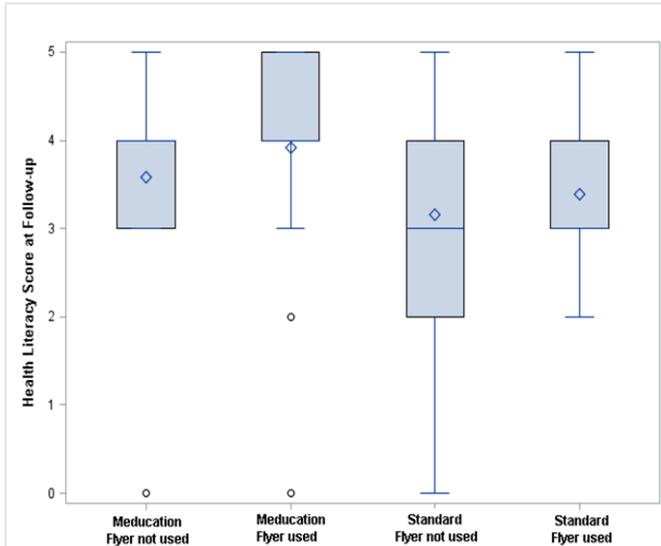


Figure 4. Flyer Usage Graph

Figure 5 Pharmacy Refill by Intervention Group and Language Use

