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Medication Adherence in Outpatient Pharmacies

by

Kylie Alissa Bain

An Honors Capstone

submitted in partial fulfillment of the requirements

for the Honors Diploma

to

The Honors College

of

The University of Alabama in Huntsville

April 16, 2021

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Abstract

Background: On average, 50% of patients on a medication for a chronic condition are nonadherent, meaning they do not take their medication as prescribed (Hilbink et al., 2016). Nonadherence can have costly and deadly effects on patients and the healthcare system as a whole. Multiple factors influence patients' medication adherence behaviors, so patient care must be examined at an individualized level in order to prevent future hospitalizations. Nurses are on the frontline of healthcare and have the ability to prevent rehospitalizations. As such, nurses must have a foundational understanding of the overall healthcare system to provide optimal education for life after hospitalization. The purpose for this study was to survey patients' medication adherence behavior's so nurses can better understand major deterrents of proper medication adherence. This knowledge can improve hospital discharge teaching, community outreach, and individualize patient-centered care. to prevent rehospitalizations.

Methods: Recruitment for the study was limited to flyers handed to patients within one pharmacy (See Appendix A). Participants completed a demographic questionnaire and the ProMAS per Qualtrics survey format or over the phone. Due to the barriers of Covid-19, in person contact was restricted in order to follow CDC guidelines, governmental restrictions, and reduce the risk of spreading the virus. Therefore, the study was significantly modified per pharmacy necessity and details will be further explained in the following thesis.

Results: The Medication Adherence in Outpatient Pharmacies (MAiOP) study examined seven outpatient pharmacy patient's medication behaviors and demographics. The results indicated that patients who have less barriers have higher medication adherence behaviors, meaning they take their medication as prescribed and consequently should have lower incidences of hospitalization.

Discussion: The study was very limited due to small sample size and biased demographics, but does illustrate the satisfactory use of the ProMAS. In ensuing studies, it is recommended to expand upon the original study plan and use a larger sample size in order to gain wider variance results.

Introduction

New diagnoses and their resulting medications can be a life-altering change for people. Adhering to a rigorous medication schedule is challenging to maintain, and can be worsened by numerous barriers. On average, 50% of patients on medication for a chronic condition are nonadherent, meaning they do not take their medication as prescribed (Hilbink et al., 2016). Nonadherence can have costly and deadly effects on patients and the healthcare system as a whole. Asymptomatic patients, such as those with high blood pressure and cholesterol, can be at a higher risk for noncompliance because patients do not feel like they need to take their medication often. The results of nonadherence for asymptomatic patients are unobservable until major consequences occur that can require expensive hospital stays or result in unexpected deaths. Numerous research studies show multiple ways nonadherent patients, including but not limited to asymptomatic patients, may improve their medication regimen.

From the review of literature, it is apparent that medication adherence is a serious issue that must be dealt with at an individualized level. Every person is different, and a personalized approach to combat noncompliance may be crucial to reduce medication administration for the betterment of the patients and the healthcare system.

Medication non-adherence poses a serious threat to nurses because nonadherent patients are at risk for hospitalization and serious complications (Kleppe, Lacroix, Ham, & Midden, 2015). Nurses have to handle the increased patient admittance and potentially lethal consequences from improper compliance. The increase in nurse and hospital workload causes rising healthcare costs that ultimately affect standard patient care. Understaffing and work inefficiency can cause issues for nurses' health and wellbeing which will also place hardships on

the delivery of conventional care. Nurses must recognize risks for non-adherence and provide patient education to better promote adherence and prevent serious complications from arising requiring hospitalization. A prophylactic intervention to reduce medication nonadherence is the best way to combat the rising healthcare costs due to treatable chronic conditions. Understanding the outpatient pharmacy aspects and implementing the proper techniques to promote better medication compliance will decrease all the previously mentioned complications that arise in nursing care.

Multiple research studies have been performed to better understand what prevents individuals from medication persistence, and how to improve it. The most difficult part about performing research studies to improve medication compliance is determining a proper tool to measure the amount and timing of medication administration of individuals. The measurements of medication adherence research studies are an issue to be dealt with to better understand nonadherence and ameliorate medication compliance.

Medication adherence measuring for research studies has improved, but still faces many challenges. Self-report and pill packaging sensors that monitor when and how many times medication vials have been opened are the easiest and best way to measure medication compliance (Kleppe et al., 2015). The practices are flawed, though, in that patient self-report are not always accurate, and pill packaging sensors do not inform the researchers with the amount/dosage taken each time the vial is opened. Patients may forget or falsify important information that can alter study results.

Most medication adherence studies focus on how to improve measurement tools, barriers, and patient motivation while a patient is taking a medication. While understanding and

improving these methods is critical, healthcare workers should use this information to better predict high risk patients and use this information to prevent patients from developing poor habits. Predicting high risk, nonadherent patients, and developing personalized interventions and communication techniques has been less studied and less implemented in outpatient pharmacies. The purpose of this paper is to understand in pharmacy patients, over the age of 18 taking three or more medications, does improved communication with outpatient pharmacy staff through use of a risk assessment questionnaire improve medication adherence compared to patients with no risk assessment? A risk assessment and personal profile can better improve pharmacy-patient communication, and promote a consistent medication compliance schedule.

A main concern that is encountered with medication adherence is the multifaceted barriers that can prevent individuals from adhering to their medication regimen (Hilbink et al., 2016). Everyone has a slightly different reason preventing them from taking their medication, rather it be money or simply forgetting to take it at a certain time every day. Due to the varied situations (education level, job status, transportation to the pharmacy, living arrangements, marital status) surrounding an individual's nonadherence, a singular solution will not benefit everyone (Mohd et al., 2016). Individuals who have to subcutaneously inject medication versus an oral tablet will change the entire medication administration perspective. People who are extremely symptomatic may adhere to their medication schedule more strictly than patients that are asymptomatic. Nurses must understand the barriers that prevent individuals from complying with the medication program so we can transfer it into a usable, reliable risk assessment that can be used in outpatient pharmacies to promote better patient-pharmacy-practitioner intercommunication and higher medication consistency. A risk assessment sheet that can define deviating important circumstances to individualize patient care can improve patient contact and

promote patient-centeredness. Then, patients can better adhere to their medication schedule with improved motivation, education, and reminders.

The majority of research studies about medication adherence focused on measurement tools (afore mentioned), behavioral patterns, and situational barriers that cause medication adherence. It has been found that cost, specific diagnoses like psychological disorders or asymptomatic diseases, and lack of education are some of the most common reasons patients are nonadherent. The research was performed to understand the reasons behind nonadherence. It is recommended these strategies be applied to outpatient pharmacies and general practitioner's offices to be more aware of the reasons and prevent the situations that may cause nonadherence. Often, there are other drugs within the same class that can provide the same effects and be less costly to the patient. The barriers can be combined to produce a profile risk assessment to make pharmacy workers more aware of high-risk patients and contact them more frequently or determine proper solutions to help them adhere to prescriptions.

Currently, outpatient pharmacies make hundreds of calls to patients daily who may not be at risk, or for reasons that are unimportant. Some unimportant reasons to call patients may be for acute medication physician refill calls or to offer refills for medications that are being filled by mail order. A practical software for some patients can sync medication pickup together, but calls to offer this service for patients taking controlled medications is inefficient. Controlled medications can only be refilled and picked up at specific intervals. The more important patient care calls that should be done include manufacturer coupons to lower medication costs, medication side effects and questions, and medication adherence. Pharmacists and technicians are overwhelmed with the number of prescriptions to fill and phone calls to make, so patient

contact needs to become more efficient to be effective for medication adherence. Through the use of a patient profile and risk assessment, pharmacies can better determine where to focus their attention efficiently to improve medication adherence and patient satisfaction.

There has not been a specific evidence-based protocol designed for outpatient pharmacies, rather every pharmacy determines specific reasons to call patients, normally based on refill completion for increased pharmacy scoring. A new standard of care for medication nonadherence is crucial for global medication regimen improvements and drastic decreases in chronic disease mortality rates. Half of all U.S. adults state having at least one chronic condition, mainly cardiovascular disease, which is the number one cause of mortality and morbidity (Hilbink et al., 2016). Such high numbers of patients at risk for nonadherence and mortality require a new standard of care to be implemented to decrease fatality rates and healthcare costs.

This study was developed based on the information discussed in the literature review and the researcher's experiences working in an outpatient pharmacy. The ProMAS tool is better suited for wider variance and more adherence behaviors, and the demographic questions are essential in order to have a clear picture of patients and determine the reasons behind medication nonadherence. The demographics tool was developed (See Appendix B) and the ProMAS (See Appendix C) was chosen as the tool for the study based on the literature review. The purpose for this study was to survey patients' medication adherence behavior's so nurses can better understand major deterrents of proper medication adherence.

Review of Literature

The selected articles were found using the University of Alabama in Huntsville library, PubMed database, and CINAHL database with inclusion criteria English language and peer-reviewed articles published within the past six years. Some key words that were used to narrow the search criteria included medication adherence education, medication adherence tools, and individualization of medication adherence.

A quasi-experimental research study by Korkmaz, Tastan, and Pay (2016) demonstrated that education is a large part of medication adherence by illustrating the effects of patient education about administration of subcutaneous and intravenous injections. The Turkish scientists aimed to increase the rates of medication adherence in rheumatoid patients when they were provided with individualized education about their diagnosis, current medications, purpose of treatment, drug usage, instructions on administration of the biologic drugs, adverse effects of the drugs, and storage maintenance of the drugs. The sample population included 30 patients administering subcutaneous injections and 30 patients receiving intravenous injections. They found from baseline pre-test and post-test results measured after 3 months, that an individualized education interview increased patients with a high knowledge level from 50% to 96.7% and the motivation levels from 56.7% to 93.3% in subcutaneous injection patients measured on the Morisky Medication Adherence Scale (MMAS or MMS) (Korkmaz et al., 2016). The MMAS is a tool used to determine adherence behaviors and conclude how well patients adhered to their medication regimen (Mohd, Phung, Sun, Morisky, 2016). The WHO-5 Well-Being Index was used to give an indication on the quality of life of the participants receiving biologic drugs. The means from both samples increased, approximately 4 points for the intravenous group and 9 for

the subcutaneous group, illustrating a better quality of life after individualized education. The limitations of this study include the focus on rheumatic disorders and biologic drugs from one clinic and measurements taken after only 3 months. The study should be further tested with oral medications in various settings and multiple diagnoses. Strengths of this study include in-depth patient personal information, widely used and validated measurement tools, and statistically significant data results.

Social support continues to play a key role for human functioning. It can be especially important to patients battling chronic health conditions and requiring multiple doctor's visits and medications. There are three very important reasons to have social support for medication adherence. First, emotional support is essential for those unwilling or unable to consistently take prescribed medication. Second, patients may require help with some alternative medications other than oral, such as injectables. Finally, transportation to and from the pharmacy when the patients is unable. Pinto and Schub (2018) defined structural support as being available to support someone and functional support as the actions that people take to provide the support. Both of these types of support, listed in the meta-analysis evidenced-based care sheet, were described as essential to increased adherence in multiple groups. Multiple statements within the evidence-based care sheet concerning an increase of adherence are important jobs for registered nurses to complete. These jobs included discharge teaching, identifying weaknesses and strengths of patients' support system, and providing the necessary tools to improve one's support system like information about support groups. Intercolloborative professional care between nurses, pharmacists, and other health care providers will create the best possible outcome for patient health. The strengths of the meta-analysis included the wide-range of data being pulled

into a concise sheet, and the large amount of data considered. A weakness is that the sheet did not provide much information for future research.

Mohd et al. (2016) also performed a study in which a 30-minute education session for diabetic patients in the United Arab Emirates improved medication adherence a statistically significant amount, also measured with the MMAS. The researchers had 446 patients partake in the study from the police health clinic in Dubai, the 223 patients of the control group received standard care and the 223 patients of the intervention group in the intervention group received the education session and telephone interviews. Both sample groups completed the initial and final 6-month MMAS questionnaire and blood tests. The control group's MMAS scores remained relatively constant throughout the study. The intervention arm's scores increased in high and medium adherence behaviors, 26.5% to 39.9% in medium adherence, and decreased low adherence behaviors, 64.6% to 44.8%. The mean HbA1c also decreased significantly in the intervention arm, and the control arm remained relatively constant. Some strengths of the study include a large sample population, widely used and validated measurement tools, and statistically significant data results. The limitations of the study are that it was performed at one police clinic in Dubai on type-2 diabetic patients only covering 6 months. MMAS is only one tool being used to study patient's adherence behaviors, other tools include the Probabilistic Medication Adherence Scale (ProMAS) and the Medication Adherence Report Scale (MARS).

Medication adherence measures remain the most difficult and focused issue in compliance studies. The ProMAS and the MARS tools use a series of questions to measure adherence behaviors. Kleppe et al. (2015) developed the ProMAS in a cross-sectional, randomized controlled study comparing the MARS and ProMAS tools. The purpose of the study

was to develop an improved tool to quantifiably measure self-reported medication adherence behaviors. A recruitment agency randomly selected geriatric patients 65+ years of age in a Dutch database who were then invited to partake in the study in exchange for agency points. 370 participants that took medication for chronic conditions were selected to participate in the study. Both the MARS and ProMAS questionnaires were administered in a single online sitting, and the results were compared. They determined that the ProMAS and MARS scores correlated, but that the ProMAS allowed a higher variance to provide a wider range of adherence behaviors and match patient's behaviors more accurately. The strengths of this study included the random selection of participants, large amount of information received from each singular online session, and the large number of participants used. Some limitations included the possible bias from the agency points payment for participation, the adaption of the educational tool/model, and that some ProMAS items could not be widely used among varying diagnoses. The ProMAS needs further testing and validation to overrule the widely accepted and used tool, MARS. With a better tool to quantifiably measure adherence behaviors, it can be appropriately transferred into a valuable risk assessment to prophylactically and continuously monitor nonadherence.

A singular study by Hilbink et al. (2016), was created using a personal profile based on ProMAS and a barrier assessment questionnaire as a predictive measurement to tailor an intervention protocol for high-risk adherence patients starting an oral blood glucose lowering or cardiovascular medication in the Netherlands. The aim was to individualize patient contact and care based on barrier profiles and questionnaires. Unfortunately, they have not completed their cluster-randomized trial as of now and we cannot gain any insight into the successes and failures of the trial. The researchers planned to administer the questionnaires at baseline, 8-months, and 1-year follow-ups to monitor progress. Some strengths from this article included the wide range

of planned pharmacies being studied (25 and across different demographics), longer term study of 1 year, the individualization among the patients with a profile, and the planned randomization of participants. The limitations of the article are that the trial has either not been completed or the results not published, the limit to diabetic and cardiovascular diagnoses, and the limit to beginner medication patients. Now if researchers can translate these measuring tools to predictive measures of nonadherence, we can better contact and review educational materials with higher risk patients to decrease nonadherence and medical costs.

There is clear evidence that education and individualization can improve medication adherence rates and in turn lower healthcare costs and healthcare worker inefficiency. Education and individualization must be implemented to increase higher adherence rates and patient-centeredness. Social support must be established or improved in order for some patients to maintain adherence. A patient will not understand the important reasons behind medication compliance without proper education, and might not take their medication appropriately. Patients then have to suffer with serious complications and expensive healthcare bills due to nonadherence. When patients are unable to avoid complications as a result from the lack of support, then patients may be less willing to participate in their own healthcare. Every patient has specific reasons for not adhering to medication, so individualized patient care must be implemented to satisfy all patients. The significant increase of adherence behaviors and motivation levels across all of the reviewed studies illustrates the importance of education on the motivation levels and subsequent medication administration of patients.

Although education and individualization need to become priority, high output pharmacies cannot manage total patient education and maintain proper refill requirements.

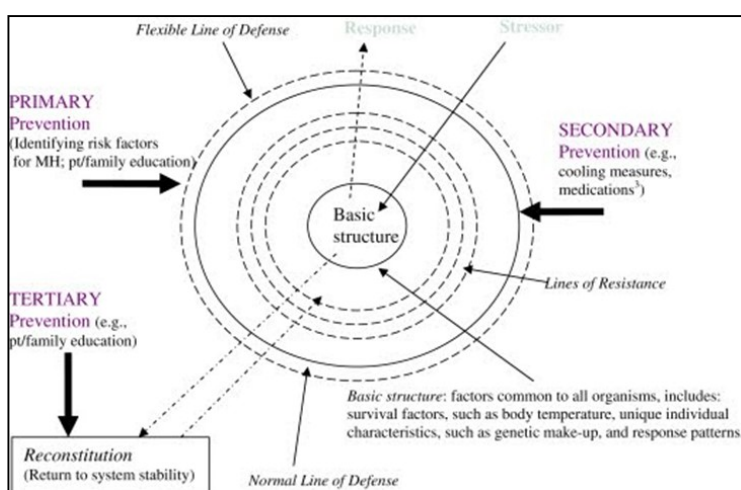
Practitioners and nurses in primary care and hospital settings need to better educate patients about the diagnosis and medications before pickup at outpatient pharmacies. Discharge education about the use, side effects, and diagnosis need to be more thoroughly examined as well as patient contact in outpatient pharmacies. It can become very costly for high output pharmacies to implement such a radical change such as a risk assessment and prophylactic call system. As a result of the implementation though, it could save the entire healthcare system millions of dollars. The motivation to implement the changes will be difficult to establish in corporate pharmacies that spread across the country, so private pharmacies may have a better chance establishing new systems to improve medication adherence. Though there may be issues with widespread outpatient pharmacy change, the implementation of individualized risk assessments and prophylactic contact is clearly a direction that must be further tested and implemented to ensure proper patient care and better medication adherence.

Theoretical Framework

The Neuman's Systems Model may be applied to medication adherence in that healthcare workers must address all of the variables that may cause patient's stress and illness. Ume-Nwagbo, DeWan, and Lowry (2006) give a brief summary of Neuman's Systems Model and presents two hypothetical instances in which the theory may be applied. Neuman's Model is a centralized circle surrounded by numerous concentric circles that symbolize lines of resistance (LOR) (See Figures, Illustrations, and Tables). The lines are penetrated by stress to eventually affect the inner circle, that represents physiological features, and cause illness. The outer two lines represent the flexible line of defense (FLD) and the normal line of defense (NLD), and are shaped by several variables such as coping patterns. There are three different types of prevention to protect the core structure; primary, secondary, and tertiary. Primary prevention reinforces the

FLD to prevent stressors from infiltrating the NLD. Secondary prevention are measures taken after the NLD has been infiltrated and must be restored. Tertiary prevention techniques involve support to reinstitute the LOR and adapt to the permeating stressors. The first hypothetical case focuses on a longstanding marriage where stressors have broken the NLD and LOR, and the marriage must be rebuilt. The second hypothetical case involves a man in need of a coronary artery bypass graft and the interventions a healthcare team must surpass to allow the patient to safely undergo the procedure and heal accordingly afterwards.

The Neuman's Systems Model



Medication adherence is similar to the concentric circles, being that multiple stressors have caused illness and now the LOR and NLD must be rebuilt with the proper medication schedule. Education and support (tertiary prevention) help patients to readapt to their new circumstances following a rigorous medication regimen. After reconditioning, patients must properly take their prescribed medications to properly maintain the NLD and prevent further illness from occurring (secondary prevention). The multiple stressors include the numerous barriers that prevent patients from following the proper prescription details, and allow the NLD

to be permeated. Further reevaluation of diagnosis/medication education (primary prevention) beyond first fill information and patient contact are crucial to maintain the support needed for protecting the FLD. All patients are affected by different variables to restrict them from adhering to medications, and personalized actions must occur to restore and maintain the NLD.

Methods

COVID-19 severely hampered the proceedings of the study. The original methodology called for the used questionnaires to be given twice, once as a baseline and again for final data collection and comparison. Originally data would have been collected in-person within the pharmacy, by Qualtrics survey, and by over the phone recruitment. Contact was supposed to be made with the participants over a 90-day period, the length of time between usual prescription pickups, based on the ProMAS score obtained with baseline data. After the 90-day period, the ProMAS questionnaire would have been readministered for comparison and analyzed for effectiveness of contact. Due to the required reduction in patient interaction, methodology was adjusted to minimize patient risks. Therefore, only baseline data was collected to encourage participation and comply with pharmacy preferences and CDC guidelines.

Due to the recent public health events, contactless research has become essential. To comply with CDC guidelines and governmental restrictions, Qualtrics surveys were made to allow patients easy access to the questionnaires. If patients were uncomfortable with over the phone confidentiality disclosure and the technological handling, then the option to mail and return all research information and questionnaires was provided. IRB approval for the modified methodology was procured by the University of Alabama in Huntsville on 1 August 2020 (See Appendix H).

Population, Sample and Setting

A convenience sample of participants was recruited for this research study. Participants received information about the research study through flyers handed out within a single pharmacy in Huntsville, Alabama. In order to have well-rounded data, a wide variance of participants was sought because people of all demographic groups experience difficulty with medication adherence for various reasons. Also, the goal was to illustrate that people within different socioeconomical levels require individualized care. A wide age range was targeted, over the age of 18, to obtain ample data. The sample size consisted of seven patients from an outpatient pharmacy. They were all of Caucasian, non-Hispanic background with the majority being male participants. Five of the seven participants were in the age range of 60-69 with two outliers, one 80+ years old and the other between the age of 50-59. All participants earn \$50,000 annually, most averaging over \$100,000. Most participants reported a strong support system, and the majority of participants have a spouse or partner and a personal vehicle for transport. All participants have a collegiate degree, with four having a masters or other graduate degree. The participants had to have a medication list of equal to or more than three maintenance medications for chronic conditions to qualify for participation in the study. Participants did not have a caregiver dedicated to medication pickup, and were be able to handle their medications and ensuing information autonomously.

Data Collection

Data was mostly collected by the Qualtrics survey format per the URL and QR code on the recruitment flyers distributed at the pharmacy (See Appendix A and D). Only two participants chose to answer the questionnaires verbally over the phone. Per the original

methodology, recruitment and wellness call phone scripts were developed for participant interaction consistency (See Appendix E and F).

Research Design

The study is non-experimental with a convenience sample of patients from an outpatient pharmacy. It does not have any comparison groups and therefore cannot qualify as a quasi-experimental experiment. This format was chosen to gain better insight from a small sample of participants. In doing so, more information can be retrieved and a trend can be better identified due to the sample being small. By breaking the sample into two groups for comparison with the same sample size the data would not be able to demonstrate a significant trend. The data would also be unable to demonstrate a significance between comparison groups with a seven-participant sample size. Due to the extreme restrictions on the original research design caused by COVID-19, a pilot study was performed in a small independent pharmacy. There have been multitudes of research done on patient medication adherence with no alterations to pharmacy functioning. The data will be compared with results that have been repeatedly tested in the conclusion of the study.

Instruments

The participants completed two questionnaires. The demographic questions include basic census questions along with questions about participants' current medications, background, conditions, and support system (See Appendix B). The information participants provided helps pharmacists and technicians educate patients and confront any issues that lead to nonadherence. The second questionnaire is the ProMAS tool developed by Kleppe, Lacroix, Ham, and Midden (2015).

The Probabilistic Medication Adherence (ProMAS) tool was used to have a wider variance of adherence behaviors (See Appendix C). It is composed of 18 questions and was created using Rasch analysis to place participants into low, medium-low, medium-high, and high medication adherence scales. Rasch analysis allows researchers to place questionnaire answers of unequal difficulty on a linear scale, meaning the ProMAS can better understand and interpret medication adherence behaviors over the other commonly used scales such as the MARS (Kleppe et al., 2015). Originally, the methodology of the study included contact with participants formulated from the baseline score of the ProMAS instrument. To reference for future studies, each category will have different amounts of participant-pharmacy contact requirements. The low category will consist of wellness calls every 2 weeks. The medium categories' wellness calls will be performed every 3 weeks. The high category will be every 4 weeks, a common length of a normal prescription.

The original research design was, after the study's 90-day duration, the participants would be asked the ProMAS questions again for comparison, and complete an experience survey (See Appendix G). The experience survey asks about the participants medication adherence evolution since the start of the survey and what they liked and disliked about the study. The experience survey can be applied to any future research for further patient satisfaction.

Procedure

First, flyers were distributed at the pharmacy to disseminate information about the research project and to recruit participants. Information was distributed to the population previously described. The flyer contained the main researcher's contact information so those that were interested could contact by phone. Also, a Qualtrics's QR code and URL was on the flyer for patients who preferred to complete the information electronically. The baseline questionnaire

and ProMAS tool were conducted over the phone and by Qualtrics URLs per the patient's preference, but the option to mail the questionnaires and have them returned was provided. All participants gave consent before completing the questionnaires, include basic demographic information and the ProMAS tool. The ProMAS tool evaluated the participants' level of medication adherence behavior. This is where the current, IRB approved study finished.

Results

The data received from the seven participants was meticulously analyzed for trends by the main researcher. The study was maintained for four months to extend time for proper recruitment and data gathering. All data was gathered per Qualtrics online format and by phone as previously mentioned. The following trends were found for the small sample size, but further testing is required to establish congruity with the population. The MAiOP is a pilot study that must be further tested in appropriate settings to build strong evidence for a complete conclusion. The following tables give an overall summary of the results for the ProMAS tool. Table 2 displays the results for each individual question of the ProMAS survey based on participant answers. Table 1 illustrates the final medication adherence categories as analyzed from Table 2 data.

It took participants an average of 19 minutes to complete the surveys, across both data collection platforms. The average ProMAS score was 12.57, which ranges in the medium-high medication adherence category. Six of the seven participants took a cardiovascular medication with an average of four of these medications for each participant. Four of the seven participants take at least one allergy medication, and three of the participants take a gastrointestinal medication. One trend observed was all participants who took cardiovascular medications also took gastrointestinal medications. This may or may not be significant due to the fact that the

majority of the participants took cardiovascular medications, and needs further research to verify a significant trend. Also, it was observed that with increasing age a stronger support system is needed for declining health but support systems seem to dwindle as age increases. Further evaluation of the results will be discussed in the following sections of the paper.

Limitations

The MAiOP study was severely hampered by the COVID-19 pandemic. The original design was significantly modified, and no face-to-face contact was permitted with any participants. Due to the significant modifications of the original research design, this paper covers the pilot study performed in lieu. No face-to-face recruitment was granted, so the sample size is significantly small, limiting data analysis. The sample was also biased in that all participants were from a single ethnicity/race, primarily one gender, from a high socioeconomic level, and all from one small area in Huntsville, Alabama. The level of participant comprehension could not be evaluated due to limited contact, so it was difficult to determine the reliability of collected data.

Discussion

Although the data suggests trends exhibited by the seven participants, the MAiOP is a pilot study and will need further testing in the future. Saying that, some significances were discovered that could prove vital to future research. The average time taken to complete the two surveys is 19 minutes, and this is a lengthy time period. The time required to complete the surveys may have limited participation. In the future, hopefully more face-to-face interaction will be allowed to reduce the stress of the lengthy surveys. Also, this would minimize the ambiguity of participant answers and assure researchers of accurate data, while also reducing

participant confusion. There was not enough data to suggest a significant trend in adherence rates with increasing age due to the majority of participants being within the same age range.

The study was completed in northern Alabama and is significant due to common lifestyle qualities. The CDC reports that 36.1% of people in Alabama are obese, most likely the result of common diet and exercise trends for the area (2020). This significance influences the type of medications required, and explains why six of the seven participants take cardiovascular medications. Heart disease is the major leading cause of death, and from the researcher's personal experience, heart disease comes with numerous comorbidities and leads to a host of complications. Also, northern Alabama has a very high pollen count as reported by the national pollen map, so it is not surprising that the majority of participants took at least one allergy medication (pollen.com, 2021).

Support systems are vital to human functioning, and the need increases with age and declining health. The majority of study participants reported a proper support system, but some did not. The older participants reported greater need for support, which illustrates that as individuals' age increases it becomes more difficult to maintain a proper support system. This is due to a number of factors, one being the death of friends and family but is also due to the increasing need of support with declining health. It is not explicitly important for the MAiOP research study, but improved geriatric programs could significantly reduce the difficulties that come with increased age such as falls and memory loss. On the same note this could improve medication adherence and reduce hospitalizations ultimately.

Insurance is a complicated matter that, from the researcher's personal experience, is ultimately misunderstood and requires education. The participants voiced concerns about the

confusion of federal and private insurance matters. Medicare Part B seems to be distinctly confusing and requires education for prescription and medical coverage. It is suggested that a future study be performed for education about federal and private insurance policies to study the effects of this type of education on hospitalization and medication adherence. The majority of participants had high level degrees, so confusion about insurance policies is quite significant. Also, the U. S Department of Health and Human Services reports that only 12% of adults have proficient health literacy (2008). While the participants have high levels degrees, it is unknown to their level of health literacy knowledge, especially when little to no time was allowed to be spent with the participants. In a future reapplication of the MAiOP study, it is recommended to include demographics questions about types of insurance and level of understanding.

In the original pre-pandemic research design, baseline data would have been collected multiple ways to determine adherence behaviors. The main researcher was going to call prospective participants in order to more effectively recruit participants, but was unable to per pharmacy concerns. Normally, participants would have been able to talk to the main researcher in the pharmacy or call for any information. For future research, the ProMAS data would have been analyzed and determined the level of contact with each patient. Some patients with lower-level medication adherence behaviors would be contacted more frequently, whereas, those with high levels would be contacted less frequently. Contact with the participants would continue at regular intervals per the protocol determined for 90 days. This duration was chosen because it is the general prescription length for maintenance medications. After the 90 days, the ProMAS tool used for baseline data would be administered once again to obtain baseline data. A comparison of the final data with the baseline data would ensue to determine whether the contact protocol improved medication adherence.

Implications to Nursing Practice

The MAiOP pilot study may not illustrate significant trends that can be applied to the population, but medication adherence is critical for nursing practice and the toll it takes on the healthcare system. Hospitalizations can be extremely taxing on the patients, patient families, and hospital systems. High medication adherence reduces hospitalizations and the impediments for patients. Detailed and understandable medication education must be given not only in outpatient pharmacies but also in inpatient discharge teaching and outpatient follow-ups. Nurses must take on this critical task to improve health outcomes and reduce complications. Education for patients should be individualized to accommodate those that lack proper health literacy and age-related memory alterations.

Increasing age comes with increased health risks, complications, and reduced support system. Education is vital throughout the lifespan to reduce the complications that arise with age advancement. Nurses should evolve with the ever-evolving technology and advance healthcare practices for the entire lifespan to ensure holistic patient-centered care. Geriatric patients are at a high risk for falls and reduced support, so medication adherence also declines with decreased abilities. Nurses can reduce nonadherence by applying appropriate support measures such as home healthcare, support groups, exercise/diet programs, and involving the appropriate familial connections. Holistic patient-centered care has become the gold standard for nurses, and as such individualized care should be given for patients in all settings to improve overall health and decrease healthcare costs.

Conclusion

Medication adherence is vital to excellent patient well-being and nurses should be aware of the gravity of it. The MAiOP was merely a pilot study that was unable to detect significant trends in data, but is an excellent source for future research and study development. The original design should be tested and implemented to produce sound data analysis and hopeful increases in adherence rates. The ProMAS was tested further to verify its accuracy of predicting medication adherence behaviors. Patient interaction is crucial for the production of an adequate and appropriate model of the original research design. As already discussed, the data does hint towards improved adherence rates with economically and educationally settled individuals, which correlates with past research. Future research needs to focus on the implementation of a standardized assessment tool in outpatient pharmacies and the collaboration of pharmacy staff with inpatient/outpatient nurses. This in itself would reduce immense confusion and create rounded patient-centered care. Recommendations for alterations to the original MAiOP research design would be to include demographic questions about insurance and medication names to have a better correlation between specific medications such as cardiovascular and acid reflux medications. Registered nurses must be educated and able to easily assess important factors that would restrict proper adherence behaviors. They must also work with the healthcare team and act as a leader and advocate to ensure the best possible patient-centered care.

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Appendix A

Recruitment Flyer

MEDICATION ADHERENCE IN OUTPATIENT PHARMACIES RESEARCH STUDY



BACKGROUND

Medication nonadherence has become an issue for healthcare costs and patient health. So, to obtain more information on this issue I, Kylie Bain, am conducting a research study about medication adherence.

I am a 2017 graduate of Arab High School, a student nurse at The University of Alabama in Huntsville, and a pharmacy technician in a retail pharmacy.

For this research project, you will provide some background information and answer some medication questions. I will use the results to see how people take their medication and look at the possible obstacles to taking medication.

CONTACT INFORMATION:

256.580.6388

kab0056@uah.edu

www.uahnursing.com

RESEARCH POINTS

GOAL:

The goal for this study is to improve medication adherence for patients on multiple medications who are at high risk for not taking their medications as prescribed.

PURPOSE:

The purpose is to analyze gaps in medication healthcare through the use of a risk assessment questionnaire and demographic questionnaire.

INCLUSION CRITERIA:

Adult patients who are taking three or more medications.

If you would like to participate, you may complete the questionnaires:

- Over the phone
- Through the mail
- Through the link on an internet browser
- Using the QR code below

Simply type the LINK below into your preferred browser or take a picture of the QR CODE with your phone using a QR scanner to complete the consent form and questionnaires:

LINK:

https://uah.co1.qualtrics.com/jfe/form/SV_4GDhTaRdq26qpxP

QR CODE:



Appendix B

Demographic Questionnaire

-----Beginning of Questionnaire-----

ID (leave blank): _____ Date of birth/Age: _____ Gender: _____

Address (zip code/city is enough if uncomfortable with full address):

Email: _____ Phone # (needed) _____

What is your preferred method of contact from the pharmacy for refill reminders on maintenance medications?

Text Message Reminders

Patient Call Reminders from a Technician

Medications that you are currently taking and approximate length you have been taking them:

- | | |
|----------|-----------|
| 1. _____ | 6. _____ |
| 2. _____ | 7. _____ |
| 3. _____ | 8. _____ |
| 4. _____ | 9. _____ |
| 5. _____ | 10. _____ |

If applicable, list the other medications at the end of the questionnaire.

List any/all chronic health conditions (see previous definition if needed):

Describe your own understanding of the chronic condition(s):

Level of education (circle one):

- | | | |
|----------------------------|-----------------|---------------------|
| Never attended high school | Some college | College Degree: |
| Some high school | College Degree: | Bachelor's Graduate |
| GED | Associate's | Degree |
| High school diploma | | |

Average annual salary (circle one):

- | | | |
|-------------------|--------------------|------------|
| <\$25,000 | \$50,000-\$75,000 | >\$100,000 |
| \$25,000-\$50,000 | \$75,000-\$100,000 | |

Transportation (circle one):

Within walking distance of pharmacy Bus/public transportation
 Personal vehicle No ability to leave the home
 Friend/family drives you

Marital status (circle one):

Single Have a partner/spouse

Support system (list any members):

Family: _____

Friends: _____

Do you feel that you have an appropriate support system for your needs? (circle one):

Definitely yes Undecided Definitely not
 Probably yes Probably not

If applicable for injections and topicals medications: Do you have the ability to administer your own medications or do you require someone to help you? (circle one): Yes, I need help or

No, I do not need help

If so then who? _____

What is your race? (circle one):

American Indian or Alaska Native

Native Hawaiian or Other Pacific Islander

Asian

White

Black or African American

What is your ethnicity? (circle one):

Hispanic or Latino or Spanish origin

Not Hispanic or Latino or Spanish origin

-----End of Questionnaire-----

Appendix C
Probabilistic Medication Adherence Scale Instrument

| | |
|--|---------------|
| It has happened at least once that I forgot to take (one of) my medicines. (R) | Y or N |
| 1. It happens occasionally that I take (one of) my medicines at a later moment than usual. (R) | Y or N |
| 2. I have never (temporarily) stopped taking (one of my) medicines. | Y or N |
| 3. It has happened at least once that I did not take (one of) my medicines for a day. (R) | Y or N |
| 4. I am positive that I have taken all the medication that I should have taken in the previous year. | Y or N |
| 5. I take my medicines exactly at the same time every day. | Y or N |
| 6. I have never changed my medicine use myself. | Y or N |
| 7. In the past month, I forgot to take my medicine at least once. (R) | Y or N |
| 8. I faithfully follow my doctor's prescription concerning the moment of taking my medicines. | Y or N |
| 9. I sometimes take (one of) my medicines at a different moment than prescribed (eg, with breakfast or in the evening). (R) | Y or N |
| 10. In the past, I once stopped taking (one of) my medicines completely. (R) | Y or N |
| 11. When I am away from home, I occasionally do not take (one of) my medicines. (R) | Y or N |
| 12. I sometimes take less medicine than prescribed by my doctor. (R) | Y or N |
| 13. It has happened (at least once) that I changed the dose of (one of) my medicines without discussing this with my doctor. (R) | Y or N |
| 14. It has happened (at least) once that I was too late with filling a prescription at the pharmacy. (R) | Y or N |
| 15. I take my medicines every day. | Y or N |
| 16. It has happened (at least once) that I did not start taking a medicine that was prescribed by my doctor. (R) | Y or N |
| 17. I sometimes take more medicines than prescribed by my doctor. (R) | Y or N |

Appendix D

Qualtrics Survey Sample (Mobile Version)

Welcome to the research study!
 Consent Form: Medication
 Adherence in Outpatient Pharmacies

You are invited to participate in a research study about medication adherence. This study is designed to help us better understand the reasons for medication nonadherence and the tools that improve adherence. By taking these into consideration, proper patient care may be provided for different degrees of medication adherence and improve patient-centered care. At the end of the study, participants will have reflected on their own medications and knowledge.

The primary investigator is Kylie Bain, from UAH College of Nursing, phone number (256)580-6388.

DISCOMFORTS AND RISKS FROM PARTICIPATING IN THIS STUDY: There are no expected risks associated with your participation. You may feel uncomfortable sharing confidential information.

CONFIDENTIALITY OF RESULTS: The information you provide will have no personal identifiers. This consent form will be destroyed after 3 years. The data from your session will only be released to those individuals who are directly involved in the research.

EXPECTED BENEFITS: Results from his study can benefit society by improving pharmacy contact with patients and allowing patients to partake a bigger part in their healthcare.

FREEDOM TO WITHDRAW: You are free to withdraw from the study at any time. You will not be penalized

because of withdrawal in any form. Investigators reserve the right to remove any participant from the session without regard to the participant's consent.

CONTACT INFORMATION: If you have questions at any time, you may contact the Principal Investigator Kylie Bain at UAH College of Nursing, at 256.580.6388 or my faculty advisor, Dr. Rebecca Davis, at 256.824.2438. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB at 256.824.6992 or email the IRB chair Dr. Ann Bianchi at irb.@uah.edu. This study was approved by the

Institutional Review Board at UAH and will expire in one year from 08/01/2020.

If you agree to participate in our research please sign and date below. If you are under the age of 18, please provide your parent or legal guardian's signature indicating consent.

I consent, begin the study

I do not consent, I do not wish to participate

Please Sign and Date below:

x
SIGN HERE

clear

Date:

2/17/2021

>>

English ▼

General Statement: This research study is strictly voluntary. Any questions that you do not wish to answer is acceptable. All answers that you provide will be protected and secured within a restricted file. All responses help to better understand and interpret the reasons behind medication nonadherence, and how to better assist patients. All information asked is relevant to the medication adherence research study, and any information that you graciously supply will be very appreciated. Thank you.

Definitions:

Medication Adherence: When you take medications how the doctor has prescribed them.

Chronic Condition: A health issue that has lasted for more than 1 year and requires ongoing medication therapy or treatment.

What is your age range?

20-29 years old

30-39 years old

40-49 years old

50-59 years old

60-69 years old

70-79 years old

80+ years old

Do you take 3 or more medications?

Yes

No

What is your gender?

Male

Female


What is your city/zip code?

What is your preferred method of contact from the pharmacy for refill reminders on maintenance medications?

Text Message Reminders

Patient Call Reminders from a Technician

Medications that you are currently taking and approximate length you have been taking them (just do your best):

| | Click to write Column 1 12345 67890 | Click to write Column 2  |
|--|--|---|
| | Number of Medications | Amount of time taken (years) |
| Heart and Blood Medications (including blood pressure, cholesterol, water pills, anti-arrhythmics, anticoagulants) | <input type="text"/> | <input type="text"/> |
| Diabetic Medications (oral tablets, insulin, glucagon) | <input type="text"/> | <input type="text"/> |
| Mental Health Medications (antidepressants, anticonvulsants, antipsychotics, mood stabilizers, anti-anxiety) | <input type="text"/> | <input type="text"/> |
| Immunosuppressant Medications (Lupus, RA, anti-cancer drugs, Sickle-Cell) | <input type="text"/> | <input type="text"/> |
| Headache Medications | <input type="text"/> | <input type="text"/> |
| Seizure Medications (EX: Dilantin/phenytoin, phenobarbital, Lamictal, oxcarbazepine) | <input type="text"/> | <input type="text"/> |
| Gastrointestinal Medications (IBS, IBD, Crohn's, Ulcerative Colitis, ect) | <input type="text"/> | <input type="text"/> |
| Pain Medications (EX: NSAIDS, narcotics, Tylenol, ect) | <input type="text"/> | <input type="text"/> |
| Respiratory Medications (asthma, COPD, bronchitis) | <input type="text"/> | <input type="text"/> |
| ADHD Medications (EX: Intuniv, Straterra, stimulants) | <input type="text"/> | <input type="text"/> |
| Movement/Musculoskeletal Disorders (MS, Parkinson's, muscle spasms, spinal injuries) | <input type="text"/> | <input type="text"/> |
| Memory Drugs (Alzheimer's, dementia) | <input type="text"/> | <input type="text"/> |
| Allergy Medications (EX: Zyrtec, epipen, Allegra, Xyzal, Montelukast/Singular) | <input type="text"/> | <input type="text"/> |
| Vitamin Deficiencies (D3, B12) | <input type="text"/> | <input type="text"/> |

| | | |
|--|----------------------|----------------------|
| Hormone Disorders (thyroid gland, adrenal gland, estrogen, testosterone) | <input type="text"/> | <input type="text"/> |
| Eye Drops/Ear Drops | <input type="text"/> | <input type="text"/> |
| Long-term Antibiotics | <input type="text"/> | <input type="text"/> |
| Long-term Antifungals | <input type="text"/> | <input type="text"/> |
| Prostate/ED Medications | <input type="text"/> | <input type="text"/> |
| Antivirals | <input type="text"/> | <input type="text"/> |

Anything you would like to add or comment to the previous question.

Describe your own understanding of your chronic condition(s):

Level of Education:

- Never attended high school
- Some high school
- GED
- High school diploma
- Some college
- College degree: Associate's
- College degree: Bachelor's
- Graduate degree

Average Annual Salary:

- < \$25,000
- \$25,000-\$50,000
- \$50,000-\$75,000
- \$75,000-\$100,000
- >\$100,000

Transportation:

- Within walking distance of the pharmacy
- Personal vehicle
- Friend/Family drives you
- Bus/public transportation
- No ability to leave the home

Marital Status:

- Single
- Have a partner/spouse

Support system (list any members):

- Close Family
- Extended Family
- Friends

Do you feel that you have an appropriate support system for your needs?

- Definitely yes
- Probably yes
- Might or might not
- Probably not
- Definitely not

If applicable for injections and topical medications:

Do you have the ability to administer your own medications or do you require someone to help you?

- Yes, I can administer my own injections
- No, I require assistance to administer my injections

If you answered "no, I require assistance" to the previous question, then who helps you?

What is your race?

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

What is your ethnicity?

Hispanic or Latino or Spanish origin

Not Hispanic or Latino or Spanish origin

<<

>>

Powered by Qualtrics [↗](#)

English ▼

Please answer the following questions to the best of your ability.

1. It has happened at least once that I forgot to take (one of) my medicines.

Choose One
Yes No

Please answer the following questions to the best of your ability.

2. It happens occasionally that I take (one of) my medicines at a later moment than usual.

Choose One
Yes No

Please answer the following questions to the best of your ability.

3. I have never (temporarily) stopped taking (one of my) medicines.

Choose One
Yes No

Please answer the following questions to the best of your ability.

4. It has happened at least once that I did not take (one of) my medicines for a day.

Choose One
Yes No

5. I am positive that I have taken all the medication that I should have taken in the previous year.

Please answer the following questions to the best of your ability.

6. I take my medicines exactly at the same time every day.

Choose One
Yes No

Please answer the following questions to the best of your ability.

| | Choose One | |
|---|-----------------------|-----------------------|
| | Yes | No |
| 7. I have never changed my medicine use myself. | <input type="radio"/> | <input type="radio"/> |

Please answer the following questions to the best of your ability.

| | Choose One | |
|---|-----------------------|-----------------------|
| | Yes | No |
| 8. In the past month, I forgot to take my medicine at least once. | <input type="radio"/> | <input type="radio"/> |

| | Choose One | |
|---|-----------------------|-----------------------|
| | Yes | No |
| 9. I faithfully follow my doctor's prescription concerning the moment of taking my medicines. | <input type="radio"/> | <input type="radio"/> |

Please answer the following questions to the best of your ability.

| | Choose One | |
|--|-----------------------|-----------------------|
| | Yes | No |
| 10. I sometimes take (one of) my medicines at a different moment than prescribed (eg, with breakfast or in the evening). | <input type="radio"/> | <input type="radio"/> |

Please answer the following questions to the best of your ability.

| | Choose One | |
|--|-----------------------|-----------------------|
| | Yes | No |
| 11. In the past, I once stopped taking (one of) my medicines completely. | <input type="radio"/> | <input type="radio"/> |

Please answer the following questions to the best of your ability.

| | Choose One | |
|---|-----------------------|-----------------------|
| | Yes | No |
| 12. When I am away from home, I occasionally do not take (one of) my medicines. | <input type="radio"/> | <input type="radio"/> |

| | Choose One | |
|--|-----------------------|-----------------------|
| | Yes | No |
| 13. I sometimes take less medicine than prescribed by my doctor. | <input type="radio"/> | <input type="radio"/> |

Please answer the following questions to the best of your ability.

| | Choose One | |
|--|-----------------------|-----------------------|
| | Yes | No |
| 14. It has happened (at least once) that I changed the dose of (one of) my medicines without discussing this with my doctor. | <input type="radio"/> | <input type="radio"/> |

Please answer the following questions to the best of your ability.

| | Choose One | |
|--|-----------------------|-----------------------|
| | Yes | No |
| 15. It has happened (at least) once that I was too late with filling a prescription at the pharmacy. | <input type="radio"/> | <input type="radio"/> |

Please answer the following questions to the best of your ability.

| | Choose One | |
|------------------------------------|-----------------------|-----------------------|
| | Yes | No |
| 16. I take my medicines every day. | <input type="radio"/> | <input type="radio"/> |

| | Yes | No |
|--|-----------------------|-----------------------|
| 17. It has happened (at least once) that I did not start taking a medicine that was prescribed by my doctor. | <input type="radio"/> | <input type="radio"/> |

Please answer the following questions to the best of your ability.

| | Choose One | |
|---|-----------------------|-----------------------|
| | Yes | No |
| 18. I sometimes take more medicines than prescribed by my doctor. | <input type="radio"/> | <input type="radio"/> |



Appendix E

Phone Script for Recruitment Calls

Researcher Recruitment Calls to Participants

Anything in the brackets is said if the call does not go to voicemail.

<if the participant is unable to answer the phone then go straight from “pharmacy” into the “I would...” researcher script and skip all participant script responses.>

Hello, this is _____ from _____ Pharmacy. [How are you today]?

<participant replies similarly to “I’m doing well”>

[Good!] I would like to talk to you about a research study I am conducting within the pharmacy. I am an (*undergraduate nursing student*) performing a medication adherence project and am looking for willing participants. [It won’t require much of your time. May I give you more information?] If you think you may be interested or have any questions then give me a call back at _____ for more information. Thank you for your time.

---End of voicemail---

---Continue if not a voicemail---

<they may at this point say they are not interested. If so then say “That’s fine.” respond “Thank you for letting me have a moment of your time, have a great day”>
<if they are interested and ask for more information proceed with script>

The study requires zero in-person contact unless you prefer to complete it in the pharmacy. I do understand that all patients are concerned with the recent public health events, and I can easily perform this study through a phone or electronic device. It only consists of 2 questionnaires at the beginning and the end of the study with a few calls in between. There is no risk to you and all personal information that you wish to provide will remain strictly confidential and secured within a locked file. If at any time you wish to not proceed with the study then there is zero recourse. All of your voluntary time is simply to provide information to produce a better way to contact patients and improve medication adherence. I want to better understand patients and the restrictions that prevent them from properly taking their medication. In order to do so I want to individualize patient care and allow patients to have more influence in their healthcare.

<again, they may at this point say they are not interested. If so then say “That’s fine. Thank you for letting me have a moment of your time, have a great day”>
<if they want are willing to participate proceed with script>

Great! There are several ways for you to complete the 2 questionnaires. One way is for me to go through both of them over the phone and you may answer or reject to answer any questions I ask. Another way to answer them is to go to the URLs on Google Chrome or any internet source you prefer and fill out the Qualtrics Survey format. Also, you can always answer the questions in pharmacy, or I can even mail you the questionnaires to fill out and return. If so, I would prefer you contact me at _____ to ensure I can perform the study at your preferred time.

<if they then and there want to perform the questionnaires over the phone, begin asking the questions. If they want to perform the online survey then repeat the URLs and tell them to have a nice day and call back at _____ if they have any questions. If they want to complete the questionnaires in pharmacy or at a later time ask for an appropriate time to call them back or give a good time for them to call you>

<if they never respond/call back/come to the pharmacy, follow up 1x to ensure they did not just forget about you>

Appendix F Phone Script for Wellness Calls

Researcher Wellness Calls to Participants

Anything in the brackets is said if the call does not go to voicemail.

<if the participant is unable to answer the phone then go straight from “study” into the “I am...” researcher script and skip all participant script responses.>

Hello, this is Kylie Bain from _____ Pharmacy and UAH College of Nursing. I am performing the medication adherence research study. [How are you today]?

<participant replies similarly to “I’m doing well”>

[Good!] I am just calling for a wellness check to see how taking your medications have been going and ask if you have any questions about anything. [If you have any questions for the pharmacist, I will gladly redirect you to talk to her/him.]

<here they will reply and ask any questions>

<if they did not answer then say “If you do have any questions or concerns you may give me a call back at _____”>

---End of voicemail---

---Continue if not a voicemail with participant questions and responses---

Appendix G

Final Experience Survey

1. What did you like about this study?

2. What did you not like about this study?

3. What part(s) of the study was helpful to you for medication adherence?

4. What part(s) of the study was not helpful to you for medication adherence?

5. Do you feel like you have a better understanding of your medications and conditions?

Explain.

Appendix H
IRB Approval Letter



Date: 1 August 2020

PI: Kylie Bain
PI Department: College of Nursing
The University of Alabama in Huntsville

| |
|--|
| <input checked="" type="checkbox"/> Expedited (see pg 2) |
| <input type="checkbox"/> Exempted (see pg 3) |
| <input type="checkbox"/> Full Review |
| <input type="checkbox"/> Extension of Approval |

Dear Kylie,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal titled: *Medication Adherence in Outpatient Pharmacies* and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with these institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g., a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

Ann L. Bianchi
IRB Chair
Associate Professor, College of Nursing

Expedited: form 2

Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Collection of data from voice, video, digital, or image recordings made for research purposes.

X Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Exempt form 3:

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews, or observation of public behavior in which information is obtained in a manner that human subjects cannot be identified directly or through identifiers linked to the subjects and any disclosure of the human subject's responses outside the research would NOT place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. The research is not FDA regulated and does not involve prisoners as participants.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior if (a) the human subjects are elected or appointed public officials or candidates for public office, or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. The research is not FDA regulated and does not involve prisoners as participants.

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The research is not FDA regulated and does not involve prisoners as participants.

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. The protocol will be conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency and does not involve prisoners as participants.

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.

1 Surveys, interviews, or observation of public behavior involving children cannot be exempt.

Table 1 Participant Adherence Scores

| Adherence Category | ProMAS Sum Scores | MAiOP frequency (number of patients) |
|---------------------------|--------------------------|---|
| Low | 0-4 | N=0 |
| Medium-Low | 5-9 | N=0 |
| Medium-High | 10-14 | N=5 |
| High | 15-18 | N=2 |

Table 2 Participant ProMAS Questionnaire Results

| ProMAS Question | Participants Answering Yes | Participants Answering No |
|--|-----------------------------------|----------------------------------|
| 1. It has happened at least once that I forgot to take (one of) my medicines. (R) | N=5 | N=2 |
| 2. It happens occasionally that I take (one of) my medicines at a later moment than usual. (R) | N=5 | N=2 |
| 3. I have never (temporarily) stopped taking (one of my) medicines. | N=4 | N=3 |
| 4. It has happened at least once that I did not take (one of) my medicines for a day. (R) | N=6 | N=1 |
| 5. I am positive that I have taken all the medication that I should have taken in the previous year. | N=4 | N=3 |
| 6. I take my medicines exactly at the same time every day. | N=4 | N=3 |
| 7. I have never changed my medicine use myself. | N=5 | N=2 |
| 8. In the past month, I forgot to take my medicine at least once. (R) | N=3 | N=4 |
| 9. I faithfully follow my doctor's prescription concerning the moment of taking my medicines. | N=7 | N=0 |
| 10. I sometimes take (one of) my medicines at a different moment than prescribed (eg, with breakfast or in the evening). (R) | N=0 | N=7 |

| | | |
|--|-----|-----|
| 11. In the past, I once stopped taking (one of) my medicines completely. (R) | N=1 | N=7 |
| 12. When I am away from home, I occasionally do not take (one of) my medicines. (R) | N=2 | N=5 |
| 13. I sometimes take less medicine than prescribed by my doctor. (R) | N=0 | N=7 |
| 14. It has happened (at least once) that I changed the dose of (one of) my medicines without discussing this with my doctor. (R) | N=0 | N=7 |
| 15. It has happened (at least) once that I was too late with filling a prescription at the pharmacy. (R) | N=4 | N=3 |
| 16. I take my medicines every day. | N=7 | N=0 |
| 17. It has happened (at least once) that I did not start taking a medicine that was prescribed by my doctor. (R) | N=0 | N=7 |
| 18. I sometimes take more medicines than prescribed by my doctor. (R) | N=0 | N=7 |

Yes (true) is scored with a 1 and No (not true) is scored as a 0 unless the question is labeled with an R for reverse coding.