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A process improvement initiative on medication reconciliation

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A PROCESS IMPROVEMENT INITIATIVE ON MEDICATION RECONCILIATION

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by

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A DNP PROJECT

Submitted in partial fulfillment of the requirements for the
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Kim Budisalech 10/23/19

Student Signature Date

DNP PROJECT APPROVAL FORM

Submitted by Kimberly Budisalich in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

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ABSTRACT
The School of Graduate Studies
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Degree: Doctor of Nursing Practice College: Nursing

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Title: A Process Improvement Initiative on Medication Reconciliation

Medication reconciliation continues to be at the forefront of improving patient safety and is essential to maintaining an accurate medication list in the outpatient setting. Discrepancies in the patient's medication list can lead to adverse events causing undue harm to a patient. The Joint Commission has made medication reconciliation a primary National Patient Safety Goal since 2005. The primary objective of this project was to improve patient safety through enhanced review of the process of medication reconciliation during a Medicare Annual Wellness Visit (AWV), conducted by a Nurse Practitioner, to increase the accuracy of the patient's medication list. A retrospective chart review was completed in a nurse-managed clinic that resides within a large academic physician residency facility providing a unique multidisciplinary interprofessional collaboration with Physicians, Pharmacists, and Nurse Practitioners. The retrospective chart review included 101 patients seen by a Nurse Practitioner in the clinic for their AWV from June 1, 2019, through July 31, 2019. A total of 213 discrepancies were identified. Of the 101 charts reviewed, 83 had at least one discrepancy and 61 had at least two discrepancies, averaging 2.1 discrepancies per patient. The most common discrepancies identified were omissions (55%) and medications no longer taken (29%). Results indicated a standardized medication reconciliation process using a blended method is beneficial in identifying discrepancies to improve the accuracy of the patient's medication list.

TABLE OF CONTENTS

SECTION II: DNP PROJECT PRODUCT

A Process Improvement Initiative on Medication Reconciliation

Introduction

Medication reconciliation is the process of comparing what medications the patient is currently taking to the recorded list in the patient's medical record. This comparison of medications is completed to increase the accuracy of the medication list to reduce medication errors and the potential for adverse drug events (ADE) (Smith et al., 2015). The medication list in the patient's electronic chart often differs from what medications the patient is actually taking, especially if the patient has multiple providers prescribing their medications, are taking over the counter (OTC) medications that are not on their list, or if they are nonadherent to their prescribed medications.

There are several methods of reconciling a patient's medication list in the primary care setting including using a patient home medication list, medication bottles, patient recall, or pharmacy claims data. These methods can be used alone or in combination with one another. Thorough medication reconciliation requires collecting a comprehensive medication history, comparing lists and other resources to identify discrepancies, and resolving or correcting those discrepancies. Discrepancies in the patient's medication list can lead to an adverse drug event, causing undue harm to a patient. Medication reconciliation can require extra time, resources, and multidisciplinary collaboration to obtain the most accurate information (Marien, Krug, & Spinewine, 2017).

The purpose of this project was to improve patient safety through an enhanced review of the process of medication reconciliation during a Medicare Annual Wellness Visit (AWV), conducted by the nurse practitioner, to increase the accuracy of the patient's medication list.

The objectives for this process improvement initiative include:

1. Complete a retrospective chart evaluation using a customized data collection tool
2. Document and clarify the process to reconcile medications
3. Improve the accuracy of the patient's medication list by identifying discrepancies.

Practice Question

In Medicare Patients, does standardizing the process of medication reconciliation, during an Annual Wellness Visit, assist with identifying discrepancies and improve the accuracy of the patient's medication list?

Identification of Need

Medication reconciliation continues to be at the forefront of improving patient safety and is essential to maintaining an accurate medication list in the outpatient setting. Medication errors are a primary patient safety concern and account for approximately 1.5 million hospitalizations each year (Phansalkar et al., 2015). Inaccurate patient medication lists contribute to medication errors which can be potentially harmful to patients and cause increased financial burden to the healthcare system (Khalil, Shahid, & Roughead, 2017). The Institute of Medicine (IOM) reported an estimated $880 million yearly treatment cost due to medication errors and adverse drug events (Vejar, Makic, & Kotthoff-Burrell, 2015). The Joint Commission has made medication reconciliation a primary National Patient Safety Goal since 2005. The 2019 National Patient Safety Goal 03.06.01 is to "maintain and communicate accurate patient medication information" (The Joint Commission, 2019, p.4). The goal of medication reconciliation is to improve patient safety through enhanced review and documentation of the patient's medications by increasing the accuracy of the medication list, lowering the use of inappropriate medications, and lessening duplicate medication therapy (Vejar et al., 2015).

Within this local facility, an improved medication reconciliation process was identified as part of a new interprofessional program for Chronic Care Management. The program required an updated medication form which documented the last medication reconciliation. Since this was a new clinic within the facility with an increased collaboration that included an additional profession, nurse practitioners, there was not a standardized process in place for reconciling patients' medications with multiple providers. Medication discrepancies were found during Medicare AWV, supporting the need for a process to be implemented to identify discrepancies and reconcile the patient's medication list.

Review of Literature

An initial comprehensive literature review was conducted to obtain evidence on current practice on medication reconciliation in the outpatient setting. The databases searched included CINAHL, PubMed/Medline, and Ovid using keywords medication reconciliation, medication adherence, outpatient clinic, patient safety, and interprofessional collaboration. The initial search retrieved a total of 128 articles. Parameters set to narrow the search included articles published within the last ten years, English language, with and without abstract, and peer-reviewed, which then narrowed the total articles included to 60. After further review and exclusions, 15 articles were included in the synthesis of evidence. There was a lack of literature on medication reconciliation in the primary care setting. A majority of the literature evaluated medication reconciliation in the hospital setting or during outpatient transition of care visits (when the patient first follows up after hospital discharge). The literature revealed strong evidence to support the collaborative benefits of including pharmacists in the medication reconciliation process to increase the accuracy of the patient's medication list, reduce healthcare cost, and improve patient safety (Smith et al., 2015).

Medication Reconciliation Methods

A study by Reedy, Yeh, Nowacki, & Hickner (2016), reported only 15% of the patient's medication lists were accurate when reconciled by patient report. These results were compared to previous studies over the past 10 years showing minimal improvement. Medications reconciled by patient report were then compared to patients who brought in their medication bottles or list which did indicate a more accurate list, although the analysis did not prove to be statistically significant. Other references discussed by Reedy concluded that patients bringing in their medication bottles or list were beneficial in completing an accurate medication list (Reedy, et al., 2016). Studies have shown that patients physically bringing all their medication bottles, including over the counter (OTC) medications, into the office helped with reconciling the patient's medication list and brought to the attention of the provider any high-risk medications or discrepancies in medications compared to the list in the patients' chart (Vejar et al., 2015).

Combining medication history on the electronic health record (EHR) and reviewing pharmacy claims data can increase the accuracy of the medication list by 17% (Phansalkar et al., 2015). Reviewing pharmacy claims data can provide objective evidence of medication history on whether a patient's prescription was filled and who prescribed it, although it does not provide the medication directions. Utilizing pharmacy claims data can assist with obtaining medication history, although it does have its limitations. If a patient paid cash for their prescription it would not appear on the pharmacy claims data. The pharmacy data claims can be directly built into the EHR to provide easy access to a patient's medication history (Phansalkar et al., 2015).

Adverse Drug Events in the Elderly

Relying on an elderly patient's ability to recall their medications can result in an inaccurate medication list. A study complete with 99 patients 65 and older with no cognitive

impairment resulted in only 22% of them accurately recalling their medications from memory (Jones, Tabassum, Zarow, & Ala, 2015). This can be common practice in some facilities, especially if the patient does not have a medication list or bottles. Patient recall history (self-reporting) of their medications may need to be verified by some other method if there are any concerns about the patient's ability to recall their medications accurately.

Elderly patients are at a higher risk for adverse drug events (ADE). Research has shown that not completing medication reconciliation can result in adverse drug events with approximately 8,000-12,000 deaths per year (Vejar et al., 2015). Educating healthcare providers on high-risk medications and the importance of medication reconciliation is critical to patient safety. The American Geriatrics Society (AGS) Updated Beers Criteria® (2019), can be used as a valuable resource to identify and avoid potentially harmful prescription and OTC medications that are frequently used by elderly patients. Identifying these high-risk medications is another reason why it is so important that patients bring in all their medication bottles including all OTC medications. Patients need to be educated on the potential risk and dangerous outcomes that could be caused by taking high-risk medications (Vejar et al., 2015).

Medication Adherence

Evaluating medication adherence is a crucial piece for the medication reconciliation process. Assessing a patients' adherence to their prescribed medication directly affects the accuracy of the medication list. Adherence is defined by the World Health Organization (WHO) as "the extent to which the persons' behavior (including medication-taking) corresponds with agreed recommendations from a healthcare provider" (Lam & Fresco, 2015, p.1). There are several tools available to measure medication adherence. The most common assessment tools to rate medication adherence are health professional assessments and self-report. A meta-analysis

study concluded that the use of a self-report survey in conjunction with a chart review improved the adherence assessment. The use of objective and subjective information offers greater reliability and identifies reasons for nonadherence. Underreporting by the patients to prevent disapproval from their provider is the most common downside (Lam & Fresco, 2015).

The WHO reports that medication adherence could have a more significant effect on health outcomes than the individual medical treatment itself. Medication nonadherence accounts for 30% of hospital admissions related to adverse drug events. Medication nonadherence can be a patient failing to initiate or refill their prescriptions to not taking their prescription medications as prescribed. Medication nonadherence poses a significant burden on healthcare costs and can lead to poor patient outcomes. The WHO reported a 50% nonadherence rate among patients living in developed countries (Lam & Fresco, 2015). Especially in the elderly population, a lack of financial resources can be a primary cause of nonadherence. Studies have shown that patients with Medicare have an increased nonadherence rate once they reached the doughnut hole (patient has to pay out of pocket). Patients will either cut back on their prescribed dose or stop the more expensive medications they are unable to afford, which can be detrimental to their health (Roumie, 2012).

Interprofessional Collaboration

A fundamental issue in healthcare is the lack of interprofessional collaboration and communication that occurs among healthcare professionals. *To Err is Human*, published in 1998 by the Institute of Medicine (IOM), reported as many as 98,000 people die every year from medical errors. In 2010 that number doubled to 180,000 and in 2013 the number of deaths per year from medical errors was estimated to be between 210,000- 440,000. Adverse drug events are one of the most common causes of medical errors (Carver & Hipskind, 2019). According to

The Joint Commission, ineffective communication between health care professionals was a principal cause of sentinel events in the hospital setting from 2004 to 2012. Poor communication amongst health care professionals is the leading cause of preventable errors that could lead to the injury or death of a patient (Poore, Cullen, & Schaar, 2014).

A qualitative study by Bell et al., (2017) found that nurses and pharmacists recognized the benefit of learning from each other and working together on interprofessional medication reviews (IMRs). They were able to learn the value in the role of each discipline and what the other could bring to the care of the patient. The nurse provided clinical information and health assessment where the pharmacist was able to provide knowledge on the pharmacotherapy and medication management (Bell, Granas, Enmarker, Omli, & Steinsbekk, 2017)

Studies have found a correlation between interprofessional collaboration and positive patient outcomes (Fewster-Thuente & Velsor-Friedrich, 2008). Improving communication and collaboration within the different disciplines will provide additional intervention to assure correct and safe medication treatment. Healthcare professionals working together to make decisions on best practices and care for the patient and open discussions on alternative treatments can improve patient satisfaction, reduce healthcare costs, and decrease mortality (Ezziane et al., 2012).

Conceptual Framework

The Six Sigma Model was used to guide this process improvement initiative to provide direction in the medication reconciliation process in promoting quality and efficiency to increase success and sustainability. See Table 1. Six Sigma was originally used in the manufacturing industry to improve efficiency by recognizing and removing the problem to improve the processes (National Learning Consortium, 2013).

Table 1. Six Sigma Model

Five Principles	Six Sigma Model	Project MR Process
1. Define	Define the problem or goals.	Inaccurate medication list
2. Measure	Track performance/Measure problem and process	Retrospective chart review/ Collect discrepancy data
3. Analyze	Analyze data to identify the causes of the problems	Analyze data for significance of problem. Descriptive statistics
4. Improve	Use results to determine changes to improve the process/ Create solutions	Make suggestions for changes to improve the medication reconciliation process/ Standardized Med Rec Process (SMRP)
5. Control	Maintain improvements/ Continue monitoring and improving the process	Maintain and monitor the process so improvements can be adjusted if needed/ analyze, publish, propose recommend educational curriculum/ Create auditing system/report/IPE piece

Implementation

Institutional Review Board (IRB) approval was obtained by The University of Alabama in Huntsville and a letter of permission was received from administration of the clinic where the project was implemented. Data was collected and reported aggregately, without any identifying patient information to protect anonymity.

Implementation of the Chronic Care Management (CCM) program brought attention to the necessity for completing and documenting medication reconciliation to key stakeholders. A meeting with stakeholders was completed four prior to implementation of the retrospective chart review to discuss the concerns, facilitators, barriers, and care gaps in the current medication reconciliation process. The meeting included administrators, six physician department heads, the clinical pharmacist in the internal medicine department, and the DNP student. Approval was granted to make necessary changes to the patient's medication list. Guidelines were provided for acceptable documentation changes permitted and a written process was provided to the Nurse Practitioners in the chronic care management clinic. The project took place over 8 months. See Figure 1 for the project timeline.

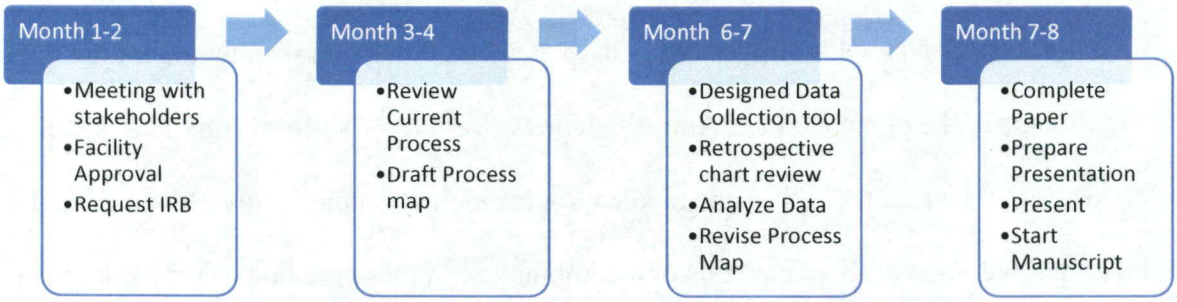

Figure 1. Project Timeline

Modifications to the previous medication reconciliation process included two changes (1) patients completing an adherence questionnaire and (2) the nurse practitioner making physical changes in the medication list within the EHR. Six months before implementing this project an additional change in procedure was implemented which implemented a pre-appointment call to patients to remind them of their appointment date and time and request, they bring all medication bottles, including over the counter (OTC) medications to their appointment. See Figure 2 for the medication reconciliation process.

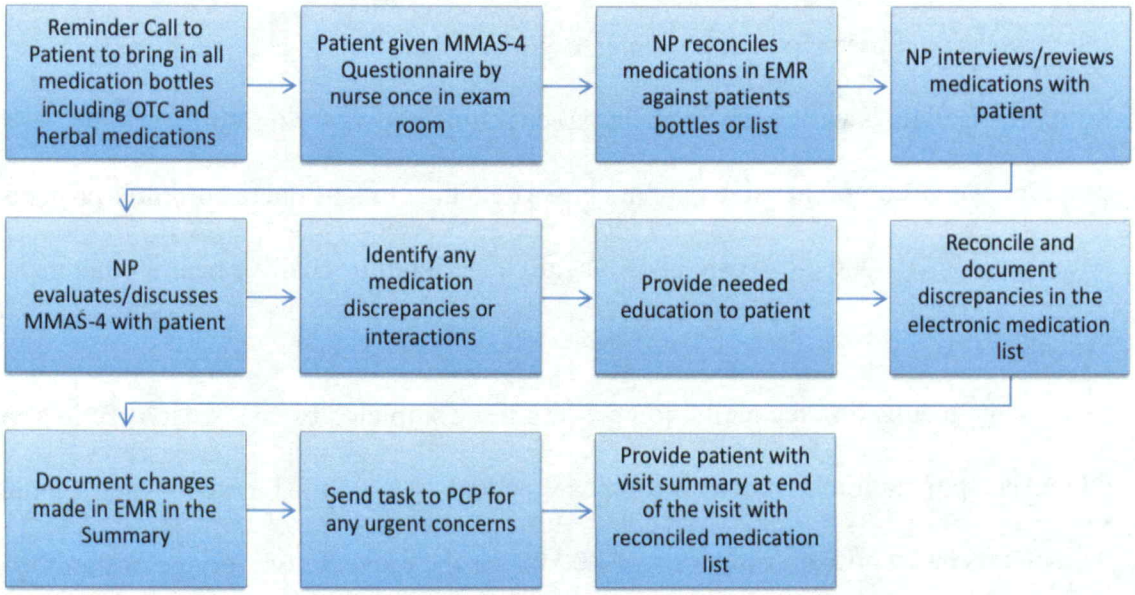

Figure 2. Project Medication Reconciliation Process

Methods

A retrospective chart review was completed on all patients seen by one of the three Nurse Practitioners in the clinic for their Annual Wellness Visit (AWV) from June 1, 2019, through July 31, 2019. During the AWV, the medication reconciliation method was documented and was completed with one of three methods or a combination of these methods: comparing the patient's medication list in the EHR to either the bottles they brought from home, their home medication list, and/or patient recall. The nurse practitioners completed a thorough patient history, from the patient, their family, or a caregiver, to determine accurate dosing and adherence of medications. The Nurse Practitioner identified if there were medication discrepancies and documented the findings in the summary section of the EHR to inform the primary provider (on record) of changes made to the electronic medication list.

Setting and Population

The chart review took place in a new nurse-managed clinic implemented within a large academic physician residency healthcare facility. The academic facility has a multidisciplinary interprofessional practice with physicians, clinical pharmacists, and nurse practitioners. Having multiple disciplines within the same outpatient clinic allows for interprofessional collaboration to provide quality comprehensive patient care. The Nurse Practitioners currently provide patients with yearly AWV and close care gaps that are beneficial for positive health outcomes as well as cost benefit.

The medication reconciliation process was completed by the Nurse Practitioners in the clinic. The population included all Medicare patients seen in the Clinic for their Medicare AWV. All patients had a primary diagnosis of Z00.00 for the preventative service of the AWV. Patients

were not excluded due to age since some patients are under the age of 65 with Medicare, making them eligible for the wellness exam. The sample size included 101 patient chart reviews.

Tools

Two evaluation tools were used to collect the research data. The Medication Adherence Questionnaire (MAQ), also known as the Morisky Medication Adherence Scale (MMAS-4, was added to the medication reconciliation process two months before the retrospective chart review to assist with evaluating medication adherence. This tool was originally published in 1986 and has been proven to be reliable and valid in the research. This is a four-item questionnaire that can provide valuable information on patient adherence to their medication regimen with minimal additional time. The questionnaire is a yes/no score of 1-4. (Morisky & DiMatteo, 2011). See Appendix B.

A data collection tool was designed within Qualtrics to track and identify medication discrepancies as well as other pertinent data. Experts in the subject matter were consulted to review the tool. No identifiable patient information was included. Data collected included the following: demographics cognitive assessment, method reconciled (bottles, list, recall), discrepancy (quantity and types), and adherence score (MMAS-4). See Appendix C.

Results

Demographics of the patient population included age, gender, and years in the practice. Gender included 61% female and 39% male. There was a diverse age group with almost half the patients between 65 and 74 and about 16%, 80 or greater. More than 50% of the patients were established in the clinic for more than 5 years. There were only 17 new patients that had recently been established in 2019. The vast majority of patients (79%) had no cognitive impairment identified.

The retrospective chart review identified a total of 213 discrepancies. Of the 101 charts reviewed, 83 of them had at least one discrepancy and 61 of them had at least two discrepancies, averaging 2.1 discrepancies per patient. Discrepancies identified were categorized by the following types: medications no longer taking, RX omissions, OTC omissions, wrong dose identified, duplicate therapy, and discrepancy due to frequency/timing. The most common discrepancies identified were OTC omissions (33%) and medications no longer taking (29%). Total omissions (OTC & RX) accounted for 55% of the total discrepancies identified. The cause of omissions was most commonly due to medication being prescribed by other providers or the patient adding an over the counter or herbal medications that had not been reported to the primary care provider. Discrepancies due to the patient no longer taking were commonly due to the patient stopped taking medication, prescription not filled due to cost, or treatment regimen completed but not removed from their list.

Table 2. Discrepancy Types Identified

Discrepancies 213 (N=101)	**#**	**%**
OTC Omissions Identified	70	33
Medications no longer taking	61	29
RX Omissions Identified	46	22
Wrong Dosage Identified	20	10
Duplicate Therapy	10	5
Discrepancy due to frequency/timing	2	1

The same percentage of patient's medications reconciled by Bottles (53/52%) was equal to the same percentage of discrepancies found by Bottles (110/52%). There were similar results

for the medications reconciled by Recall (23/23%) compared to the number of discrepancies found by Recall (51/24%) and medications reconciled by List (25/25%) compared to the number of discrepancies found by List (52/24%), a difference of only 1%. The bottles provided accurate medication name, dose, and directions needed to update the patient's medication list if a medication was identified that was not on the list. Anecdotally, having bottles made it easier for the nurse practitioner to reconcile the patient's medication list, although the results revealed that the method of which the medications were reconciled did not correlate with the number of discrepancies identified.

The results of the Morisky Medication-Taking Adherence Scale (MMAS-4) indicated that 71% of the patients were at low risk for medication adherence, while 27% were at moderate risk, and only 2% were at high risk. Once interviewing the patient, the survey was not always an accurate depiction of the patient's adherence risk with some patients acknowledging issues with compliance. The patient's reported sometimes forgetting to take their medications, not taking medications when feeling better or worse, and not picking up refill medications from the pharmacy. Although this survey may not be an accurate measure of the patient's adherence risk it does promote further discussion and provide an opportunity to educate the patient on the importance of taking medications as prescribed.

As a result of the retrospective chart review, there were a few incidental findings that could cause potential harm to a patient. These included wrong doses, high alert medications not on the list, non-adherence, and duplicate therapy. Some examples include coumadin missing from the patient's list, duplication in Tylenol dosing, double maximum dose of Losartan, and non-adherence for refilling Digoxin prescription.

The retrospective chart review revealed documentation issues within the EHR. The data indicated medications were not reconciled at the previous visit in 67% of the charts reviewed. Was this due to it not being performed or failure of the provider to document that it was completed? To document in the EHR that the medications were reconciled there is a reconciliation button that has to be clicked. Through reading the chart in several instances I know some form of reconciliation was completed even though it was not documented.

Medication reconciliation is not considered complete until the medication list has been updated with any discrepancies identified. The results from the data collected revealed that the medication list was not updated 101 of the 213 discrepancies found. Further discussion with the nurse practitioners revealed their reluctance to make changes to the patient's list. First, if they were unable to verify the correct medication or dose with the bottle or list. They were hesitant to add the wrong medication, particularly any controlled substances. The medications needed to be reviewed by the patient's primary care provider before discontinuing. The patient may have stopped taking the medication on their own. Medication directions were not changed if the patient reported they were taking differently than what the Nurse Practitioner could verify in the chart. Further evaluation is needed to improve documenting changes in the medication list.

Currently, changes made to the medication list are communicated to the PCP in the summary of the visit note, as well as through a task sent in the EHR if urgent changes were made. There are challenges to providing care to other providers' patients including a hesitancy to making changes to the patient's medication list. Improving communication and collaboration is a continuous process and needs to be reassessed frequently to ensure the best care for the patient.

Positive practice changes have occurred since implementation of this project. Other clinics within the same facility have implemented procedures to improve the medication

reconciliation process. Changes include, upon patient arrival they are now given a printed copy of their electronic medication list currently in their chart. While waiting in the lobby, they review the list and mark any discrepancies they find and add any additional medications they are taking. The provider can then review this list with the patient during the visit.

Barriers to successfully implementing an improved medication reconciliation program include incorrect medication list, time restraints, insurance reimbursement, lack of guidelines specifying the process, patients unaware of what medications they are taking, and an emphasis on documentation instead of the method of assuring accurate and safe medication management.[4] Identifying these barriers in the outpatient setting is essential to making the necessary changes to improve the process of reconciling medications as well as making practice changes that will positively affect patient care and safety.

Limitations

While every effort was made to minimize any bias affecting the results of this project there were some limitations identified. The sample size used was a small percentage of the total population of the facility. Additionally, this project focused only on the clinic that provides Medicare AWV by a nurse practitioner. The process of medication reconciliation was limited to the methods discussed (bottles, list, recall). There was no evaluation with refill data or other data from the pharmacy that could further help with the process.

Application to Practice

Medication reconciliation is an essential step in an accurate and effective patient care process. The future of healthcare has shifted to team-based patient care and interprofessional collaboration is imperative to improve the quality of patient care. Medication changes must be highlighted and communicated between all health professionals involved in a patient's care.

Educating healthcare professionals on where to find the information and best practice on methods of medication reconciliation and documentation provides a firm foundation for improving the process and compliance with medication reconciliation, as well as promotes interprofessional collaboration.

Teaching and empowering patients and/or family members to take responsibility for managing their medications is essential to the medication reconciliation process and ensuring an accurate medication list. Patients need to understand the importance of their medication in the treatment process of their disease state, side effects and safe care. Patients need to be aware of the importance of keeping an updated medication list and communicating all changes to all providers, including their pharmacy. Educating patients is a vital step in the process of improved medication reconciliation.

This project informed a revised medication reconciliation process, developed with the other nurse practitioners. The process was refined by adding steps to clarify roles improve communication. Patients review of their medication list in the waiting room was added. This helps empower patients to manage their medications and offers an opportunity to educate patients on their medications. Specifically, what they should be taking and why. This also provides a discussion to re-enforce the importance of communicating all changes made to their medications by the patient or other providers. The final step was added to refer the patient to the clinical pharmacist for medication review when unable to reconcile the medication list. The changes in the medication reconciliation process will support the most accurate medication list for each patient. The process should be monitored, evaluated and revised periodically. See Figure 3 for the revised medication reconciliation process.

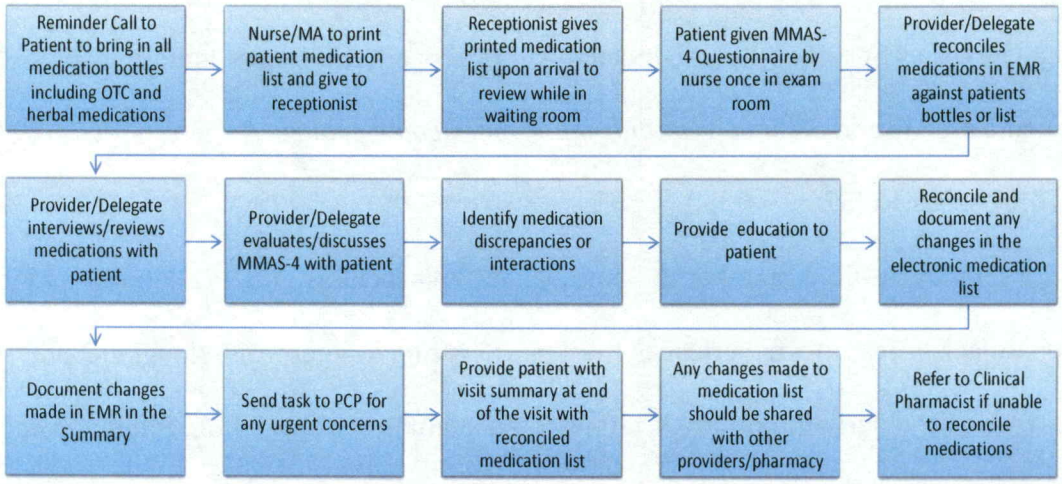

Figure 3. Revised Medication Reconciliation Process

Conclusion

The project concluded that there is a need for an effective process to complete medication reconciliation in the outpatient setting. A standardized medication reconciliation process using a combination of methods to reconcile medications is fundamental in identifying discrepancies to improve the accuracy of the patient's medication list. Although the results were not as expected, the knowledge and experience gained will be valuable to improve practice and expand research on the process of medication reconciliation in the outpatient setting.

Future project plans include developing an Interprofessional Education (IPE) simulation case on Medication Reconciliation in collaboration with a clinical pharmacist and a simulation expert. A study by Lindquist et al., 2008, will be used to guide the development of this IPE simulation. Through interprofessional education, the strengths of each discipline can be combined to promote learning about, with, and from each other to improve the quality of patient care and safety. Interprofessional collaboration and empowering patients through clear clinical processes and education is essential to accurate medication lists to improve patient safety.

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SECTION II: DNP PROJECT PRODUCT

Professional Journal Selection

Scope of Journal

"The *Journal of Patient Safety* is a peer-reviewed, scholarly journal that publishes articles on all aspects of patient safety, including but not limited to:

• original late-phase translational research (from research findings to patient settings);

• original articles that focus on clinical applications of research;

• reports on best practices at the level of institutional process and policy;

• detailed, objective technology reports and reviews."[14] (Journal of Patient Safety, 2019).

My manuscript will be submitted as an original study, focusing on improving patient safety through a standardized medication reconciliation process in the outpatient primary care setting.

Aims of Journal

The *Journal of Patient Safety* aims to add research advances for patient safety. The journal also publishes articles describing important medication lessons such as near-miss, system changes which limit improvements with medication errors, and regulatory impact on healthcare delivery.

A Process Improvement Initiative on Medication Reconciliation by Nurse Practitioners in the Outpatient Setting

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The University of Alabama in Huntsville, College of Nursing

Lori Lioce DNP, FNP-BC, CHSE-A, CHSOS, FAANP, Clinical Professor

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Submission declaration: This manuscript is original, has not and will not be submitted elsewhere for publication.

Keywords: medication reconciliation, medication discrepancies, process improvement, patient safety, outpatient

Abstract

Objectives

The purpose of this project was to evaluate a nurse-practitioner led medication reconciliation process to enhance review and documentation to improve the accuracy of the patient's medication list.

Methods

A retrospective chart review was completed in a nurse-managed clinic that resides within a large academic physician residency facility providing a unique multidisciplinary interprofessional collaboration with physicians, pharmacists, and nurse practitioners. The retrospective chart review included patients seen for their AWV between June 1st and July 31st, 2019.

Results

A total of 101 patients were included in this retrospective review. A total of 213 discrepancies were identified. Of the 101 charts reviewed, 83 had at least one discrepancy and 61 had at least two discrepancies, averaging 2.1 discrepancies per patient. The most common discrepancies identified were omissions (55%) and medications no longer taken (29%). The method of how the medications were reconciled found a similar number of discrepancies.

Conclusions

The project concluded that having a process in place assisted with identifying medication discrepancies. There is a need for an effective process to complete medication reconciliation in the outpatient setting. A standardized medication reconciliation process using a combination of methods is fundamental in identifying discrepancies to improve the accuracy of the patient's medication list.

Introduction

Medication reconciliation is the process of comparing what medications the patient is currently taking to the recorded list in the patient's medical record. This comparison of medications is completed to increase the accuracy of the medication list to reduce medication errors and the potential for adverse drug events (ADE).[1] The medication list in the patient's electronic chart often differs from what medications the patient is actually taking, especially if the patient has multiple providers prescribing their medications, are taking over the counter (OTC) medications that are not on their list, or if they are nonadherent to their prescribed medications.

Medication reconciliation continues to be at the forefront of improving patient safety and is essential to maintaining an accurate medication list in the outpatient setting. Medication errors are a primary patient safety concern and account for approximately 1.5 million hospitalizations each year.[2] Inaccurate patient medication lists contribute to medication errors which can be potentially harmful to patients and cause increased financial burden to the healthcare system.[3] The Institute of Medicine (IOM) reported an estimated $880 million yearly treatment cost due to medication errors and adverse drug events.[4] The Joint Commission has made medication reconciliation a primary National Patient Safety Goal since 2005. The 2019 National Patient Safety Goal 03.06.01 is to "maintain and communicate accurate patient medication information".[5]

Methods

This was a retrospective chart review intended to evaluate the medication reconciliation process to enhanced review and documentation to improve the accuracy of the patient's

medication list. A total of 101 charts were included and the data was collected in Qualtrics. Descriptive statistics in Qualtrics and Excel was used to analyze the data.

The retrospective chart review was completed on all patients seen by one of the three nurse practitioners from June 1, 2019, through July 31, 2019. During the AWV, the medication reconciliation was completed with one of three methods or a combination of these methods: comparing the patient's medication list in the electronic health record (EHR) to either the bottles they brought from home, their home medication list, and/or patient recall. The nurse practitioner also took a thorough history and reviewed the Morisky Questionnaire to determine accurate dosing and patient medication adherence. The history was provided by the patient, family member, or a caregiver. The nurse practitioner identified medication discrepancies, made changes to the electronic medication list, then narrated the findings in the summary section of the EHR to inform the primary care provider of any changes made. A written standardized process was implemented and followed by the nurse practitioners before the retrospective chart review to assure consistency in the process and the data collected

Institutional Review Board (IRB) approval was obtained by the University of Alabama in Huntsville. See Appendix A. A letter of permission was received from the Regional Dean of the facility where the project was implemented. See Appendix B. Data was collected and reported without any identifying patient information to protect anonymity.

The chart review took place in a nurse-managed clinic that resides within a large academic physician residency facility. The academic facility has a multidisciplinary interprofessional practice with physicians, clinical pharmacists, and nurse practitioners. Having multiple disciplines within the same outpatient clinic allowed for interprofessional collaboration to provide quality comprehensive patient care. The nurse practitioners currently provide patients

with their yearly AWV and close care gaps that are beneficial for both positive health outcomes for the patient as well as reimbursements.

The population included all Medicare patients seen in the clinic for their Medicare AWV. All patients had a primary diagnosis of Z00.00 for the preventative service of the AWV. Patients were not excluded due to age since some patients are under the age of 65 with Medicare, making them eligible for the wellness exam.

Two evaluation tools were used to collect the research data. The Medication Adherence Questionnaire (MAQ), also known as the Morisky Medication Adherence Scale (MMAS-4, was added to the medication reconciliation process two months before the retrospective chart review to assist with evaluating medication adherence. This tool was originally published in 1986 and has been proven to be reliable and valid in the research. This is a four-item questionnaire that can provide valuable information on patient adherence to their medication regimen with minimal additional time. The questionnaire is a yes/no score of 1-4.[6] See Appendix C.

A data collection tool was designed within Qualtrics to track and identify medication discrepancies as well as other pertinent data. Experts in the subject matter were consulted to review and revise the tool. No identifiable patient information was included. Data collected included the following: demographics cognitive assessment, method reconciled (bottles, list, recall), discrepancy (quantity and types), and adherence score (MMAS-4). The demographics of the patient population included age, gender, and years in the practice.

Results

The retrospective chart review identified a total of 213 discrepancies. Of the 101 charts reviewed, 82% of the charts at least one discrepancy was identified and 60% had at least two discrepancies. An average of 2.1 discrepancies per patient were identified. Discrepancies

identified were categorized by the following types: medications no longer taking, RX omissions, OTC omissions, wrong dose identified, duplicate therapy, and discrepancy due to frequency/timing. The most common discrepancies identified were OTC omissions (33%) and medications no longer taking (29%). Total omissions (OTC & RX) accounted for 55% of the total discrepancies identified. See Table 1. Discrepancy Types Identified. The cause of omissions was most commonly due to medication being prescribed by other providers or the patient adding over the counter or herbal medications that had not been reported to the primary care provider. Discrepancies due to the patient no longer taking were commonly due to the patient stopped the medication, prescription not filled due to cost, or treatment regimen completed but not removed from the list.

The same percentage of patient's medications reconciled by Bottles (53/52%) was equal to the same percentage of discrepancies found by Bottles (110/52%). There were similar results for the medications reconciled by Recall (23/23%) compared to discrepancies found by Recall (51/24%) and medications reconciled by List (25/25%) compared to discrepancies found by List (52/24%), a difference of only 1%. The bottles provided accurate medication name, dose, and directions needed to update the patient's medication list if a medication was identified that was not on the list.

Demographic results concluded there were a greater number of females than males, 61% female and 39% male. See Figure 2. There was a diverse age group with almost half the patients between 65 and 74 and about 16%, 80 or greater. See Figure 3. More than 50% of the patients were established in the clinic for more than 5 years. There were only 17 new patients that had recently been established in 2019. The vast majority of patients (79%) had no cognitive impairment identified.

The results of the Morisky Medication-Taking Adherence Scale (MMAS-4) indicated that 71% of the patients were at low risk for medication adherence, while 27% were at moderate risk, and only 2% were at high risk. Once interviewing the patient, the survey was not always an accurate depiction of the patient's adherence risk with some patients acknowledging issues with compliance. The patient's reported sometimes forgetting to take their medications, not taking medications when feeling better or worse, and not picking up refill medications from the pharmacy. Although this survey may not be an accurate measure of the patient's adherence risk it does promote further discussion and provide an opportunity to educate the patient on the importance of taking medications as prescribed.

As a result of the retrospective chart review, there were a few incidental findings that could cause potential harm to a patient. These included wrong doses, high alert medications not on the list, non-adherence, and duplicate therapy. Some examples include coumadin that was not on the patient's list, duplication in Tylenol dosing, double maximum dose of Losartan, and non-adherence for refilling Digoxin prescription.

Discussion

Discrepancies in the patient's medication list can lead to adverse events, causing undue harm to a patient. Medication reconciliation is fundamental to patient safety and should be completed at every patient encounter including outpatient clinic visits. Medication reconciliation can require extra time, resources, and multidisciplinary collaboration to obtain the most accurate information.[7] There are several methods of reconciling a patient's medication list in the primary care setting including using a patient home medication list, medication bottles, patient recall, or pharmacy claims data. These methods can be used alone or in combination with one another. The purpose of this project was to improve patient safety through an enhanced review of the process

of medication reconciliation during a Medicare AWV and evaluate the effectiveness of the medication reconciliation methods.

Reconciling the patient's medication list with bottles did not identify more discrepancies, however, it did assist with completing a more accurate medication list as found with other studies. Reedy et al[8] found bringing in patient medication bottles or list were beneficial in completing an accurate medication list.[8] Vejar et al[4] found that patients physically bringing all their medication bottles, including over the counter (OTC) medications, into the office helped with reconciling the patient's medication list and brought to the attention of the provider any high-risk medications or discrepancies in medications compared to the list in the patients' chart.[4] When adding medications that were omitted from the list the bottles provided the necessary information to add that medication accurately with the correct medication, dose, instructions, and provider who prescribed the medication. Anecdotally having bottles made it easier to reconcile the patient's medication list, although the results revealed that the method of which the medications were reconciled did not correlate with the number of discrepancies identified.

Relying on an elderly patient's ability to recall their medications can result in an inaccurate medication list. A study completed with 99 patients 65 and older with no cognitive impairment resulted in only 22% of them accurately recalling their medications from memory.[9] This can sometimes be common practice, especially if the patient does not have a medication list or bottles. Patient recall history of their medications may need to be verified by some other method if there are any concerns about the accuracy of the patient's ability to recall their medications.

Evaluating medication adherence is a crucial piece for the medication reconciliation process. Assessing a patients' adherence to their prescribed medication directly affects the

accuracy of the medication list. Adherence is defined by the World Health Organization (WHO) as "the extent to which the persons' behavior (including medication-taking) corresponds with agreed recommendations from a healthcare provider".[10] There are several tools available to measure medication adherence. The most common assessment tools to rate medication adherence are health professional assessments and self-report. The self-report medication adherence survey used in this clinic found similar results as a meta-analysis study done by Lam & Fresco,[10] which concluded that the use of a self-report survey in conjunction with a chart review improved the adherence assessment. Utilizing both objective and subjective information provides greater reliability and assist with identifying the reasons for nonadherence. Patients tend to under-report because they do not want to disappoint their provider.[10]

The WHO reports that medication adherence could have a more significant effect on health outcomes than the individual medical treatment itself. Medication nonadherence accounts for 30% of hospital admissions related to adverse drug events. Medication nonadherence can be a patient failing to initiate or refill their prescriptions to not taking their prescription medications as prescribed. Medication nonadherence poses a significant burden on healthcare costs and can lead to poor patient outcomes. The WHO reported a 50% nonadherence rate among patients living in developed countries.[10] Especially in the elderly population lack of financial resources can be a primary cause of nonadherence. Studies have shown that patients with Medicare have an increased nonadherence rate once they reached the doughnut hole (patient has to pay out of pocket). Patients will either cut back on their prescribed dose or stop the more expensive medications they are unable to afford, which can be detrimental to their health.[11] Identifying the cause of nonadherence is crucial to finding a resolution to improve adherence.

A unique advantage to this clinic is the opportunity to collaborate with pharmacists. This can be beneficial to assist with future projects to improve medication reconciliation within the facility. A fundamental issue in healthcare is the lack of interprofessional collaboration and communication that occurs among healthcare professionals. A qualitative by Bell et al[12] found that nurses and pharmacists recognized the benefit of learning and working together on interprofessional medication reviews (IMRs). They were able to learn the value in the role of each discipline and what the other could bring to the care of the patient. The nurse provided clinical information and health assessment where the pharmacist was able to provide knowledge on the pharmacotherapy and medication management.[12]

Medication reconciliation is an essential step in the patient care process. Identifying causes of discrepancies can provide valuable data to improve the process of medication reconciliation. The future of healthcare is moving towards team-based patient care and interprofessional collaboration for the benefit of quality patient care. Medication changes need to be communicated between all health professionals involved in that patient's care. Educating healthcare professionals is the foundation for improving the process and compliance of medication reconciliation, as well as promoting interprofessional collaboration.

Barriers to successfully implementing an improved medication reconciliation program include incorrect medication list, time restraints, insurance reimbursement, lack of guidelines specifying the process, patients unaware of what medications they are taking, and an emphasis on documentation instead of the method of assuring accurate and safe medication management.[4] Identifying these barriers in the outpatient setting is essential to making the necessary changes to improve the process of reconciling medications as well as making practice changes that will positively affect patient care and safety.

While every effort was made to minimize any bias affecting the results of this project there were some limitations identified. The sample size used was a small percentage of the total population of the facility. Additionally, this project focused only on the clinic that provides Medicare AWV by a nurse practitioner. The process of medication reconciliation was limited to the methods discussed (bottles, list, recall). There was no evaluation with refill data or other data from the pharmacy that could further help with the process.

Conclusion

The project concluded that there is a need for an effective process to complete medication reconciliation in the outpatient setting. A standardized medication reconciliation process using a combination of methods to reconcile medications is fundamental in identifying discrepancies to improve the accuracy of the patient's medication list. Although the results were not as expected, the knowledge and experience gained will be valuable to improve practice and expand research on the process of medication reconciliation in the outpatient setting.

There is a need for further studies to improve the process and provider compliance of medication reconciliation in the outpatient setting. Further study plans include developing an Interprofessional Education (IPE) simulation case on standardized process of medication reconciliation in collaboration with a clinical pharmacist and a simulation expert. Through interprofessional education, the strengths of each discipline can be combined to promote learning with and from each other to improve the quality of patient care and safety.

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Table 1. Discrepancy Types Identified

Discrepancies 213 (N=101)	#	%
OTC Omissions Identified	70	33
Medications no longer taking	61	29
RX Omissions Identified	46	22
Wrong Dosage Identified	20	10
Duplicate Therapy	10	5
Discrepancy due to frequency/timing	2	1

Figure 1. Project Medication Reconciliation Process

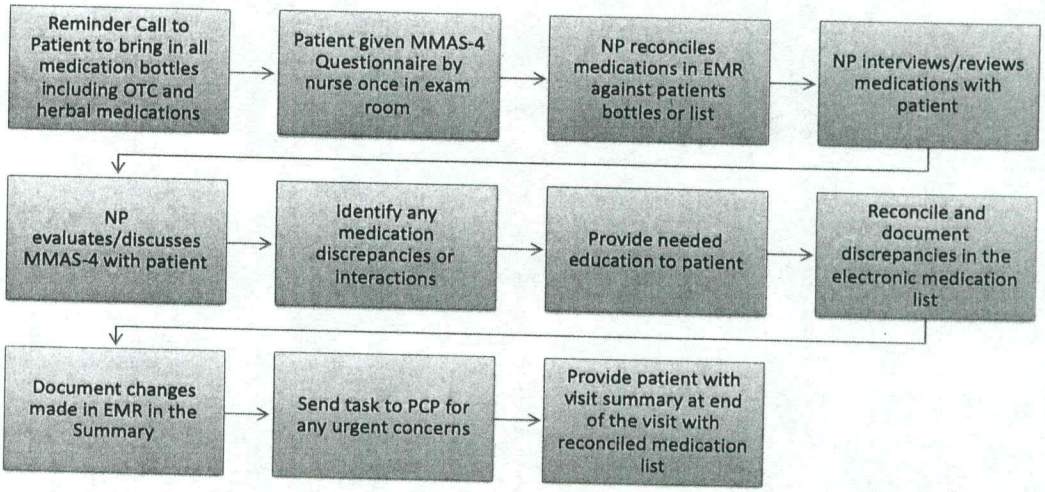


Figure 2. Gender Demographics

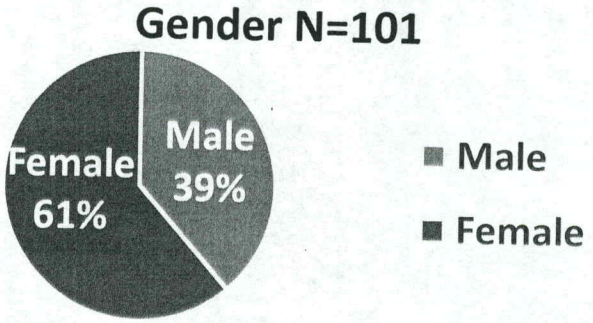
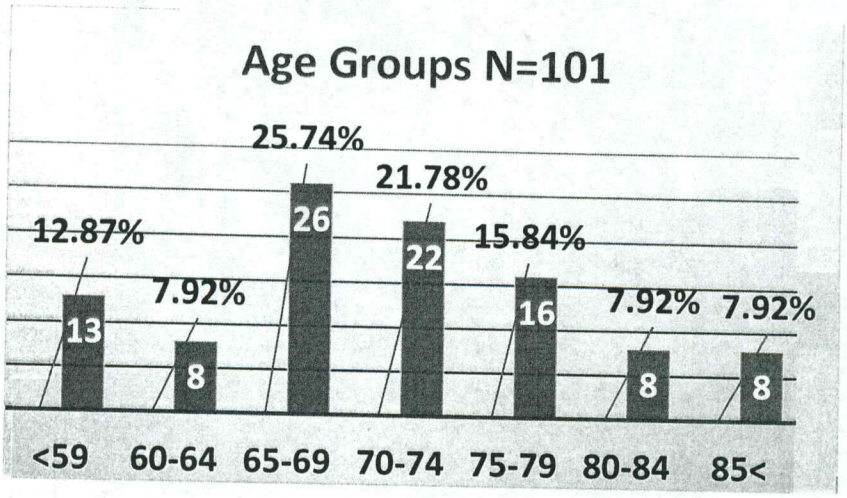


Figure 3. Age Demographics



APPENDIX A

THE UNIVERSITY OF
ALABAMA IN HUNTSVILLE

__ Expedited (see pg 2)
_X_ Exempted (see pg 3)
__ Full Review
__ Extension of Approval

Date: 4 July 2019

PI: Kim Budisalich
PI Department: College of Nursing
The University of Alabama in Huntsville

Dear Kim,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal titled: *A Process Improvement Initiative Medication Reconciliation* 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

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

Expedited:

☐ 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 nonresearched purposes (such as medical treatment or diagnosis).

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

☐ 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

☐ 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 [1] 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.

X☐ 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.

APPENDIX B

July 3, 2019

MEMORANDUM

TO: Kimberly Budisalich, MSN, CRNP

FROM: Roger D. Smalligan, M.D., MPH, FACP
Professor and Regional Dean
UAB School of Medicine, Huntsville Campus

SUBJECT: DNP Project involving Collaborative Care Clinic patients

I approve and support your request to complete retroactive chart reviews on medication reconciliation process for patients seen in the Collaborative Care Clinic. These patients have been referred from the Family Medicine and Internal Medicine clinics for their annual wellness visits. I understand that this project will have been reviewed and approved by an IRB within the UA System. No identifying patient information will be obtained in the course of this project.

Thank you.

APPENDIX C

Morisky Medication-Taking Adherence Scale-MMAS (4-item)

English Version

(Please check one box on each line)

	Yes	*No*
1. Do you ever forget to take your (name of health condition) medicine?	o	o
2. Do you ever have problems remembering to take your (name of health condition) medication?	o	o
3. When you feel better, do you sometimes stop taking your (name of health condition) medicine?	o	o
4. Sometimes if you feel worse when you take your (name of health condition) medicine, do you stop taking it?	o	o

MEASUREMENT AND SCORING CRITERIA

The MMAS is a generic self-reported, medication-taking behavior scale in which the specific health issue (high blood pressure, diabetes, elevated cholesterol, HIV, contraception, etc.) is inserted for the "health concern".The MMAS consists of four items with a scoring scheme of "Yes" = 0 and "No" = 1. The items are summed to give a range of scores from 0 to 4.

APPENDIX D

Editor-in-Chief
David Westfall Bates, MD, MSc
Journal of Patient Safety

Dear Dr. David Westfall Bates,

I would like to inquire about your interest in a manuscript titled "A Process Improvement Initiative on Medication Reconciliation in the Outpatient Setting". The project was a retrospective chart review in an outpatient nurse-managed clinic that resides within a large academic physician residency facility. The purpose of this project was to evaluate a nurse-practitioner led medication reconciliation process to enhance review and documentation to improve the accuracy of the patient's medication list.

Medication reconciliation continues to be at the forefront of improving patient safety and is essential to maintaining an accurate medication list in the outpatient setting. Discrepancies in the patient's medication list can lead to adverse drug events causing undo harm to a patient. A standardized process of medication reconciliation and assessing patient adherence will improve the accuracy of the patient's medication list and reduce the patients risk for an adverse drug event.

I would like to see if you have any interest in reviewing my manuscript for possible publication in your journal.

Thank you for your time and consideration, we look forward to hearing from you,

Sincerely,

Kimberly Budisalich MSN, CRNP
Clinical Instructor
University of Alabama Huntsville
Office NB 332
256-221-4486 (C)
kimberly.budisalich@uah.edu