MEDICATION RECONCILIATION IN AMBULATORY SURGERY TO PREVENT ADVERSE DRUG EVENTS

by

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A scholarly project submitted in partial fulfillment
of the requirements for the degree

of

Doctor of Nursing Practice

In

Family and Individual Health

MONTANA STATE UNIVERSITY
Bozeman, Montana

April 2021

ACKNOWLEDGEMENTS

I want to extend my sincerest thank you to my committee, Dr. Susan Luparell and Dr. Yoshi Colclough, for their assistance and guidance through this process. I especially want to express my deepest appreciation for my committee chair, Dr. Amanda Lucas, who spent countless hours supporting and encouraging me through this process.

The past four years have been both challenging and rewarding. Yet regardless of whether times were good or bad the support of the people who started as classmates, but have now become family, was what got me through each day. To Meghan Kirk, Brielle Toole, Jordan Overstreet, and Melissa Bowen—thank you for always being there for me, for all the decompression dinners, and especially for enduring my rants.

Thank you to my family—Donald Ayres, Sally Johnson, Charles Doolittle, Caitlin Ayres, and Alison Ayres. Without your support and encouragement (and meals) I would not have made it to this point.

Finally, the deepest gratitude goes to my husband and best friend, Noah. I have been in school for the majority of the almost 9 years we have been together. Yet never once did you complain or tell me slow down. You have supported me unconditionally through every step while also growing your own career. There is no way to ever thank you enough. Cheers to life on the river without textbooks!

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ABSTRACT

Adverse drug events (ADEs) cause a significant burden to the healthcare system. Medication reconciliation (MR) is a well-documented method to reduce ADEs in a variety of healthcare settings. The purpose of this project was to determine best practice for performing MRs, implement best practice into practice, and evaluate outcomes based on successful completion of MRs. This project was implemented at an ambulatory surgery center (ASC) in southwestern Montana with a focus on adult orthopedic patients. Four PDSA cycles were completed over a 6-week period to improve the MR process. Improvement of the MR process was deemed necessary to meet evidence-based MR guidelines for patient safety and to meet accreditation standards. The definition of a complete MR was based on current literature and state and national accreditation guidelines. Over the 6-week process, MR completion rates increased from 0% at implementation to 52% at project completion. Continuation of improvement utilizing the processes implemented in this project is recommended.

CHAPTER ONE

BACKGROUND AND SIGNIFICANCE

Adverse drug events (ADEs) account for 3.5 million office visits, 1 million emergency department visits, and 125,000 hospitalizations costing the healthcare system an estimated $21 billion annually (U.S. Department of Health and Human Services [DHS], 2020). DHS defines an ADE as "an injury resulting from medical intervention related to a drug" (DHS, 2020, para 1). Performing medication reconciliations (MRs) at all points of transition of patient care has been well-documented to mitigate ADEs. MR is the process of assessing a patient's comprehensive medication list and incorporating into care. Although the importance of MRs in the reduction and prevention of ADEs is well understood, many healthcare facilities do not adequately employ this practice (Accreditation Association for Ambulatory Health Care [AAAHC], 2019). The purpose of this project was to determine best practice for performing MRs, implement it into practice, and evaluate outcomes based on successful completion of MRs for at least 95% of all adult orthopedic patients at an ambulatory surgery center (ASC) in southwestern Montana.

Background

Risk factors for ADEs include age, polypharmacy, comorbidities, new medications, changes to existing medications, high-risk medications, transitions of care, and multiple providers (Lodhi & Thompson, 2020; Renaudin et al., 2020). Morin et al. (2018) highlights the frequency of polypharmacy in adults over 65 years of age, as an estimated 44% were found to take five or more drugs and 11.7% ten or more drugs. Omission of medications during patient or

caregiver interview is the most common cause of ADEs accounting for up to 86% of all ADEs (Al-Hashar et al., 2018; Renaudin et al., 2020).

Factors that increase the risk for ADEs in ambulatory surgery patients include new medications, changes to medications, high-risk medications, and multiple providers. Estimates show 60.3% of outpatient surgical patients experience one ADE with 43.3% percent of those having the potential to cause harm (Renaudin et al., 2020). High-risk medications commonly prescribed and administered during ambulatory procedures include opioids, sedatives, and anticoagulants. It is also common practice for the surgical physician assistant (PA) to perform the history and physical and for a presurgical assessment nurse to complete the ASC specific preoperative assessment, meaning ambulatory surgery patients may not be well-known to the ASC providers. The lack of an ongoing relationship between patient and provider creates the potential for medication information to be missed or overlooked, further potentiating the need for accurate MR. MR is a widely accepted process for preventing ADEs by improving communication and promoting interfacing between providers (Renaudin et al., 2020).

The Institute for Healthcare Improvement (IHI) (2011) defines MR as "the process of creating and maintaining the most accurate list possible of all medications a patient is taking… and using that list to guide therapy" (p.4). They describe the process as consisting of three steps: verification, clarification, and reconciliation (IHI, 2011). Verification is the process of creating a list of all the medications a patient is currently taking (IHI, 2011). Clarification is the process of determining whether medications and their doses are correct and appropriate (IHI, 2011). Reconciliation is the process of updating the medication list with any changes made by the provider (IHI, 2011). The IHI (2011) states an MR is complete "when each drug the patient is

taking has been actively continued, discontinued, held, or modified at each transition point" (p.4). With over half of medication errors occurring at the transition of care, a complete MR at every point of transfer is critical to patient safety (IHI, 2011).

Project Site

As an Accreditation Association for Ambulatory Health Care (AAAHC) accredited ASC with Medicare Deemed Status (MDS), the project facility must meet or exceed the standards required by the Centers for Medicare & Medicaid services (CMS) and those required by AAAHC to maintain accreditation, which is a requirement for licensure and operation (AAAHC, n.d.). AAAHC provides expectations and guidelines for the elements of an MR process in the following six steps (AAAHC, n.d.):

- Commit to medication reconciliation as part of the culture of safety of your organization
- Implement a single source document policy for tracking a patient's current and past medications
- Verify and document medications before and after each patient exam/procedure
- If a medication collection form is used which is not the single source document, compare this form against the single source document
- Resolve any discrepancies by communicating with the patient, provider, and/or pharmacy and
- Communicate with patients and have them verify they agree with the current medication list

MDS facility standards also include that "specific instructions for discontinuation or resumption of medications prior to and after a procedure are provided to the patient with corresponding documentation in the patient's clinical record" (AAAHC, 2020, p.12). The MR process at the project facility did not meet these expectations, thus increasing the risk for ADEs and jeopardizing patient safety.

Current Process

The pre-project process involved a presurgical assessment nurse performing a phone interview with the patient. The patients were asked to list their medications and the nurse recorded the list in a blank box in the EHR. The blank box provided no indication of what information should be collected or any prompts to help prevent medication omissions. The nurse did have access to previous medication lists for comparison only if the patient was known to the facility. The nurse also had access to the EHR system used by many of the primary care providers in the area; however, the charts were not directly linked, meaning medication information would have to be transferred by hand, leaving more room for error. Once this process was completed, the list was not further amended or verified. On the day of surgery, the preoperative nurse would verify when the patient last took any medications, but this was not a thorough review or verification of the full medication list and would not alter the original list. This process did not satisfy the current guidelines of usage of a single source document, assessment for discrepancies, or verification and reconciliation occurrence at the appropriate transitions of care. To prevent these issues, AAAHC recommends using "one consistent form for medication reconciliation that the patient receives upon discharge" (2020).

The lack of an adequate MR process put the project facility at risk for ADEs, patient harm, and increased costs related to readmissions or prolonged recovery (AAAHC, 2019). Stakeholders at this facility recognized this issue and were motivated to implement an improved MR process to promote patient safety and prevent harm. As MRs are also an expectation for continued accreditation, failure to meet these standards presents risk for maintaining accreditation status, a requirement for state licensure and Medicare certification.

Proposed Project

The purpose of this project was to implement a MR process that met current AAAHC standards, thus promoting patient safety. The DNP project targeted point of entry, which was performed by a presurgical assessment nurse for all adult orthopedic patients at the project facility. The project intervention was chosen to promote high quality patient care as defined by the Institute of Medicine (IOM) as being safe, effective, patient-centered, timely, efficient, and equitable (2001). Current literature and quality standards were reviewed, as well as expectations set forth by accrediting bodies, to create an improved MR process. The process was implemented with the goal of completing MRs on 95% of adult orthopedic ASC patients within a 6-week period. The project coincided with the new EHR implementation that included a component for MR and was deemed essential by the project stakeholders.

Charts were reviewed on a weekly basis for 6 weeks to determine MR completion rates. The project team included the DNP student, a presurgical assessment nurse, and the preoperative nurse manager. This team represented staff involved in direct patient care and stakeholders invested in improving patient care and facility operations.

Congruence of Project to Organization's Mission

The project facility strives to provide high quality and economical same-day outpatient surgical services to the community and surrounding areas. To meet this organizational mission, the facility must ensure adequate steps are taken to prevent ADEs and patient harm. In addition, CMS and AAAHC have provided accreditation standards for the MR process. Therefore, improving the MR process will help the facility meet their organizational goals, as well as maintain its accreditation status necessary for financial reimbursement and continued operation.

CHAPTER TWO

REVIEW OF LITERATURE

Literature Search Criteria

Databases searched for this project included the Cochrane Library, Web of Science, CINAHL, and PubMed. Search terms used were "medication reconciliation," "adverse drug events," "medication discrepancy," "medication error," "ambulatory surgery," "outpatient surgery," and "patient safety." Articles reviewed were limited to those published between 2010 and 2020 and were evaluated based on level of evidence and USPSTF grading criteria. A total of 11 articles were included based on quality of evidence and relevance to the project purpose (see Appendix B).

Synthesis of Literature

Research on utilization of MR for patient safety proliferated after the Institute of Medicine (IOM) published the ground-breaking reports *To Err is Human* (2000) and *Crossing the Quality Chasm* (2001). *To Err is Human* (2000) sheds light on the reality of preventable medication errors as one of the leading causes of morbidity and mortality in the US. *Crossing the Quality Chasm* (2001) further explores the disparities between what we know to be quality care and the care we are providing.

To Err is Human was a call to action for the entire healthcare system to improve patient safety (IOM, 2000). As the title indicates, human error is inevitable. Since human error can never be fully prevented, steps must be taken to intervene in areas where human error is common or

likely in order to catch the error and prevent it from leading to harm. One of the major areas requiring reform was medication safety.

The IOM recommended various strategies to reduce medication errors, all of which are aimed at reducing complexity in the medication system. Medication management is an inherently complex process involving multiple points of care. Errors are known to increase the greater the complexity of a system (IOM, 2000). Healthcare systems are known as complex adaptive systems because they encompass significant interconnections between humans who are constantly learning and changing (IOM, 2001). Adequate MR processes help reduce the complexity in the system.

Since the publication of these reports, efforts to reduce medication errors have increased dramatically. Through extensive investigation of problems within the healthcare field, MR has become a promising solution to the prevention of medication errors. Since 2000, thousands of studies and reviews have been conducted to determine the efficacy of MR on reducing ADEs. The current evidence is largely consistent in finding the incorporation of a complete MR process (verification, clarification, and reconciliation) at all transitions of care as a successful method in reducing ADEs (Christensen & Lundh, 2016; Khalil, Bell, Chambers, Sheikh, & Avery, 2017; Redmond et al., 2018; Lehnbom, 2014; Mueller 2012).

Due to significant variability among studies, however, providing a quantitative value for the benefit of MRs based on the current literature is difficult (Christensen & Lundh, 2016; Khalil, Bell, Chambers, Sheikh, & Avery, 2017; Redmond et al., 2018; Lehnbom, 2014; Mueller 2012). Major factors that vary between studies are site (inpatient versus outpatient), owner of the MR process (pharmacist, physician, nurse), timing of MR intervention (preadmission, at time of

care, at discharge, or during follow-up), elements of the MR process (interviews, EHRs, specific tools), and outcomes measured (ED visits, readmission, resource utilization, etc.).

Site

Priority for research on MR and ADEs is largely based in the inpatient setting due to the complexity and high-risk nature of care provided in that area (Rosen & Mull, 2016). Therefore, the majority of current studies focus on hospital-based care (Mendes et al., 2016; Bell et al., 2016; Renaudin et al., 2020; Rungvivatjarus et al., 2020; Redmond et al., 2018; Al-Hashar et al., 2018; Christensen & Lundh, 2016; Lehnbom et al., 2014; Mueller et al., 2012). This has left a significant gap in the literature regarding the use of MR in the outpatient setting, making generalizability to the ambulatory surgery setting difficult.

Timing of Intervention

Timing of intervention was also highly variable among studies. All studies performed one or a combination of preadmission, admission, during-hospitalization, discharge, and/or post-discharge MR interventions (Mendes et al., 2016; Bell et al., 2016; Renaudin et al., 2020; Rungvivatjarus et al., 2020; Redmond et al., 2018; Al-Hashar et al., 2018; Christensen & Lundh, 2016; Lehnbom et al., 2014; Mueller et al., 2012). However, the common element aligning the research is the importance of MR occurring at any transition of care (Mendes et al., 2016; Bell et al., 2016; Renaudin et al., 2020; Rungvivatjarus et al., 2020; Redmond et al., 2018; Al-Hashar et al., 2018; Christensen & Lundh, 2016; Lehnbom et al., 2014; Mueller et al., 2012). This is applicable to the ASC setting as the patient experiences multiple transitions of care between admission, procedure, recovery, and discharge, making attention to the MR process critical.

Elements of the MR Process

Mueller et al. (2012) performed a review in hopes of discerning the necessary elements of a successful MR. The review found the majority of studies used "usual care" as the control group, as opposed to comparing two distinct interventions. This was found to be a limitation to their review (Mueller et al., 2012). While this made it difficult to define the best MR practices, they found the use of a heavily pharmacist-based process directed at a high-risk subgroup of a defined population may be beneficial to successful MR implementation (Mueller, 2012).

Specifics of the MR process were highly varied and vaguely defined throughout the literature. Lehnbom et al. (2014) stated 23 of the 33 studies they reviewed performed MRs by comparing the consistency of medication histories obtained at admission by two separate providers (one doctor and one pharmacist). Each of these studies reported using a standardized form; however, details of the elements included on said forms were not provided (Lehnbom et al., 2014). A review by Christensen & Lundh (2016) reported one trial that used the Screening Tool for Older Persons' potentially inappropriate Prescriptions (STOPP) in their MR, another trial that used the STOPP and Screening Tool to Alert Right Treatment (START) tools, and the final trial that used the MiniQ decision support system.

A systematic medication review process, which was not clearly defined, was used in an additional seven trials (Christensen & Lundh, 2016). Redmond et al. (2018) stated that all trials included in their review met the IHI criteria for MR (verification, clarification, reconciliation), but provided no further description of the process. All studies reviewed by Redmond et al. (2018) reported performing a patient interview as part of the MR process, indicating this is an important component for obtaining an adequate MR.

Outcome Measures

A systematic review by Christensen & Lundh (2016) reported MRs reduced emergency department (ED) contact, but did not significantly reduce mortality or hospital readmission. However, short follow-up periods (30 days to one year) were noted as a significant limitation to these studies (Christensen & Lundh, 2016). Another review found no significant reduction in hospitalization, ED visits, or mortality, but cited heterogeneity among studies as a major limitation of the review (Khalil, Bell, Chambers, Sheikh, & Avery, 2017). A third review similarly reported the inability to directly link reduced hospital utilization to MR interventions, but stated low-certainty evidence and variation among studies were important limitations (Redmond et al., 2018).

Medication Discrepancies

While the value of MR for specific outcomes was inconsistent, a significant finding among studies was the importance of preventing ADEs by catching medication discrepancies and resolving any issues before they reach the patient (Christensen & Lundh, 2016; Khalil, Bell, Chambers, Sheikh, & Avery, 2017; Redmond et al., 2018; Lehnbom, 2014; Mueller 2012). Medication discrepancies are defined as "unexplained differences in documented medication regimens across different sites of care" (Mueller et al., 2012). While medication discrepancies are a common occurrence during MR and do not always lead to harm, studies have shown up to one third of medication discrepancies have the potential to cause harm (Mueller et al., 2012). Preventing medication discrepancies, therefore, reduces the risk of ADEs and patient harm. Preventing discrepancies is accomplished by reducing complexity in the process through streamlined practices and multiple points of verification (Christensen & Lundh, 2016; Khalil,

Bell, Chambers, Sheikh, & Avery, 2017). This is a highly valuable finding for the promotion of patient safety and these findings were incorporated into the project to reduce process complexity.

Limitations of Current Evidence

The heterogeneity among study designs limits the strength of the evidence on best practice for MR. Major areas of variation among studies include the individual conducting the MR, MR methods, definition of ADEs, and measured outcomes. Furthermore, the majority of studies also focused on pharmacist-based MRs, leaving a gap in the literature regarding MRs performed by other healthcare professionals (Bell et al., 2016; Renaudin et al., 2020; Redmond et al., 2018; Al-Hashar et al., 2018; Christensen & Lundh, 2016; Lehnbom et al., 2014; Mueller et al., 2012).

The majority of studies were conducted using one MR intervention with results compared to usual care with usual care varying significantly between studies (Mendes et al., 2016; Bell et al., 2016; Renaudin et al., 2020; Rungvivatjarus et al., 2020; Redmond et al., 2018; Al-Hashar et al., 2018; Christensen & Lundh, 2016; Lehnbom et al., 2014; Mueller et al., 2012). Usual care was most often defined as a nurse or physician performing the MR, but timing and methods (written, verbal, electronic, or a combination) were still highly variable (Redmond et al., 2018; Christensen & Lundh, 2016; Lehnbom et al., 2014; Mueller et al., 2012). The current evidence presents significant heterogeneity of interventions, making the superiority of any one difficult to discern.

Indication for Practice Change

Lack of consistency in the recommendations for an MR process is attributable to the differences between facilities and the patients they serve. While the MR process should be tailored to the specific needs of the facility, research indicates all MRs should include a complete list of all medications currently being taken by the patient (Wang et al., 2018). Since the evidence overwhelmingly cites omission as the number one medication discrepancy, the MR tool should ensure the medication list addresses all prescriptions, including those taken on an as needed basis, over the counter and herbal medications, and supplements (Rungvivatjarus et al., 2020; Wolfe et al., 2018; Redmond et al., 2018). These requirements were also supported by AAAHC and indicated on the MR form.

Every medication identified should include name, dose, frequency, route, and purpose (Wang et al., 2018; Rungvivatjarus et al., 2020; Wolfe et al., 2018; Redmond et al., 2018; Lodhi & Thompson, 2020; Christensen & Lundh, 2016). Every medication should also have a specific indication of start and stop times (Rungvivatjarus et al., 2018). Identifying high-risk patients and high-risk medications in the MR process is also beneficial (Hias et al., 2017; Anderson & Ferguson, 2019; Wolfe et al., 2018). Incorporating these literature findings into the facility's MR process was therefore critical to ensuring patient safety.

CHAPTER THREE

SETTING AND METHODS

Process Improvement Model

The DNP project was a quality improvement project focused on improving presurgical nursing assessment of MR rates in adult orthopedic patients of an ASC. The IHI (2011) recommends the use of the Model for Improvement for implementing MR into practice. This model starts with the following three prompts: set clear aims, establish measures that will tell if changes are leading to improvement, and identify changes that are likely to lead to improvement (IHI, 2011). Once these items are agreed upon, Plan-Do-Study-Act (PDSA) cycles are conducted to implement small, progressive changes (IHI, 2011). This process creates a manageable project foundation on which further improvements can be built based on learning and growth from each subsequent cycle (IHI, 2011). This method for implementing a new process was chosen because incremental changes allowed unexpected challenges and issues to be appreciated and solved without the need to redesign the project or start from scratch (IHI, 2011).

For this project, PDSA cycles were performed on a weekly basis. Electronic chart audits of the presurgical MR assessment were performed by the DNP student at the end of each week to determine strengths and limitations of the MR process. Areas for presurgical nursing process improvement were then conveyed to involved staff via e-mail or personal communication to be implemented in the next cycle. The methodology aligned with the current practice of weekly leadership meetings where progress was shared.

Agency Description

Setting. The project facility was an ASC in southwestern Montana serving the local community, as well as many surrounding areas. The ASC is a for-profit organization that functions independently of a larger healthcare system. Nursing and administrative staff are employed directly by the ASC. Surgeons and anesthesiologists are contracted through their respective organizations. The project facility is run by a board of directors composed of a medical director, CEO, and three surgeons. All other surgeons, as well as the local hospital, are also investors. The local population is roughly 48,000 with a county population of roughly 115,000 (United States Census Bureau, 2019). Surrounding counties represent another potential 44,000 individuals (United States Census Bureau, 2019). On average, there are 2,500 orthopedic surgeries performed at the facility per year.

Target Population. The project focused on adult orthopedic patients preparing for ambulatory surgery during a 6-week period. Preliminary data anticipated at least 200 potential patients served during project implementation.

Description of Stakeholders. Project stakeholders included the clinical director, presurgical assessment nurses, preoperative nurses, OR nurses, PACU nurses, surgeons, PAs, anesthesiologists, and patients and their families. Presurgical assessment nurses were invested in the MR process as they are responsible for the initial patient contact and acquisition of medication information. Preoperative, OR, and PACU nurses were invested in the MR process because they are responsible for determining which medications the patient has been taking prior to arrival. This requires the original MR to be accurate and complete. Surgeons, PAs, and

anesthesiologists were invested in the MR process because they are responsible for prescribing and administering medications during the perioperative period. Patients and their families were presumably invested in the MR process because they seek safe and appropriate care and may require education regarding medication interactions and side effects. Although all of these individuals are stakeholders, for rapid change required in the PDSA cycles, the predominant focus of a three-member team was used (presurgical assessment nurse, DNP student, and preoperative nurse manager) with dissemination to other stakeholders at the completion of the project.

Site-Specific Facilitators and Barriers to Implementation. Barriers to implementation included limited resources, patient compliance, and access to medical records. Limited resources included staff time to perform and review the MR, large patient loads on presurgical nurses, and the ability to reconcile medications due to lack of access to records. Patients' ability to adequately provide a complete list of medications is limited by their knowledge of the medications, health literacy, memory, and motivation. The project facility also runs on a different EHR system than the local community healthcare system making it difficult to obtain medication lists from other providers (Appendix A, Figure 1). Facilitators include stakeholder motivation to promote safety and an already planned implementation of a new ASC EHR system during the project timeframe.

Project Design

Purpose

The purpose of this project was to implement and evaluate a new MR process at an ASC in southwestern Montana.

SMART Goals

- Short term: MR process will be implemented on January 4, 2021.
- Mid: MRs will be completed for at least 95% of adult orthopedic patients by February 26, 2021.
- Long term: MR process completion will be sustained for >90% of all patients.

Project Methods

Description of Project

The project MR process was implemented alongside the transition to a new EHR program occurring at the project facility beginning in December, 2020. The intervention included the use of the AAAHC Patient Medication Reconciliation Form in Surgical/Procedural Setting (Appendix A, Figure 2). This form was chosen due to literature support, and it contains all the components necessary for a complete MR (preoperative medications, post-operative medications, stop/start times, and new medications). The presurgical section of the form was intended to be filled out in its entirety by a presurgical assessment nurse during the presurgical phone call. The phone call occurred once the surgery was scheduled, which ranged from one week prior to the day of surgery. The form was to be completed on paper and scanned into the

patient chart. If data were missing, the presurgical nurse would reconcile the list by contacting the prescribing provider or pharmacy (Appendix A, Figure 4).

Once EHR content for MR was reviewed upon implementation on January 4, 2021, project process was adapted to promote EHR use, which increased transparency to other ASC providers and allowed automatic download from the pharmacy database. This impacted a larger number of patient transitions and providers in real-time through EHR use; however, the same AAAHC Patient Medication Reconciliation Form content was utilized.

Human Subjects' Protection. Subjects consisted of adult orthopedic patients at the project facility. All subjects received the new MR process as part of consent for care under facility policy. The facility does not have a separate institutional review board (IRB). Since the DNP project was deemed a quality improvement project, exempt status was requested and granted from the Montana State University IRB. The quality improvement project was focused on performing complete, standardized MR, which is a component of standard care recommended by AAAHC and determined to be included in the facility policy. EHR chart review and data collection on the MR completion rates did not include any patient-specific information or identifiers. All collected data were de-identified and stored in a password-protected Excel spreadsheet maintained at the project setting on an organizational computer.

Measures and Instruments. Measurements included a "yes" or "no" regarding whether the MR was fully completed. As endorsed by literature recommendations, a fully completed MR included all current prescription medications, over-the-counter medications, and nutritional supplements. Every medication must have included medication name, dose with units,

medication form, route of administration, and frequency/time taken in order to be fully completed. Each medication needed an indication of whether it should be started, stopped, or resumed with specific dates and times for these actions. Reasons for failure to complete the MR were documented and categorized in the project database to facilitate improvement methods. Reasons for failure not identified in project planning were further categorized once they were determined through PDSA cycles.

Procedures/Implementation Plan

General Description. Following IRB approval, the project team met on December 16, 2020, and education was provided to preoperative nurses on the project process and expectations. Other staff and stakeholders were informed of the project during the December staff meeting. Staff not present at the staff meeting were sent a copy of the information resulting in 100% of staff (nurses and providers) receiving the information. The MR process was implemented on January 4, 2021, when the new EHR was initiated. The project data collection focused only on MR completion within the adult orthopedic patients, as this was deemed the most predominant ASC population. All subjects received the MR process as part of routine presurgical nurse assessment.

Data Collection Plan. Chart reviews were completed on a weekly basis by the DNP student. Charts to be reviewed were determined by reviewing the weekly surgery schedule and selecting the patients who met the inclusion criteria (adult, orthopedic). Each subject's electronic chart was reviewed by the DNP student to determine if the MR was completed or not. Subject information was de-identified and collected in a password-protected spreadsheet at the project

facility. MRs not completed were organized by reason for failure to complete. Information regarding reason for failure was presented at weekly leadership meetings in the form of a histogram. These data were used to improve the process during each PDSA cycle over the course of 6 weeks.

Data Analysis Plan. Information was shared with the project team on a weekly basis and at the completion of the project. The project team consisted of the DNP student, the clinical director, and the presurgical assessment nurse. Rates of MR completion were calculated and reported in a run chart at weekly project team meetings. Reasons for failure to complete MRs were determined, categorized, and reported to the project team on a weekly basis as frequencies in the form a histogram. Reasons for failure illuminated during PDSA cycles were addressed in all subsequent meetings. However, if new reasons were determined that did not fit in any existing categories, those were added to the weekly report.

Timeline of Project Phases

The project proposal was presented to university nursing leadership in November, 2020, and approved for implementation once IRB exemption was obtained. Subsequently, IRB submission occurred in November, 2020, and was granted exempt status. Project implementation occurred on January 4, 2021, and four PDSA cycles were performed for 6 weeks. After completion of four PDSA cycles, data analysis occurred in late February, 2021. Data were synthesized and evaluated in March, 2021. The completed DNP project was presented on April 8, 2021 (Appendix A, Figure 3).

Resources

Personnel. The project team included: (1) DNP student, (2) preoperative nurse manager/site representative, and (3) one presurgical assessment nurse. A memo was provided to surgeons, PAs, and anesthesiologists in December, 2020, informing them of the project and of the increased attention that will be paid to patient preoperative and postoperative medications as this may affect perioperative medications and prescriptions given at discharge.

Technology

- Surgical Information Systems Complete™ EHR program
- Organization password-protected computer and Microsoft Excel already provided by the organization and with no additional charge for the project

Budget

- N/A. This process was already accounted for in the implementation of a new EHR system at the facility.

Feasibility and Plan for Sustainability

The project was deemed feasible as it required limited resources and staff time. The DNP student leading the project provided volunteered time as a component of academic requirements, saving the organization at least $2,500 (10 hours/week at $30.80/hr for 8 weeks). The DNP student's involvement in this project also saved the presurgical assessment nurse valuable time, since regular operations requiring their attention were still occurring during the implementation period and would have otherwise not allowed the oversight time the DNP student provided. The

project was also implemented alongside a larger EHR process change at the facility; therefore, stakeholder buy-in, budget, and the expectation for change were already achieved. To ensure sustainability, the presurgical assessment nurse and preoperative nurse manager were involved in each PDSA cycle to promote the development of an efficient and feasible MR process. The need for complete and accurate MRs for both patient safety and accreditation were required for continued ASC operation; thus motivation for sustainability after project completion was preserved.

CHAPTER FOUR

OUTCOMES

The purpose of this DNP quality improvement project was to enhance the MR process and incorporate safety and accreditation standards to decrease ADEs amongst adults receiving orthopedic surgery within an ASC. Goals for this project were that (1) MR process will have been implemented by January 4, 2021, (2) MRs will have been completed for at least 95% of adult orthopedic patients by February 26, 2021, and (3) MR process completion will have been sustained for >90% of all patients. Project implementation began in December, 2020, with education provided to the project team, as well as the general staff. The first phase of direct implementation was initially planned to begin on January 4, 2021, when the new EHR went live at the project facility. Each subsequent week involved chart reviews to assess the rate of successful MR completion within the new EHR. Issues related to completion were then discussed weekly with the project team and changes were made in the following week's PDSA cycle. This process continued for 6 weeks, ending on February 26, 2021. For PDSA cycle summary, see Table 1.

Table 1. Summary of PDSA cycles, actions implemented, and barriers determined

PDSA Cycle	Week/Dates	Action Implemented	Barriers Determined
1	Week 1: 1/18/21 – 1/22/21	Project implementation	Duplicate medications
2	Weeks 2-3: 1/25/21 – 2/5/21	Decrease SureScript® data range from 4 months to 3 months	Discrepancies in dosage
3	Weeks 4-5: 2/8/21 – 2/19/21	Use medication name only	Lack of indication of OTC or supplement use
4	Week 6: 2/22/21 – 2/26/21	Note template to indicate OTC use discussed	Project complete

Pre-Project Implementation

Once direct implementation began on January 4, 2021, the project team determined that staff were overwhelmed with the transition to the new EHR system due to limited training, creating a barrier to PDSA cycle initiation. To allow staff time to familiarize themselves with the new system, the project team decided to postpone PDSA implementation by two weeks, changing the start date to the week of January 18, 2021, and shortening the project implementation to 6 weeks from the intended 8-week timeline.

Demographics

Throughout PDSA Cycles 1, 2, 3, and 4, a total of 234 charts were evaluated. Of these, 133 were female and 101 were male, with an average age of 51.

PDSA Cycle 1

The first intervention consisted of the implementation of the new EHR system and included MR assessment. Following the first week of data collection, the project team met to discuss initial flaws and barriers to the MR process. Week 1 yielded that 100% of the 54 charts reviewed were incomplete due to one or more missing components deemed required. Of note, the team also found roughly 40% of patients had no information in the SureScript® system. Unfortunately, this issue was beyond the scope of this project to resolve as not all pharmacies report to the SureScript® system and changing that would require policy changes at all pharmacies not connected to the system. For patients who did have SureScript® data, there was a significant amount of redundancy and duplication in their medication lists, which increases the

risk for medication error. Through analysis of the program settings, the DNP student determined this was due to the program downloading all prescriptions filled within the past 4 months, therefore listing medications filled on a monthly basis up to four separate times. Reducing duplication was determined to be the goal of the next PDSA cycle.

PDSA Cycle 2

The first action the team decided upon was to decrease the date range from which SureScript® was obtaining information to be downloaded into the MR. Originally, the program was providing pharmacy information from the previous 4 months. However, the project team agreed the majority of prescriptions are filled on a 3-month or monthly basis. Therefore, SureScript® settings were changed to only search and download medications to the MR that were filled in the past 3 months. The goal of this intervention was to decrease the number of duplicate medications, thus preventing possible medication error and improving nursing efficiency.

After 2 weeks (January 25–February 5, 2021), the impact of the intervention was analyzed. Twelve of the 62 charts reviewed (19%) contained completed MRs. The team then met again to discuss further barriers. A second identified issue was the extensive medication library the preoperative nurse had to navigate when adding a medication to a patient's MR. This was causing medications to be entered in inconsistent formats and creating discrepancies in medication details. This became the focus of the next PDSA cycle.

PDSA Cycle 3

The extensive list of medications a search returned led to discrepancies between the name and dose of medications in the MR. For example, if “aspirin” was typed into the search bar, a list of 45 options appeared in the drop-down menu. From that list, if simply “aspirin” was selected, another drop down was provided with another 42 options. Furthermore, if “aspirin 81 mg tablet” was selected from the drop down, the nurse was still required to input “dose,” “units,” “form,” and “route.” This led to significant discrepancies in the completed list and identified as a potential safety issue for patients and an ineffective process for nursing. In detail under “aspirin 81 mg tablet,” the dose column may state “1 mg” instead of “1 tablet,” which was found to be the case on at least one medication for 100% of 62 charts reviewed.

The cause of this discrepancy was determined to be the redundancy of the dose being listed in the name and as a separate EHR column. The preoperative nurses stated they would either skip the dose section if the name section already contained a dose or enter a number without changing the corresponding units, leading to significant inconstancies and conflicting information in the patients MR. These issues impacted efficiency for the admitting nurses as they often needed to go back and correct the MR, as opposed to simply having the patient verify the accuracy of the list. This further created the risk for medication errors throughout the perioperative process if discrepancies in the MR were not caught and resolved during admission.

After discussion, the project team agreed that all medications would be entered as name only (e.g., “aspirin’) and all other medication information (dose, route, etc.) would be listed only under the appropriate category column. The goal of this process standardization was to avoid inconsistencies and ensure complete, accurate medication details. This intervention was

implemented and assessed after 2 weeks. Chart reviews revealed 22 of 57 (39%) MRs were completed. This week's project team meeting identified the continued lag of MR completion to be attributable to the inability to determine if OTC or supplemental medications were discussed. To maintain compliance with AAAHC MR standards, the use or lack of use of OTC or nutritional supplemental medications must be assessed and explicitly documented. This element was deemed necessary for a complete MR as the literature shows up to 86% of ADEs occur due to omission of medications (Al-Hashar et al., 2018; Renaudin et al., 2020). This became the focus of the fourth PDSA cycle.

PDSA Cycle 4

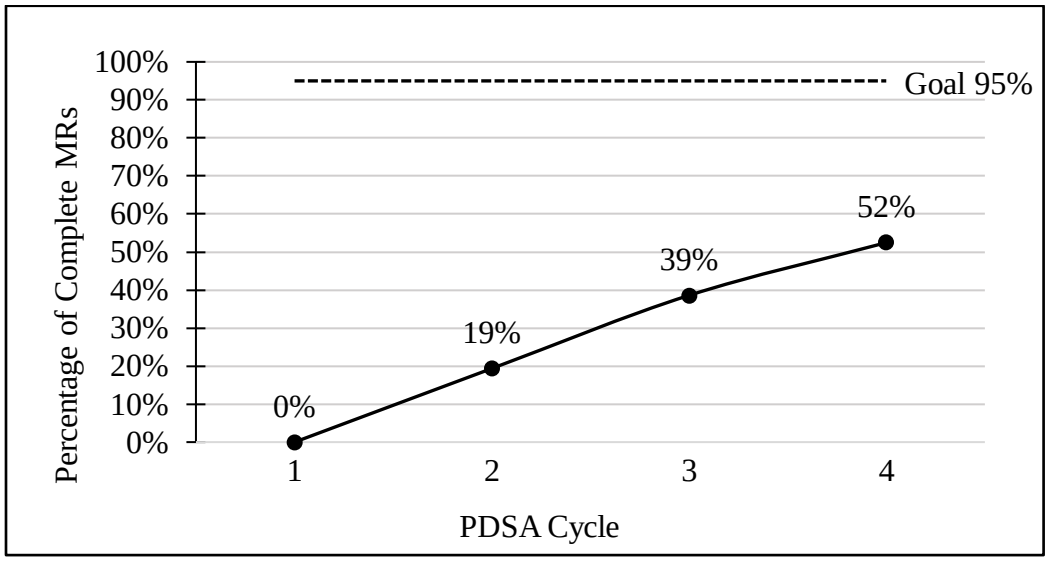
If a patient had no OTC medications or supplements listed, it could not be determined if they simply were not taking any or if the presurgical assessment nurse had neglected to ask about usage. To improve compliance with OTC and supplement data, the team chose to create a note template indicating OTC and nutritional supplements were discussed. The presurgical assessment nurse would include this note template in the MR when relevant, thus demonstrating an assessment was completed. The note template was developed by the DNP student and stated, "Patient denies any use of OTC/herbal medications or supplements." The final review at week 6 showed 32 of 61 (52%) of charts were complete.

Summary

Each PDSA cycle produced higher rates of MR completion. At the onset of the project, 0% of MRs were completed. Through PDSA cycles 2, 3, and 4, the MR completion increased to 19%, 39%, and 52% respectively (Figure 1). These completion rates are based on the entire MR

being completed, as described in the literature review, not only on completion of the specific implementation focus of each PDSA cycle. Therefore, the increasing trend indicates overall MR completion improved. While the goal of completion of MRs for 95% of all adult orthopedic patients was not achieved, an upward trend was achieved with each subsequent PDSA cycle.

Figure 1. Run Chart of Percentage of Complete MRs Over Four PDSA Cycles



CHAPTER FIVE

DISCUSSION

The DNP project was a quality improvement project focused on increasing MR completeness rates in adult orthopedic patients at an ASC. The project was chosen because the project facility's MR process did not meet the standards outlined by current evidence or the standards required by the accrediting body. High-quality MR is necessary for patient safety by preventing ADEs and for the continued accreditation required for the ASC to operate. Both the current evidence and the accreditation standards supported the use of a standardized process and single form be implemented in order to achieve an adequate and complete MR. Because the project facility did not have a standardized process, 0% of MRs were considered complete at the outset of the project. Improving and standardizing the process was therefore of benefit to patient safety, efficiency for the presurgical assessment nurse, and continued ASC operation through accreditation standards.

The intervention included four PDSA cycles completed over 4 weeks in which areas for improvement in the MR process were closely analyzed and evidence-based interventions were implemented. The interventions were applied by the presurgical assessment nurse who was responsible for initial MR completion. The project began with the implementation of a new EHR system at the project facility. Subsequent process improvement interventions included reducing duplicate medications, reducing discrepancies in medication dosages, and increasing acknowledgment of OTC medication use. Completed MR rates increased from 0% at implementation, to 19%, 39%, and 52% with each PDSA cycle.

Results and Current Literature

Current literature states that reducing medication discrepancies, defined as "unexplained differences in documented medication regimens across different sites of care" (Mueller et al., 2012, p.1057), is the most important factor in preventing ADEs (Christensen & Lundh, 2016; Khalil, Bell, Chambers, Sheikh, & Avery, 2017; Redmond et al., 2018; Lehnbom, 2014; Mueller 2012). Preventing medication discrepancies through complete and accurate MRs prior to surgical procedures was thus the focus of each PDSA cycle, as the quality of the initial MR determines the quality of the MR throughout the patient stay and upon discharge.

The first PDSA cycle found duplicate medications to be one cause of discrepancy of MRs reviewed. Because the EHR system pulls information directly from pharmacies through the SureScript® program, medications filled monthly were listed multiple times. The literature states that decreasing complexity reduces error (IOM, 2000). By decreasing the number of duplicate medications, the process complexity was reduced. With the change to 90 days of downloadable medication lists through SureScript ®, 19% improvement in MR completion occurred. Through team collaboration, and the presurgical nurse's openness to adaptation, a rapid improvement occurred within 1 week and with one change. This was followed in the second PDSA cycle as well.

Current literature highlights the importance of all medications specifically stating name, dose, frequency, route, and purpose (Wang et al., 2018; Rungvivatjarus et al., 2020; Wolfe et al., 2018; Redmond et al., 2018; Lodhi & Thompson, 2020; Christensen & Lundh, 2016). Therefore, decreasing discrepancies in dosage was determined to be of high importance. By changing the MR process to listing medications by name only (i.e., "aspirin" as opposed to "aspirin 81mg

tablet") and placing dosage only under "dose," the risk for medication dosage discrepancies would be decreased. This standardization of nursing process further improved completion by an additional 20% and was found by nursing staff to greatly improve efficiency.

The third PDSA cycle addressed the issue of omission of OTC medications as literature states up to 86% of ADEs occur due to omission of medications (Al-Hashar et al., 2018; Renaudin et al., 2020). Due to the lack of standardization in the original MR process, OTC medications were not consistently assessed leading to the risk of medication omission and not meeting accreditation standards. By creating a standardized template stating the assessment of OTC medications was completed, it was ensured OTCs were discussed, thus reducing the risk of omission and promoting patient safety. This also further improved efficiency for nursing through standardizing the process. MR completion rates increased from 39% to 52% following this intervention.

Challenges

Challenges to the DNP project included time constraints and employee motivation and willingness to participate in change. The project was originally planned to be implemented over an 8-week period. However, due to unforeseen challenges with transitioning to a new EHR system, the project timeline was reduced to 6 weeks. This decreased the number of PDSA cycles and interventions that could be implemented. Limited time hindered achieving the goal of 95% MR completion as there was not enough time for continued investigation and to solidify change.

Employee motivation and willingness to participate in change significantly limited the DNP student's ability to implement interventions. While the transition to a new EHR was originally seen as a benefit to the DNP project implementation, it became overwhelming to staff

to learn a new system and determine and implement improvements simultaneously. Staff were resistant to drastic changes so soon after being introduced to the new EHR. Project interventions were therefore chosen to be simple and minimally cumbersome to nursing staff.

Limitations

Adaptability of the EHR system was the major limiting factor to project interventions. For example, not all patients had information in the SureScript® system. This was in part due to the rural nature of the project site and limitations of all pharmacies to have access to this system. Furthermore, the format of the MR was built into the EHR. This limited what information could be entered and how it was presented in the MR, which limited the adaptability by nursing.

The final PDSA cycle of the project achieved an MR completion rate of 52% of all adult orthopedic patients. Barriers to the goal of >90% that remained at the completion of the project included missing data (dose, frequency, purpose) and lack of information regarding when patients should start, stop, and/or resume medications. These are areas for continued improvement that could not be addressed during this project due to time constraints.

Recommendations for Future Work

Continued implementation of PDSA cycles by nursing staff to further improve the MR process is highly recommended. It is recommended that the charge nurse takes the role of the team leader since they are familiar with the work done in this project and already have an oversight role of nursing staff. Based on Lewin's Change Theory, the facility has accomplished "unfreezing" by understanding the deficits in the old MR process and the importance to patient safety and accreditation in improving the process, and it is now in the "change" phase

(Zaccagnini & White, 2017). Continued change is recommended to ensure the MR process meets all current standards before "refreezing" the process can occur (Zaccagnini & White, 2017). Recommendations for future changes prior to "refreezing" the presurgical MR process include incorporating start/stop/resume information for each medication on the patient list and continued assessment of barriers to missing data through PDSA cycles (Zaccagnini & White, 2017).

Strengths and Sustainability

While the project goal was not met, the DNP project did improve overall MR completion rates by 52% from 0% compliance with regulatory standards. This improvement was able to be achieved due to the 80 hours donated to the project by the DNP student. Further strengths of the project included the implementation of a new EHR, the use of the Model for Improvement and the dynamic PDSA cycle format allowing for rapid improvement. The visualization of improvement reported through histogram use aided support, stakeholder buy-in, and the opportunity for ongoing improvement. The use of a small team focusing on one nursing role further helped in implementing rapid change. Ongoing improvements can be made through continuation of monthly PDSA cycles and team meetings led by the charge nurse. The extension to intraoperative and postoperative processes would only require inclusion of staff members from those departments into the process improvement team. Transitions to subsequent departments would be facilitated by the experience the preoperative team has already developed in this process.

DNP Essentials

Quality improvement is critical to the DNP role. Applying quality improvement to the practice setting is foundational to all eight of the DNP essentials (Moran, Burson, & Conrad, 2020). The DNP-prepared nurse excels in quality improvement because they combine evidence from research with the practical, clinical setting, in both of which the DNP is trained (Moran, Burson, & Conrad, 2020). The DNP student demonstrated each of the *DNP Essentials* in this quality improvement DNP project.

Through awareness of the deficiency of the MR process at the project facility and acknowledgment of the need for improvement for both patient safety and organizational sustainability, the DNP student demonstrated Essential II: organizational and systems leadership for quality improvement and systems thinking, Essential V: healthcare policy for advocacy in health care, and Essential VII: clinical prevention and population health for improving the nation's health (Moran, Burson, & Conrad, 2020).

The DNP student exhibited Essential VI: interprofessional collaboration for improving patient and population health outcomes by seeking to improve patient health and safety through an interdisciplinary, quality improvement project. This was achieved by establishing relationships with stakeholders and those directly involved in the process and its improvement and creating and functioning within an interdisciplinary project team. This collaboration allowed for a synchronized approach to improving facility processes in order to improve patient care.

Scholarship of Essential I: scientific underpinnings for practice, was demonstrated through the review of literature and current evidence-based practice that led the DNP student to create a project that was both scientifically supported and clinically relevant. The subsequent

project implementation and analysis of outcomes and the impact of those outcomes on clinical practice and future improvement utilized Essential III: clinical scholarship and analytical methods for evidence-based practice. Implementation of the EHR system and the DNP student's ability to adapt it to incorporate evidence-based guidelines for complete MRs demonstrated Essential IV: information systems/technology and patient care technology for the improvement and transformation of health care.

Proficiency of Essential VIII: advanced nursing practice was apparent through the DNP student's ability to incorporate Essentials I–VII in a quality improvement project focused on improving patient safety and organizational systems. The comprehension of the DNP role demonstrated in this project is the outcome of significant growth and knowledge acquisition by the DNP student.

Conclusion

The DNP project illuminated the dynamic role of the DNP as a clinical change agent. From awareness of an area for improvement, review of current literature, implementation of a quality improvement project, determination of change success through PDSA cycles, and analysis of the potential for ongoing improvement, the DNP student has solidified the importance and benefit of quality improvement at this level. The DNP project instilled the importance of being a lifelong learner and flexible team member for the betterment of patient and population health. The literature suggests the importance of collaboration and adaptability to achieving complete MRs through a standardized process to decrease ADEs and promote safe patient care.

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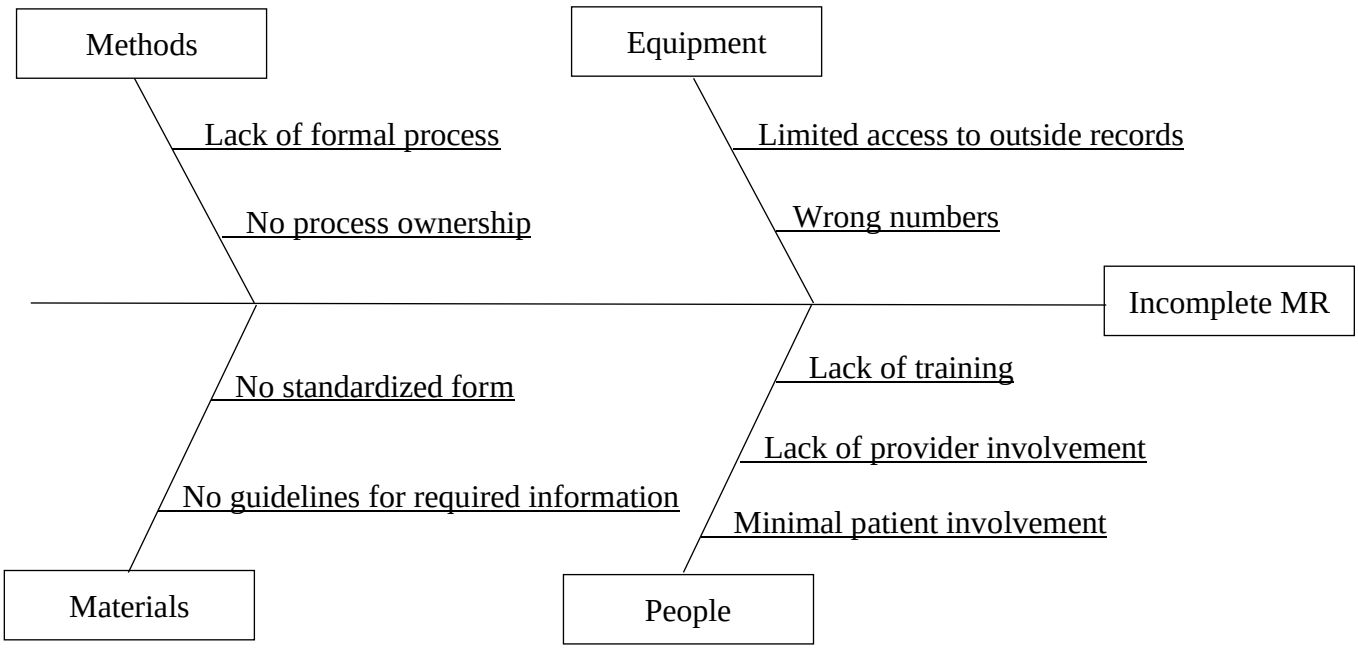
APPENDICES

APPENDIX A

PROJECT GRAPHICS

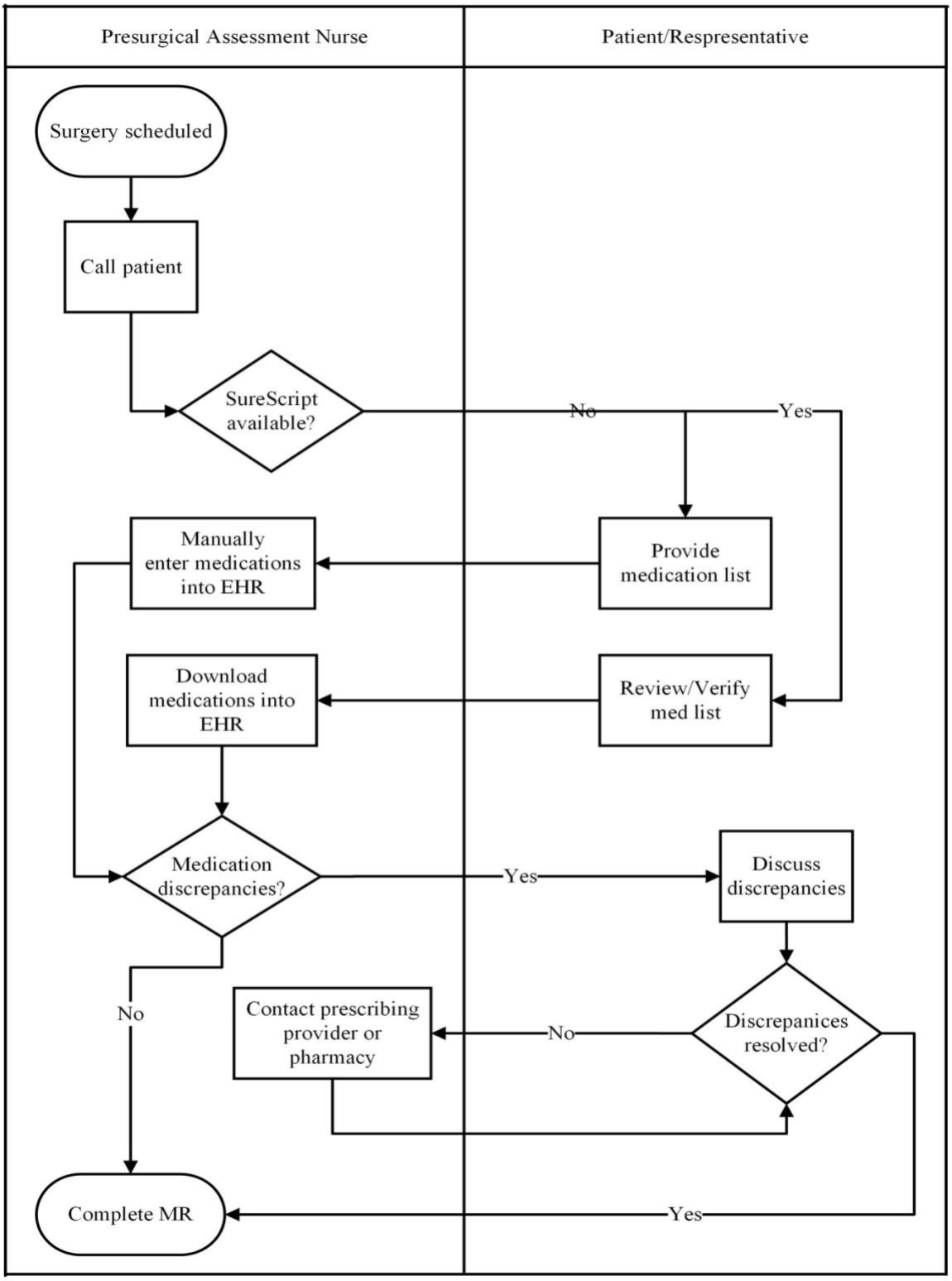
Figure 1. Fishbone diagram. This figure demonstrates barriers to the current MR process.



	November 2020	December 2020	January 2021	February 2021	March 2021	April 2021
IRB Submission						
Staff Education						
Implementation						
PDSA Cycle 1						
PDSA Cycle 2						
PDSA Cycle 3						
PDSA Cycle 4						
Data Analysis						
Project Defense						

Figure 2. GANTT Chart. This figure outlines the project timeline.

Figure 3. Swimlane diagram of MR process



APPENDIX B

LITERATURE TABLE

CITATION	CONCEPTUAL FRAMEWORK	DESIGN/ METHOD	SAMPLE/ SETTING	MAJOR VARIABLES	MEASUREMENT OF MAJOR VARIABLES	DATA ANALYSIS	STUDY FINDINGS	STRENGTH OF EVIDENCE
Al-Hashar et al. 2018 Impact of medication reconciliation and review and counselling, on adverse drug events and healthcare resource use	Not stated	Prospective RCT Impact of a medication reconciliation and counselling intervention on admission and discharge on rate of preventable ADEs and healthcare use at 30 days following discharge	>18 years, admitted to medical ward, at least 1 med prior to admission, admitted for at least 24hr START Intervention group (n=286) Standard care group (n=301) END Intervention group (n=243) Attrition = discharge on weekends or outside working hours, no	IV: MR on admission and discharge, medication review, bedside medication counselling, take-home medication list DV: Primary: rate of preventable ADEs Secondary: impact on healthcare resources (rates of readmission, ED visits, unplanned visits to hospitals/health centers, and	Categorical variables: Pearson's Chi squared test or Fisher's test for <5 Continuous variables: summarized with means and standard deviations, analyzed with t test Threshold = 0.05	Significant difference between two groups on preventable ADEs (p=0.008) Significantly fewer patients from intervention group hospitalized due to ADE (p=0.040) No significant difference for any of the secondary outcomes	MR intervention significantly reduces ADEs MR intervention significantly reduces hospitalization due to ADE MR intervention does not significantly reduce the use of healthcare resources related to ADEs	Level of Evidence: I USPSTF Grade: A -Significant findings -No risk to implementation Strengths: RCT, sample size, thorough explanation of methods and analysis Weaknesses: attrition

CITATION	CONCEPTUAL FRAMEWORK	DESIGN/ METHOD	SAMPLE/ SETTING	MAJOR VARIABLES	MEASUREMENT OF MAJOR VARIABLES	DATA ANALYSIS	STUDY FINDINGS	STRENGTH OF EVIDENCE
			response to follow-up, death	the three combined)				
Bell 2016 Effect of Pharmacist Counseling Intervention on Health Care Utilization Following Hospital Discharge: A	NA	RCT	>18 admitted for ACS or ADHF	Pharmacist-assisted medication reconciliation Time to first unplanned health care event (readmission, ER)	CI 95%	No significant effect on time to readmit or ER Decrease for low health literacy group	Pharmacist based health literacy sensitive intervention beneficial for low health lit groups	Level of Evidence: I USPSTF: A
Christensen & Lundh (2016) Medication review in hospitalized patients to reduce morbidity and mortality	NA	Systematic Review	10 RCTs (3575 participants) hospitalized adults	All-cause mortality Readmission, ED visit, ADEs	CI 95%	No significant effect on mortality or readmission	Uncertain due to heterogeneity	Level of Evidence: I USPSTF: B

CITATION	CONCEPTUAL FRAMEWORK	DESIGN/ METHOD	SAMPLE/ SETTING	MAJOR VARIABLES	MEASUREMENT OF MAJOR VARIABLES	DATA ANALYSIS	STUDY FINDINGS	STRENGTH OF EVIDENCE
Lehnbom 2014 Impact of Medication Reconciliation and Review on Clinical Outcomes	NA	Systematic Review	83 RCT and non-RCTs	Unintentional medication discrepancies	%	Discrepancies found in 3.4-98.2% of patients	MR catches discrepancies	Level of Evidence: I USPSTF: A
Mendes 2016 Medication reconciliation at patient admission: a randomized controlled trial	NA	RCT 6 months Effect of MR on length of hospital stay (LHS)	Adults over 18 new admitted into general wards	Primary outcome: LHS for intervention and control groups Secondary outcomes: number of discrepancies	LHS (days) # of discrepancies			Level of Evidence: I USPSTF: A
Morin, Johnell, Laroche, Fastbom, & Wastesson 2018	N/A	Prospective cohort study	≥ 65 years, from register data Sample size: 1,742,336	Rates of polypharmacy	Prevalence of polypharmacy (5+ drugs) and excessive polypharmacy (10+ drugs) Incidence rate	N/A	Prevalence polypharm: 44% Prevalence excessive: 11.7%	Level of Evidence: III USPSTF Grade: N/A Strengths: sample size Weaknesses:

CITATION	CONCEPTUAL FRAMEWORK	DESIGN/ METHOD	SAMPLE/ SETTING	MAJOR VARIABLES	MEASUREMENT OF MAJOR VARIABLES	DATA ANALYSIS	STUDY FINDINGS	STRENGTH OF EVIDENCE
The epidemiology of polypharmacy in older adults: register-based prospective cohort study					of polypharmacy and excessive polypharmacy		Incidence polypharm: 19.9 per 100 person-years Incidence excessive: 8.0 per 100 person-years	Level III evidence
Mueller 2012 Hospital based medication reconciliation practices: a systematic review	NA	Systematic Review	26 controlled studies	Study design, setting, participants, intervention components, timing, comparison group, outcome measures	# of studies	Reduction in discrep, potential ADEs and ADEs	MR helpful with heavy pharmacist use and high-risk groups	Level of Evidence: I USPSTF: A
Redmond 2018 Impact of medication reconciliation for improving	NA	Systematic Review	25 RCTs	Effect of MR on med discrepancies, patient related outcomes, and healthcare utilization	# of discrepancies	Reduced risk in intervention group (95% CI)	MR may reduce risk High heterogeneity	Level of Evidence: I USPSTF: A

CITATION	CONCEPTUAL FRAMEWORK	DESIGN/ METHOD	SAMPLE/ SETTING	MAJOR VARIABLES	MEASUREMENT OF MAJOR VARIABLES	DATA ANALYSIS	STUDY FINDINGS	STRENGTH OF EVIDENCE
transitions of care								
Renaudin et al. 2020 Impact of a preoperative pharmaceutical consultation in scheduled orthopedic surgery on admission: a prospective observational study	N/A	Prospective observational study Rate of unintended medication discrepancies (UMDs) discovered during pre-operative pharmaceutical consultation	Orthopedic surgery department >18 years, elective orthopedic surgery with inpatient stay Pharmaceutical consultation and MR at admission n=360	Primary outcome: percentage of patients conciliated at admission with at least one UMD Secondary outcomes: nature, potential clinical impact, and acceptance rate of each UMD	Categorical variables: counts and percentages Continuous variables with normal distribution: means and standard deviations Others: median and quartiles	At least one UMD: 13.0% (n=47) Most common types of UMD: omission (25.4%), incorrect drug (23.8%), incorrect dose (23.8%) Most common type of drug: cardiovascular (34.9%)	Outlines importance of pharmaceutical consultation/ MR in surgical patients All UMDs discovered were corrected	Level of Evidence: III USPSTF Grade: B -Net benefit, minimal risk Strengths: sample size, recent Weaknesses: Level III evidence
Rungvivatjarus et al.	Model for Improvement	Quality improvement	Large academic children's	Primary outcome:	Percentages	95% completion was reached	Interdisciplinary team and PDSA cycles	Level of Evidence: IV USPSTF

CITATION	CONCEPTUAL FRAMEWORK	DESIGN/ METHOD	SAMPLE/ SETTING	MAJOR VARIABLES	MEASUREMENT OF MAJOR VARIABLES	DATA ANALYSIS	STUDY FINDINGS	STRENGTH OF EVIDENCE
2020 Medication reconciliation improvement utilizing process redesign and clinical decision support		project Increase percentage of hospital admission MR completion to ≥ 95% in 12 months PDSA cycles	hospital Interdisciplinary team: physicians, nurses, pharmacists, and analysts	percentage of admission encounters with completed MR Secondary outcome: change in completed MR percentages between pre- and postintervention periods		at 7 months and sustained for 3 months Ongoing average = 94%	necessary for successful QI project	Grade: N/A Strengths: thorough description of methods Weaknesses: Level IV evidence

CITATION	CONCEPTUAL FRAMEWORK	DESIGN/ METHOD	SAMPLE/ SETTING	MAJOR VARIABLES	MEASUREMENT OF MAJOR VARIABLES	DATA ANALYSIS	STUDY FINDINGS	STRENGTH OF EVIDENCE
Wolfe et al. 2018 Incidence, causes, and consequences of preventable adverse drug reactions occurring in inpatients: a systematic review of systematic reviews	N/A	Systematic review 13 systematic reviews encompassing 37 primary studies What is the incidence of PADRs in acute and continuing/long-term care hospitals/institutions?	Varied	Primary outcome: incidence of PADRs experienced by inpatients Secondary outcomes: effects of patient age, setting, and clinical specialty on PADR incidence	Incidence rates	PADR incidence 0.006 to 13.3 per patient, pooled incidence estimate 0.59 per 100	Incidence of PADRs Significant heterogeneity across reviews and studies	Level of Evidence: I USPSTF Grade: N/A Strengths: systematic review, thorough discussion of selection and analysis process Weaknesses: significant heterogeneity

APPENDIX C

PROJECT DOCUMENTS

Figure 1. AAAHC Patient Medication Reconciliation Form in Surgical/Procedural Setting.

AAAHC
ACCREDITATION ASSOCIATION for AMBULATORY HEALTH CARE, INC.

Patient Medication Reconciliation Form in Surgical/Procedural Setting

Patient Name: _____ Patient Preferred Pharmacy Name/Phone #: _____

Source of Medication List *(Check All That Apply)*: ❑ Patient Interview ❑ Patient's Own List ❑ Caregiver Interview ❑ Pharmacy
❑ State Prescription Drug Monitoring Program (POMP) ❑ Primary Care Provider ❑ Surgeon ❑ Other, please specify: _____

Allergies (include drug and materials)	Reaction

PRE-OPERATIVELY						Stop Medication Prior to Procedure (YES/# of days prior or NO)	POST-OPERATIVELY	
Routinely Taken Medications (includes OTC)	Dose	Frequency	Indication	Start Date	Prescriber		Continue Medication after the Procedure (YES/# of days after or NO)	Comments

New Prescriptions Added Post-Operatively					
Medication	Dose	Frequency	Start Date	Prescriber	Comments

Patient Signature: _____Date: _____ Provider Completing Form: _____ Date: _____

**NOTE: IF THERE ARE ANY DISCREPANCIES IN THIS FORM COMPARED TO INFORMATION CONTAINED IN THE PATIENT'S MEDICAL RECORD, RESOLVE THE ISSUES BY CONTACTING THE PHARMACY, PRESCRIBING PHYSICIAN, AND/OR THE PATIENT.

06/18

Figure 2. IRB approval

INSTITUTIONAL REVIEW BOARD
For the Protection of Human Subjects
FWA 00000165

MONTANA STATE UNIVERSITY

2155 Analysis Drive
c/o Microbiology & Immunology
Montana State University
Bozeman, MT 59718
Telephone: 406-994-4706
FAX: 406-994-4303
E-mail: cheryl@montana.edu

Chair: Mark Quinn
406-994-4707
mquinn@montana.edu
Administrator:
Cheryl Johnson
406-994-4706
cheryl@montana.edu

MEMORANDUM

TO: Kirsten Marion and Amanda Lucas

FROM: Mark Quinn Mark Quinn CTJ
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: December 7, 2020

RE: *"Medication Reconciliation in Ambulatory Surgery to Prevent Adverse Drug Events" [KM120720-EX]*

The above research, described in your submission of November 23, 2020, is exempt from the requirement of review by the Institutional Review Board in accordance with the Code of Federal regulations, Part 46, section 101. The specific paragraph which applies to your research is:

____ (b) (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

_X_ (b) (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation; and (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by section 16.111(a)(7).

____ (b) (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

____ (b) (4) 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 the subjects cannot be identified, directly or through identifiers linked to the subjects.

____ (b) (5) 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.

____ (b) (6) 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 FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Although review by the Institutional Review Board is not required for the above research, the Committee will be glad to review it. If you wish a review and committee approval, please submit 3 copies of the usual application form and it will be processed by expedited review.

Figure 3. Request for IRB minor modification

MONTANA
STATE UNIVERSITY

Montana State University
Institutional Review Board
Request for Minor Modifications/Amendments

Instructions: E-mail completed form and all revised and/or new study documents to: irb@montana.edu

Note: The project's IRB-approved Research Protocol must be kept current and followed throughout the life of the project with yearly renewals. Protocols approved in the Exempt category do not require yearly renewals. All study documents are subject to review.

1. **IRB approval number:** KM120720-EX

2. **Project Title:** Medication Reconciliation in Ambulatory Surgery to Prevent Adverse Drug Events

3. **Principal Investigator:** Kirsten Marion
   Contact information (phone/e-mail): (303) 868-7404 / kirstenamarion@gmail.com
   Address (where you want approval letter sent): 3801 Renova Ln, Bozeman, MT 59728

4. **Requesting modification/amendment to:**
   ⊟ *Research protocol*
   ⊟ *Consent form*
   ☐ Recruitment materials
   ☐ Survey instrument, interview questions
   ☐ Research personnel
   ☐ Other, please explain:

   _____

   _____

5. **Describe the modification being requested:**
   Note: with each requested change, provide a detailed description of where within the study documents (e.g. Research protocol, survey instrument, etc.) **the changes are reflected** (e.g., section, question #, etc.).

   Research protocol: *After implementation of a new EHR system at the project facility, which included a new medication reconciliation process, it was determined that use of the AAAHC PMR form would place more burden than benefit on improving the med rec process. The project team therefore decided to use current literature recommendations to assess and improve the medication reconciliation process within the EHR as opposed to using the form.*

   Consent form: *Consent was included in the facility "Consent to Treatment" as an adaptation to the current process.*

Figure 4. IRB approval of minor modification

Hi Kirsten,

This email acknowledges receipt of the request for a minor modification to the IRB Protocol #KM120720-EX and serves as the official Approval Letter that the modification is **approved**.

Thank you,
Kelly Beiswanger

IRB Administrator & Program Manager
Office of Research Compliance
Hamilton Hall 114
Montana State University
kelly.beiswanger@montana.edu
406-994-4706
https://www.montana.edu/orc/irb