Nurse-Led OPAT (Outpatient Parenteral Antimicrobial Therapy) Care-Coordination Program to Improve Outcomes in Adult Osteomyelitis Patients

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Abstract

Overview: Outpatient Parenteral Antimicrobial Therapy (OPAT) offers numerous benefits and risks. Formal OPAT programs have been proposed to mitigate the risk of complications, but there is a paucity of evidence regarding the specific design and efficacy.

Purpose: To evaluate the impact of the nurse-led OPAT care coordination program, on the primary outcomes: 30-day readmissions, and adverse central line and/or adverse drug events in adult osteomyelitis patients using the Quality Assurance/Quality Improvement (QA/QI) process. A further purpose is to underscore the contributions of registered nurses as viable members of the interdisciplinary OPAT team and to support program funding.

Materials and Methods: The patients in the control group received the traditional post-discharge care while the intervention group received nurse-led OPAT care coordination in addition to traditional care. A retrospective chart review was completed of 456 patients, over 18 months, diagnosed with osteomyelitis, and discharged on parenteral antibiotics to Carilion Clinic home health. The search yielded 54 Intervention and 13 Traditional patients. Fisher's exact tests and Bonferroni adjustment were used to analyze the impact of OPAT care process on outcomes.

Results: There was no evidence to suggest a statistical association or dependence between the intervention and the primary outcomes among the Traditional or OPAT groups. However, a 12.96% readmission rate in the OPAT group is of clinical significance. This is comparable to readmission rates in similar studies that offered formal OPAT care programs.

Limitations: Limitations noted were the small sample size, exclusion of non-Carilion facility readmissions, non-standardized charting of adverse events, and a lack of sensitivity of the primary outcome measure to nursing interventions.

Application to practice: It is recommended that electronic health records be equipped to capture nurse-led care coordination and that future studies utilize outcome variables that are sensitive to nursing interventions in OPAT care programs. These may improve the safety, design, and sustainability of OPAT care.

Keywords: Outpatient Parenteral Antimicrobial Therapy (OPAT), osteomyelitis, quality assurance and quality improvement (QA/QI), care coordination, 30-day readmission, adverse drug events, central line events.

Dedication

In Loving Memory of Late Mrs. Beatrice Oladoyin Akuru,

My Mother & My Hero.

The one who loved and gave all.

Acknowledgments

I thank God, my strength and rock, with whom nothing shall be impossible.

Taiwo mi, my one & only, friend, and mentor. Thank you for believing in me. I could not have done this without your support all the way. What can I say about our jewels-Toluwanimi, Mosimiloluwa, and Oluwajomiloju? You all spurred me on and made this seemingly insurmountable task worth the while. I wish to express my gratitude to my late parents Engr. & Mrs. Oladipo Akuru. Thank you for teaching me that there is dignity in labor. I cannot but appreciate my sisters and brother- Olanike, Omolareni, and Oladimeji. Only you can understand the journeys we have been through. Thank you for always being there. A special thank you to the Principal Investigator- Dr. Kimberly Ferren Carter. Thank you for your time and effort to make this project a reality. I am also deeply grateful to the members of Carilion Health Analytics Research Team (HART), including Ronex Muthukattil, the Solutions Developer, and Sharp Hunter, the Biostatistician. I would like to show my sincere appreciation for the supervisory guidance and support given me by my advisor- Dr Marjorie Young, and the rest of the project committee members- Dr Katie Katz and Dr. Virginia Weisz, for their insights and reviews towards the successful completion of this project. Dr. Eunyoung Lee deserves a special mention for her oversight at the initial stages of this project. I thank Dr. Sarah Gilbert for her guidance in selecting the conceptual framework. I am deeply grateful to the members of the Carilion Infectious Disease Outpatient Clinic, especially Dr. Anthony Baffoe-Bonnie and Dr. Dorothy Garner for the opportunity accorded me as an OPAT nurse. I sincerely appreciate my preceptor Dr. Okoroafor Maduagwu for his ongoing clinical guidance. I am perennially indebted to the remainder of the doctor of nursing practice program faculty and staff. Finally, I say a big “thank you” to my cohort members who have now become a part of my extended family.

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INTRODUCTION

Nurse-Led OPAT (Outpatient Parenteral Antimicrobial Therapy) Care-Coordination Program to Improve Outcomes in Adult Osteomyelitis Patients

Osteomyelitis is an umbrella term for various infections of the bone. It has multiple etiologies and is diverse in its pathophysiology, clinical presentation, and treatment modalities (Kremer et al., 2015). Osteomyelitis often requires extensive, long-term medical treatment and rehabilitative therapies and reportedly one of the most common indications for OPAT (Muldoon, 2015; Winkler & Haiden, 2016). According to the Infectious Diseases Society of America (IDSA), Outpatient parenteral antimicrobial therapy (OPAT) is "defined as the administration of parenteral antimicrobial therapy in at least 2 doses on different days without intervening hospitalization" (Norris et al., 2019, p. 1). The delivery of parenteral antimicrobial medication in a non-hospital environment was first successfully recorded in 1974 in the treatment of chronic bronchopulmonary infections in children with cystic fibrosis (Norris et al., 2019). According to Jacob et al. (2018), "250,000 patients receive OPAT in the USA each year" (p. 783). Despite the success and expanding acceptance of OPAT, hospital readmissions within 30 days of discharge, adverse drug reactions, and other adverse events have been reported in research studies (Huang et al., 2018). This calls for a need to investigate the factors that increase the risk of unplanned hospital readmission and other adverse events that can inform interventions to mitigate the risks.

Significance of the Problem

According to research studies, factors that can lead to 30-day readmissions in OPAT patients include adverse drug reactions, therapy failure, mechanical problems with central lines, a lack of follow up with an infectious disease (ID) specialist, and discharge disposition (Huang et al., 2018). Central Line Associated Bloodstream Infections (CLABSI) are among the deadliest

hospital acquired infections, cause significant financial losses, and lead to readmissions or death (Barnes, Rearden, & McHugh, 2016; Dumont & Nesselrodt, 2012). Patients who receive OPAT are among the 1.2 million individuals that receive therapy through long-term central venous catheters in non-hospital settings (Keller et al., 2019). Studies suggest that CLABSIs in non-acute care hospitals can exceed those that occur in acute care setting (Keller et al., 2019).

OPAT Management

Care coordination provides avenues for nurses to work at the full extent of their professional skill while collaborating with an interprofessional team. Enhanced patient-provider communication guided by a nurse manager-led care coordination program proved to be a practical means to quality care enhancements and reduced inpatient hospital cost for the management of chronically ill Medicaid beneficiaries (Jingping Xing et al., 2015). A statewide study, using the Chronic Care Management program in Washington state, observed a reduction in monthly overall medical costs for high-risk Medicaid beneficiaries, who received nurse manager-led care coordination efforts. In a similar study, results suggest that a comprehensive care transitions program can reduce unplanned readmissions (Huck et al., 2014; Marbach et al., 2018). Conversely, Altfeld et al. (2013), in their study showed no difference in 30-day readmissions among patients who received enhanced discharge planning process. However, results suggested that a post discharge telephone care intervention provided by an experienced social worker can positively impact patient transitional care outcomes.

Benefits of OPAT care. Despite the risks associated with OPAT, numerous studies have demonstrated evidence to support its benefits, such as reduced hospital stays, prevention of hospital acquired infections, significant healthcare cost savings, improved patient independence, and patient experience (Bodycot et al., 2021; Chapman et al., 2019; Norris et al., 2019). Other

benefits are improved quality of life, ability to return faster to work or school, and reduced healthcare costs (Huang et al., 2018; Mackintosh et al., 2011).

Guidelines for OPAT

The Infectious Disease Society of America (IDSA) has recommendations for the delivery and management of OPAT and the management of the recipients. These include the monitoring of laboratory tests and therapeutic or nontoxic levels of appropriate antimicrobials, outpatient infectious disease physician visits, and antimicrobial stewardship review (Norris et al., 2019). Research studies report an increasing acceptance of this care delivery model in the United States with the implementation of evidence-based practice guidelines (Bhavan et al., 2015). According to Huang et al. (2018), "an estimated 1 out of 1000 Americans today receive OPAT annually, and this number is projected to grow with the continual advances in the healthcare environment and shifts in healthcare delivery" (p. 1).

Care Coordination

As the American population grows older, and more medical services are being provided on an outpatient basis along with advanced technology, the period after discharge to an outpatient setting can expose patients to complications due to ineffective communication among providers and patient; lack of follow-up care; and lack of collaborative care among the various levels of non-acute care providers (Jingping Xing et al., 2015). Care coordination has been proposed as a solution to the increasing healthcare costs, limited equitable healthcare access, and failed patient outcomes (Camicia et al., 2013). The Center for Medicare and Medicaid Services, in an effort to combat wasteful healthcare spending related to 30-day readmissions, limits reimbursement for hospitals with high rates of avoidable readmissions (Patient Protection and Affordable Care Act, 2010). Research studies showed that 20% of Medicare patients could have

avoidable 30-day readmissions costing the healthcare system approximately $26 to $44 billion per year (Marbach et al., 2018).

Significance to Nursing

According to data from the Healthcare Cost and Utilization Project in 2010, approximately 20% of the patients undergoing OPAT with procedures related to the amputation of lower extremities, heart and valve procedures, wound debridement, infection, or burns were readmitted within 30 days of discharge (Agency for Healthcare Research and Quality [AHRQ], 2013). In 2017, the Center for Medicare and Medicaid Services withheld $2.6 million of Carilion Roanoke Memorial Hospital (CRMH) payments due to 30-day patient readmission events (AHQR, 2013). It is important to note that the amount withheld is less than that which was deducted two years prior and this reduction in 30-day readmission was attributed to the transitions care management protocol (AHRQ, 2013). The focus of this model of care is care coordination for patients recently discharged from the hospital. It is an evidence-based intervention that has demonstrated a positive impact on healthcare cost and readmission rates although its implementation has often been limited due to poor reimbursement and lack of nurses with the required skills (Altfeld et al., 2013). The implementation of the transitional care management model reflects the commitment of CRMH to continuous improvement in healthcare (Carilion Medicine, 2018).

The AHRQ is one of the numerous organizations that sponsor research into the practice of care coordination and its contribution to patient centered quality care. According to a synthesized definition from a systematic review of authors, care coordination is “the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient’s care to facilitate the appropriate delivery of health care services”

(McDonald et al., 2014, p. 6). Care coordination and transition management have been recommended as key elements in the provision of safe, high-quality care to vulnerable individuals, which can include those receiving intravenous antibiotics in non-hospital settings. The Institute of Medicine has suggested an increase in interprofessional communication and collaboration as a means to decrease medical errors and promote safe patient care (Institute of Medicine, 2001). In light of the changes of the Affordable Care Act and increased access to primary care, collaborative teamwork as well as prevention and wellness promotion, is expected to decrease cost and emergency department visits, ultimately improving patient outcomes and quality of life. Provided that nurses are a part of the interdisciplinary healthcare team, it is critical to develop evidence-based models for care coordination and transition management roles for registered nurses (RN) with measures to assess the impact on patient outcomes (McDonald et al., 2014).

Nurses as Leaders in Care Coordination

Nurses have been suggested as natural leaders in the care coordination role, possessing the knowledge and skills to impact patient health outcomes. Haas and Swan (2014) in their study on the value of RNs in care coordination in outpatient care settings, reported that nurses have performed care coordination activities in ambulatory settings for more than 20 years. However, their work in this area was invisible due to inadequate care documentation until a national study documented their contributions in this role. Some of their roles include supportive relationships, resource person, care coordination, needs assessment, referrals, and education (Hass & Swan, 2014). To facilitate appropriate measures of nurses' input in care coordination and impact on patient outcomes, the electronic record documentation software needs to include platforms that accurately reflect the activities, processes, and outcomes that RNs in ambulatory care accomplish

(Haas & Swan, 2014). In the EPIC Electronic Health Record (EHR), each provider has a designated entry point for their activities and these can be tracked to reveal the average time nurses spend on specific activities and outcomes achieved. Platforms like these can demonstrate the contribution of nurses in care coordination, although it is more appropriate to use more specific outcome measures, linked to nursing interventions, to demonstrate the impact of nurses in care coordination. Performance measures like 30-day readmission and emergency department visits are commonly being used to evaluate the impact of care coordination on patient outcomes. However, they often fail to capture the intricacies of care coordination that prevent care breakdown or unplanned hospital readmissions (Izumi et al., 2018). While further studies have been suggested to develop appropriate outcome measures of care coordination, statistical analysis can help draw an association between the care coordination activities of nurses and their impact on patient outcomes (Haas & Swan, 2014). The principles of nurse driven care coordination and transitions management protocols, in the care of chronically ill patients in the ambulatory settings, form an integral part of the management of OPAT patients to lower rates of complications and improve outcomes.

Purpose of the Study

One of the ways to ensure quality and drive improvements in patient care is to monitor the outcomes of current healthcare delivery patterns and ascertain the effectiveness of patient healthcare systems. Program evaluation is defined as the "process of collecting, analyzing, and using data to measure the impact or outcome of a program…" (Singer & Holly, 2014, p. 157). This DNP project is designed to retrospectively evaluate the impact of the nurse-led OPAT care coordination program on health outcomes in osteomyelitis patients over an 18-month period. A two-group comparison study was used to measure the effect of Nurse-led Care Coordination by

comparing the patient outcomes in osteomyelitis patients who received Traditional OPAT [Control Group] to the patients who received the Nurse-led care coordination in addition to traditional care [Intervention Group]. The independent variable was the nurse-led OPAT care coordination while the dependent variables were the 30-day unplanned readmission, adverse drug events, and central line events. The dependent outcomes were examined as components of a retrospective patient chart review. The outcome variable results can be utilized to identify factors that can predict patient outcomes, which could lead to enhanced OPAT program design and sustainability.

The Objectives of the DNP Project

The primary study objective is to evaluate the impact of a nurse-led OPAT care coordination program in patients 18 years of age and older with osteomyelitis, who required a minimum of two weeks post hospital discharge antimicrobial therapy on the following:

1. To determine or assess the significance of the impact that the program has on patient outcomes as evidenced by 30-day unplanned hospital readmission after discharge, central line events, and adverse drug events.
2. To identify the risk factors that can impact patient outcomes.
3. To provide suggestions on how to improve the program.

Research Question

Does a Nurse-led OPAT Care Coordination program positively decrease (a) the rate of 30-day hospital readmission, (b) incidence of adverse drug events, and (c) central line events; and in adult patients receiving outpatient antimicrobial therapy at home under the supervision of a home health agency, compared with the traditional OPAT?

PICOT Question

In adult patients who received OPAT treatment for osteomyelitis, how does a nurse-led care coordination OPAT program, compared with traditional home health nurse visits only, affect unplanned 30-day hospital readmission, central line adverse events, and adverse drug events within the first 30 days of hospital discharge.

Hypothesis

H0. The null hypothesis is that the intervention and control groups would report the same rates of 30-day readmission, central line, and adverse drug events.

H1. The alternative hypothesis is that there will be a difference between the intervention and control groups in the rates of 30-day readmission, central line, and adverse drug events.

Study Evaluation Plan

1. 30-day unplanned hospital readmission.
2. Adverse drug reactions that resulted in nephrotoxicity, as evidenced by elevated creatinine and blood urea nitrogen (BUN) and neutropenia.
3. Adverse central line events that include:
    i. Inadvertent removal before the planned end of therapy
    ii. Chemical or mechanical phlebitis
    iii. Occlusion requiring anticoagulant use
    iv. Catheter-Associated Deep Vein Thrombosis
    v. Line migration requiring chest –x-ray evaluation
    vi. Premature removal, venous thrombosis
    vii. CLABSI, and lumen occlusion.

Definition of Key Terms in the Study

The Delivery Models for Outpatient Parenteral Antimicrobial Therapy

Hospital Based OPAT Program

This is the administration of intravenous antimicrobials while the patient remains in the hospital. Most insurance companies would not cover in-patient hospital services solely for the administration of intravenous antimicrobial therapy in stable patients that can be discharged. In the United States, safety-net hospitals often have to bear the cost of extended hospital stays solely for intravenous antibiotic administration (Bhavan et al., 2015).

Home-Health based/self-administered OPAT Program

Home based administration can be further divided into two types: administration by the visiting infusion nurse or administration by the patient with routine visits from the home health nurse for maintenance of central venous access lines. The patient may also be required to commute to an outpatient clinic for maintenance of venous access or completion of laboratory tests to monitor therapy and response (Butcher, 2017; Paladino & Poretz, 2010).

Sub-acute care-based OPAT Program

Some patients receive parenteral antimicrobial therapy at sub-acute healthcare facilities such as infusion clinics, hemodialysis centers, or skilled nursing facilities (SNF) as well as nursing homes. The antimicrobial is administered and managed by nurses who provide central line care and collect specimens for laboratory tests if ordered. Given that OPAT service in the home is a not a Medicare covered service, patients are sometimes discharged to a SNF to receive antimicrobial therapy (Mansour et al., 2018; Suleyman et al., 2017).

Definition of Outcome Variables

30-day Readmission

This refers to a 30-day OPAT-related readmissions from the date of discharge for the current admission while on OPAT. The OPAT-related reasons for readmission include

complications that necessitated a visit to the Emergency Department and resulted in rehospitalization.

Adverse Drug Events

Commonly reported adverse drug events (ADE) related to antimicrobial therapy include *Clostridium difficile*; laboratory abnormalities such as creatinine kinase levels, elevated BUN/ creatinine > 24/2.0, cytopenia; gastro-intestinal problems, cutaneous reactions, nephrotoxicity, hepatotoxicity, muscle pain, ototoxicity, and general malaise (Keller et al., 2018).

For this QA/QI study, the ADE were categorized based on the patients' abnormal laboratory test results as evidenced by elevated creatinine or BUN levels. Neutropenia was defined as a white blood cell count less than 2.0 per microliter. Glomerular filtration rate, and creatinine clearance though indicative of adverse drug reactions, were not included for this study (Keller et al., (2018).

Adverse Central Line Events

The adverse central line events included the following defined problems with the central line utilized for OPAT administration. First on the list is a clinically diagnosed CLABSI. Others are line issues that resulted in an unscheduled removal; termination of therapy before the scheduled end of date; or which required a diagnostic imaging study to assess thrombus or migration. The central line events were classified as:

a. CLABSI
b. Inadvertent removal before the planned end of therapy
c. Chemical or mechanical phlebitis
d. Occlusion requiring anticoagulant use
e. Catheter-Associated Deep Vein Thrombosis

f. Line migration requiring chest –x-ray evaluation

g. Premature removal, venous thrombosis

h. Lumen occlusion.

Introduction Summary

The practice of OPAT has been demonstrated to be a safe methodology to provide care beyond the walls of the traditional hospital setting. Nurses have an important role to play as a part of the interdisciplinary team in a nurse-led OPAT monitoring program. The results of this QA/QI project can demonstrate the impact of nursing care coordination on OPAT outcomes.

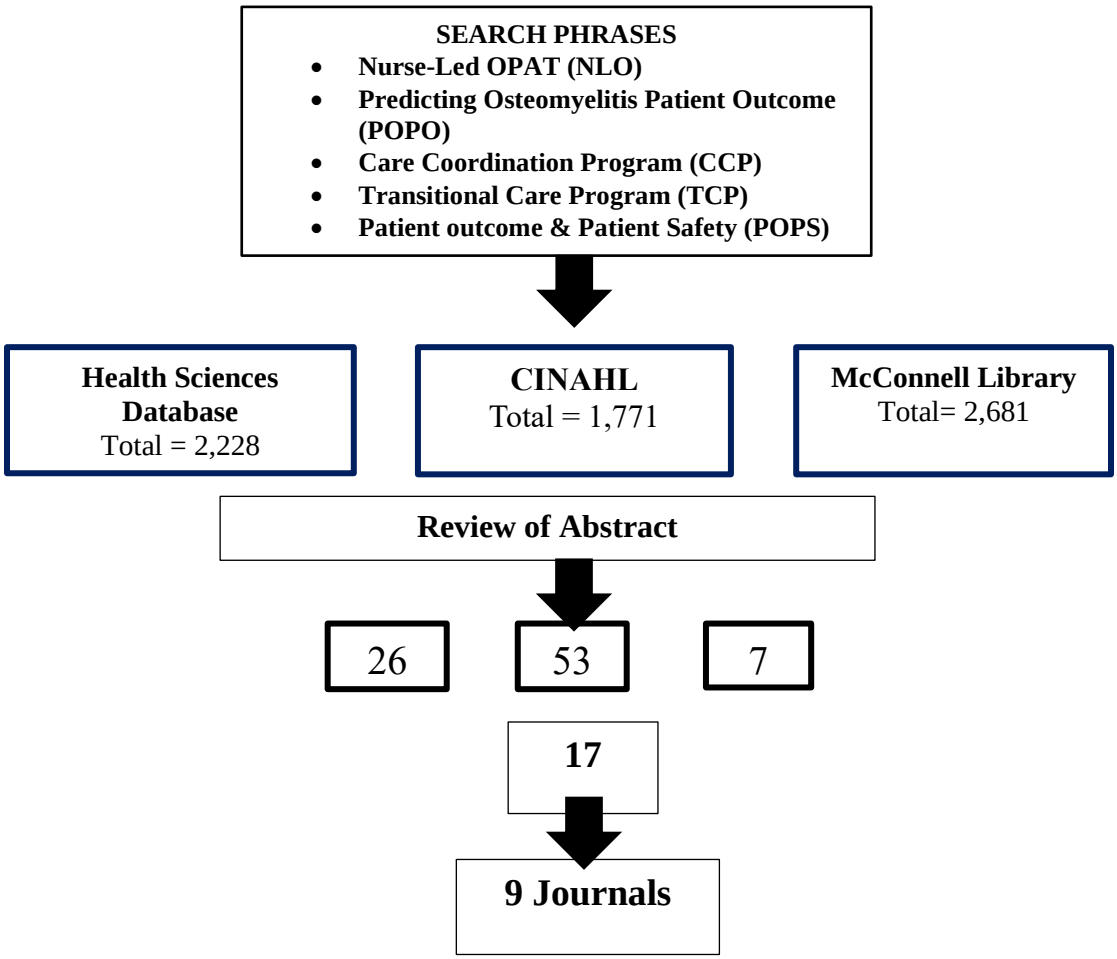
Integrated Review of the Literature

A comprehensive search was conducted using three electronic databases: the Cumulative Index of Nursing and Allied Health Literature (CINAHL), the Health Sciences Database, and the Radford University electronic McConnell Library Catalog. The literature search was conducted using search phrases and the project title as indicated in Figure 1. The search phrases are (a) Nurse-led OPAT (NLO), (b) Predicting Osteomyelitis Patient Outcome (POPO), (c) Care Coordination Program (CCP), and (d) Patient Outcome and Patient Safety (POS). The inclusion criterion for the search was a time frame of 10 years, 2009 to 2019, and academic journals published in English. The literature search was completed via the Radford University McConnell online Library. A rapid critical appraisal of the study abstracts, focusing on relevance to the desired age group (18 years and older) and keywords, was completed. Relevant abstracts without a full text were requested through the Radford University interlibrary loan. Following the primary review of abstracts, a total of 86 journals were selected. A full journal text of each of these studies was reviewed, out of which 17 journals were shortlisted. A manual search of the reference list of closely related journals yielded two additional studies making a total of 19 sub

selections. Eleven of these studies were selected and included in table of analysis of synthesized outcomes. A secondary search was conducted in the year 2020 to obtain more recent studies. Subsequently, five studies were removed from the synthesized table of outcomes and four new studies were added, making a total of 10 studies. The synthesized table of outcomes includes one randomized control trial, one prospective observation study, six retrospective studies, and one qualitative study. The summary of individual studies and the search results can be found in Appendix A- Search Strategies Process and Outcome and Appendix B- Summary/Evaluation of Studies.

Figure 1

Search Strategies and Results



Comprehensive Examination of Literature

Indication of Osteomyelitis for Long-Term Antimicrobial Therapy

In-patient admission may increase the risk of hospital acquired infections. Lai et al. (2012) estimated 17.6% risks of hospital acquired infection, which approximately doubles the likelihood of increased length of hospital stay. Outpatient parenteral antimicrobial therapy facilitates early discharge from the hospital and has been successfully utilized in the treatment of various types of infections. It is becoming a widely accepted clinical practice in the United States and Europe (Mackintosh et al., 2011). Skin and soft tissue infections, followed by bone and joint infection, are among the most common types of infections requiring longer antibiotic therapy that could be supported by OPAT.

Lai et al. (2012) evaluated the rates of OPAT completion and complication using a retrospective chart review of the Veterans Affairs healthcare system in Greater Los Angeles. The OPAT team consisted of the infectious disease physician/fellow, pharmacist, and a home health coordinator. Among the 333 patients who received OPAT over a 3-year period, osteomyelitis and bacteremia were the major diagnosis that required OPAT; 39.7% and 19.3% respectively. The study results showed that 79.6% of the patients successfully completed OPAT therapy without complications. Although complications occurred in 24.4% of participants, which included hospital readmission, adverse drug reactions, or problems with central venous access device, the program was still able to record significant cost savings of about $4 million per year (Lai et al., 2012).

Formal OPAT Program

A research study at the Parkland safety-net Hospital in Texas was conducted to assess the safety and impact of OPAT on 30-day readmission and 1-year mortality rate among uninsured,

non-English speaking patients, over a 5-year period. The intervention group was comprised of the patients who received standardized training on antibiotic administration, follow-up visits at the OPAT clinic with the physician, IV access care, and lab monitoring at the OPAT clinic. The traditional group received non-standardized services from unregulated home health agencies and other sub-acute-care settings contracted by the hospital. A review of the 30-day readmission rate was significantly lower (p-value) in the intervention group. A comparison of the 1-year mortality rates was low in both groups at approximately 5% (Bhavan et al., 2015). In another study at the Parkland hospital in Dallas, Texas, results demonstrated significant cost savings in patients who self-administered IV antibiotics compared to those received administration by nurses in their homes, a skilled nursing facility, or an infusion center (Butcher, 2017).

Although OPAT is being practiced in different facilities across the United States, there exist considerable variations in the program design. In general, studies lean in favor of formal OPAT programs with defined protocols for patient monitoring to promote safety. A formal OPAT program promotes increased physician participation and patient satisfaction by enhancing communication between inpatient and outpatient physicians, a systematic method to track laboratory results, and completion of patient follow up with ID physicians (Muldoon et al., 2015).

Another difference in OPAT delivery protocols across facilities is the absence of quality improvement measures. In the study by Muldoon et al. (2015), out of the 316 infectious disease physicians surveyed about their practices related to OPAT, only 28% utilized readmission as a quality measure while 43% reported readmission as one of the complications of OPAT. Formal OPAT program would provide a means to monitor and address quality improvement measures.

As efforts are being taken to address the disparities in OPAT protocols, a major threat to its progress is the liability, a lack of institutional support, and inadequate reimbursement. A tenable approach to the success of OPAT programs therefore depends on evidence-based research studies that can assess and evaluate its impact on patient outcomes in order to justify its continuation (Muldoon et al., 2015).

Complications and Risk Factors for Poor Outcomes in OPAT

There are diverse studies that have established the safety of OPAT. However, the literature is also replete with complications that can occur leading to readmissions in about 20% to 30% of OPAT patients who are readmitted before the end of their therapy (Jacobs et al., 2018). As a result of reduced healthcare provider supervision and environmental factors, OPAT has also been associated with adverse drug reactions, hospital readmissions, and other adverse events (Huang, 2018).

Some studies have evaluated the associations between patient characteristics and factors that can predispose them to complications in order to identify risk factors, then targeting the highest risk groups to develop strategies to reduce treatment failure. As mentioned earlier, some of the complications associated with OPAT as mentioned earlier include failed treatment, adverse drug events, and central line complications (Hicks et al., 2014; Jacobs et al., 2018). The suggested risk factors associated with these complications are previous hospitalizations in the preceding year, history of malignant lymphoma, extended OPAT duration, advanced age, infection caused by drug-resistant organisms, use of aminoglycoside antibiotics, and the lack of a primary care doctor (Shrestha et al., 2018). Infection relapse was found to occur in patients with Methicillin Resistant Staphylococcus Aureus (MRSA) and diabetic-related bone and joint infections, during the first few months of OPAT (Mackintosh et al., 2011). Emergency

department visits were also found to be associated with hospitalizations, although not all emergency visits in OPAT care led to readmissions. Vascular access problems that warrant a visit to the ED are more likely to lead to readmissions along with female gender and parenteral penicillin use (Shrestha et al., 2018). In contrast, a lower rate of ED visits in OPAT patients was demonstrated by Shrestha et al. (2018) and this was attributed to the fact that the practice had a well-organized OPAT program with ID follow-up. Furthermore, the number of admissions in the previous year and a diagnosis of sepsis have also been identified as additional risk factors in OPAT (Jacobs et al., 2018).

Mitigating Risk Factors in OPAT

Jacobs et al. (2018) recommended a coordinated and evidence-based OPAT program to monitor OPAT patients in order to reduce unnecessary ED visits or readmissions. Protocols can be designed to address vascular access occlusion in the patient's home since it has been identified as one of the most common reasons for ED visits (Shrestha et al., 2018). Additionally, Shrestha et al. (2018) identified that a higher risk for ED visits was associated with females and diabetic patients. In essence, these individuals could be monitored closely especially after the first few weeks of initiating OPAT therapy to reduce the risks and promote successful outcomes.

Keller et al. (2018) performed a prospective cohort study of 339 OPAT patients discharged home from 2015 to 2017 and found that approximately one fifth of the participants experienced an adverse drugs event. Risk factors for adverse drug events (ADEs) were identified as female gender and administration of vancomycin or daptomycin. The findings suggest that ADEs are more likely to occur within the first 2 weeks of hospital discharge. It was therefore recommended to closely monitor patients for ADEs, clinical response, and abnormal laboratory

results in the first few weeks of hospital discharge especially among women who receive vancomycin or daptomycin (Keller et al., 2018).

The association between availability of laboratory test results and readmissions in OPAT patients was analyzed in the study by Huck et al. (2014). The study found a "2.53-fold increased odds of hospital readmission" in patients receiving OPAT whose laboratory test results were not available to ID physicians (p. 231). Patients discharged home were also more likely to have laboratory tests results made available to the OPAT clinic than those discharged to skilled nursing facilities or long-term acute care facilities. The authors proposed that obtaining laboratory test results in a timely fashion allows for early detection of abnormalities and intervention, which can preempt unplanned hospital readmissions (Huck et al., 2014). A multidisciplinary, formal OPAT team is therefore recommended for successful OPATs.

Significance of Nurse-Led Care Coordination

The registered nurse plays a pivotal role in the effectiveness of a formal OPAT program. While it may be difficult to ascertain a direct relationship between nurse care coordination and patient outcomes, previous studies have demonstrated an association between post discharge telephone calls to patients and reduced ED visits or hospital readmission (Harrison et al., 2014; LeBar, 2020; Halilovic et al., 2014). It is recommended that programs that provide an avenue for patient care coordination in OPAT care be promoted. In a formal OPAT program, the nurse care coordinator reinforces education related to intravenous antibiotic administration and central line care, obtains and reviews laboratory results to monitor patents' response to therapy, and schedules ID follow-up appointments among other tasks.

The practice of OPAT is a safe alternative for selected patients (Chapman et al., 2019). Nurse-led training on IV administration for OPAT at the home promotes patient empowerment,

and low levels of venous access device events and catheter-related bloods reduced hospital readmission rates, and reduced duration of OPAT (Bodycot et al., 2021; Mace et al., 2018). Studies suggest protocols that will facilitate nursing management of midline accesses during hospital admission to promote patient and family confidence upon discharge (Bodycat et al., 2021). A similar study demonstrated that a nurse-led formal OPAT program in collaboration with pediatricians and infectious disease specialists proved effective in improving antibiotic stewardship and on-time discharge (Tanner et al., 2020). It is the objective of this quality improvement project to evaluate and highlight the contributions of the nurse in improving the care of OPAT patients through care coordination.

Key Factors Contributing to Improved Health Outcomes in OPAT Program

Despite the increasing adoption of OPAT program in the United States, not all delivery models have a formal protocol to monitor patients. A well-defined OPAT program should include a plan to track laboratory test results, identify missing or overdue laboratory results, and establish multidisciplinary team communication to enhance patient safety. Research shows that a methodical approach to OPAT care delivery provides a strong foundation for safe and effective care, which also facilitates the establishment of quality improvement measures (Muldoon et al., 2015).

An interesting OPAT management model that has not been mentioned in this literature review is the use of telecommunication and information technology to manage OPAT patients. In a pilot telemedicine OPAT program, the administration of antibiotics was performed by local nursing services while the weekly medical supervision was provided by the ID physician via video conferencing. The weekly laboratory monitoring was facilitated by the local nursing staff. Successful outcome was characterized as completion of OPAT without requiring oral antibiotics,

while a failed therapy resulted in un-planned OPAT-related readmission, lack of improvement in condition, need for surgical intervention, or death (Shu et al., 2017). Results from this study were comparable to similar non-telemedicine studies with low rates of line and drug-related adverse events and low rates of unplanned readmissions (Shu et al., 217, p. 2899). Essentially, effective monitoring, which could be provided via telemedicine or in-person follow-up, is key to the success of OPAT.

OPAT Best Practice Guideline

Hospitals are incentivized to reduce readmission rates and improve patient outcomes since they can be penalized through the Medicare Hospital Readmission Reductions Program for up to a maximum of 2% of hospital revenue for excessive unplanned readmissions (Boccuti & Casillas, 2017). Since OPAT has been shown to reduce healthcare spending and improve patient outcomes (Huang et al., 2018; Mackintosh et al., 2011; Norris et al., 2019), hospitals should consider best practice guidelines in their delivery of OPAT. The national guidelines developed for safe practice in OPAT recommend the establishment of an effective communication channel among a dedicated OPAT multidisciplinary team comprising of the infectious disease physician, a nurse experienced in parenteral administration and central line care, home health coordinator, and a pharmacist (Chapman et al., 2012; Lai et al., 2012). It is vital to have a program in place for continuous surveillance by the OPAT team to reduce complications including 30-day readmissions (Luu et al., 2019). The role of the RN is critical to the success of a monitoring program because it hinges on the ability of the OPAT nurse to coordinate the care of the patients effectively.

Nurse-Led Care Coordination

Nurses and nurse practitioners can be the facilitators in care coordination models since they are often the first and last point of contacts in the patient care continuum. Nurse care coordination in healthcare delivery models has been proven effective in improving clinical outcomes and reducing overall cost of healthcare delivery (Yang & Meiners, 2014). Research studies support comparable or better patient outcomes in health status, patient satisfaction, cost, and length of stay on care provided by physicians and nurse practitioners. Some studies suggest that nurse practitioners spend more time with their patients providing care and treatment options than physicians (Yang & Meiners, 2014).

The care protocol for OPAT patients, which is sometimes referred to as the OPAT care bundle, is based on the IDSA guidelines. It includes careful patient selection, patient or care giver education, discharge planning, and outpatient monitoring or tracking. This is known collectively as “care coordination” (Vaz et al., 2018, p. 136). Care coordination can lead to improved family experiences and health outcomes, and reduction of medical expense.

Care Coordination Outcome Measure

The Care Coordination Measurement Tool developed by Antonelli et al. (2004) captures the essence of care coordination activities. A pediatric OPAT program tracked the care coordination activities in the monitoring of their pediatric OPAT populations. These activities were classified as “prevented” if an intervention prevented the occurrence of a complication like unplanned PICC removal or “occurred” if a complication resulted in a visit to the emergency room. Out of the 154 care coordination activities recorded on 29 patients over a 44-day period, 10 ER visits were prevented. Complications included problems with the vascular access, neutropenia, drug rash, and parent concerns relate to patients’ clinical symptoms. Care

coordination activities, although time consuming, yielded positive results (Vaz et al., 2018). Further research studies are needed to develop instruments that can quantify the care coordination activities of nurses in OPAT in order to drive appropriate reimbursement for OPAT care.

Laboratory Monitoring

The absence of regular monitoring of patient's laboratory results by the clinician is related to a higher risk of readmission in OPAT patients (Mansour et al., 2018). For example, inflammatory markers such as erythrocyte sedimentation rate and C-reactive protein can be utilized in the diagnosis of diabetic foot infections and also to monitor the patient's response to antimicrobial therapy (Ong et al., 2017). At the John Hopkins Bayview Medical Center, a research study was conducted to evaluate the impact of a nurse-managed multidisciplinary OPAT program on all-cause 3-day hospital readmission. The RN-managed OPAT program was associated with a 39% reduction in the risk of readmission ($p < 0.05$) and laboratory findings were lower with the intervention group ($p = ns$). It was estimated that $649,416 in inpatient cost was saved over 15 months based on the reduced rate of readmissions. The study attributed the cost savings to the utilization of a RN designated to coordinate care rather than the ID physician or pharmacist interventions (Mansour et al., 2018).

A retrospective research study at an academic infectious disease clinic in Detroit, Michigan from 2012 to 2015 assessed the clinical outcomes in patients who received OPAT care. Most of the patients received therapy administered by registered nurses via a peripherally inserted central catheter (PICC), while others had tunneled ports, or midline intravenous catheters. Out of the 122 patients, only 13% experienced adverse events during treatment. The success rate was attributed to the careful selection of patients and their close monitoring

(Suleyman et al., 2017). In a related study that assessed the correlation between availability of test results to the infectious disease physician and hospital readmission during the course of OPAT, non-availability of the recommended laboratory test results to the OPAT team increased the probability of hospital readmission by approximately 2.5 (Huck et al., 2014).

Strengths and Weaknesses of the Current Body of Knowledge

Numerous studies have established OPAT as a safe way to administer long-term antibiotic therapy in non-hospital settings. While OPAT can take place in different environments, there is insufficient data to guide the specific design of a formal OPAT program that can mitigate complications and improve patient outcomes. According to the IDSA guidelines, evidence is lacking regarding the specific laboratory tests and frequency of monitoring and outpatient follow-up visits with ID physician. In addition, the IDSA recommends a protocol for effective monitoring of vascular access complications and antimicrobial adverse events even though there is insufficient data to support an evidence-based recommendation on specific tests and frequencies of monitoring (Norris et al., 2019).

The need for effective monitoring attests to the role of the OPAT registered nurse care coordinator. This position can oversee OPAT delivery in collaboration with the interdisciplinary team under the guidance of the ID physician. Unfortunately, the care coordination activities of the ambulatory care nurse are not readily measurable in concrete terms due to a lack of care quality measures similar to that of the inpatient nurse with nursing sensitive indicators that can demonstrate nurses' impact on quality care. The qualifiers of nursing activities "identify structures of care and care processes, both of which in turn influence care outcomes" (Haas & Swan, 2014; Montalvo, 2007, para. 4). The Affordable Care Act of 2010 has made the

development of quality measures for reporting and reimbursement essential, especially for nurses' contributions in the outpatient settings (Martinez et al., 2015).

Notwithstanding the absence of standard quality measurement for care coordination, performance measures such as 30-day remissions, rates of adverse drug events, and central line events would be analyzed in this QA/QI study. It is intended that this would serve as indirect indicators of the impact of nurses in improving patient outcomes in OPAT. Further research is needed to identify evidence-based interventions that support quality care in OPAT patients and the role of the RN as a viable member of the multidisciplinary OPAT team.

Theoretical Framework

On a system wide level, the OPAT program can be considered to be in the pilot stage. The results of this evaluation project can assist in the awareness and dissemination of knowledge to the rest of the facility to highlight the importance of OPAT care coordination. Subsequent modifications and suggestions to the project can then be adopted. In the change process, education, communication, support, and time are crucial.

Analysis of the Project through a Theoretical Framework

The project began in September 2017 when the stakeholders' team in the Infectious Disease department met to discuss an evidence-based intervention to address healthcare gaps in the care of patients receiving intravenous outpatient antibiotics. The infectious disease doctors led the deliberations. A review of best practice guidelines, transitional care management practices, antimicrobial stewardship recommendations, and nursing coordination care was conducted. A neighboring facility was also consulted for suggestions on how they implemented a similar project. The result was the formulation of a standardized protocol for the OPAT team. A program was approved to hire a registered nurse as the OPAT care coordinator. The other

members of the OPAT team were the ID physician, the pharmacists, medical information assistant, and a designated phlebotomist. In another meeting, at which this writer was present, the OPAT team met with the social worker and the case management representatives to make them aware of the OPAT protocol and foster smooth patient transitions from one level of care to another.

According to the Kurt Lewin's Force Field Model and the Unfreezing-Change Refreezing Model, it is imperative for leaders to reach a decision to acknowledge the shortcomings of a status quo, reject prior knowledge, and replace with new evidence-based information. In order to accomplish this, there must be at the minimum a balance between the forces that support the change and those that go against it. In the force field model, two opposing forces are identified namely the "Driving forces and the Restraining forces." The driving forces push in a direction that causes the change to occur or facilitates the change by moving a person or system in a desired direction. The opposing forces are the "Restraining forces," which can hinder or slow down change. Successful change occurs when the driving forces override or diminish the effects of the restraining forces (McFarlan et al., 2019).

Table 1

Forces surrounding nurse-driven care coordination and traditional care in OPAT patients at Carilion Clinic

Driving Forces	Restraining Forces
Home health nurse unable to verify or obtain patient orders	Funds to hire RN

Infectious disease Clinic request- best practice guidelines per IDSA	Physician skepticism
Transition Care Management reimbursement; Increased patient satisfaction; Value-based care	Nursing staff skepticism Individual patient constraints- transportation; distance; Socioeconomic factors

Given that the driving forces were strong enough to overcome the restraining forces, the OPAT care coordination program was initiated in October 2017. According to Lewin's theory of change, the change process is broken into three stages: "Unfreezing, Change, and Refreezing" (Udod & Wagner, 2018). In the first stage of Unfreezing, the goal is to find a method to overcome the restraining force either by "increasing the driving forces, decreasing the restraining forces, or a combination of the first two methods" (Udod & Wagner, 2018).

Unfreezing

In this phase, a combination of reduced restraining forces and increased driving forces was employed. The stakeholders agreed on the need for change and the OPAT coordination team was formed. Another driving force motivation was the possibility of increased revenue for patient follow-up visits during their therapy, which is essential to evaluate response to therapy and identify complications for a timely intervention. The OPAT protocol was designed to include an OPAT nurse visit prior to discharge, patient telephone contact by the OPAT nurse within 48 hours of discharge, OPAT clinic follows up within the first 2 weeks of discharge unless otherwise stated, collaborative communication between the pharmacy and home health agency to verify medication and laboratory orders, review of laboratory results, and resolution of other

patient needs such as medication coverage and duration of therapy. The program was first implemented in October 2017 and for the next 6 months thereafter, the team engaged in revising the protocol and hiring of necessary staff members.

Change

This is known as the implementation phase. The ID OPAT team held random audits and meetings to assess need and address issues. The major obstacle that was identified was the unavailability of laboratory results in a timely manner. There was also the problem of scanning lab reports to the EHR for non-Carilion clinic facilities. According to Lewin theory, the change phase involves persuading others of the benefits of the new process, providing education and support while establishing strong relationships with influencers who can make the change successful. It is important to have a supportive team and clear communication for success in this stage (Udod & Wagner, 2018).

The identification of gaps in the communication between specialist and infectious disease physicians as it relates to care of OPAT patients discharged from the hospital was enough reason to make a decision for change. The home health nurse sometimes encounters deadlocks in identifying and locating the physician that would take the responsibility to provide clinical orders related to changes in patients' conditions. In a formal OPAT program, the patient's progress is regularly monitored and there is an established communication between the infectious disease physician and the patient's primary care or specialist to facilitate timely and appropriate interventions, which can prevent undue utilization of hospital resources, readmission, or failed therapy. Thus, this phase of "change," which involved a review of best practice guidelines and consultation with other facilities that have an established OPAT clinic, was a relatively easy one.

The aim of this quality improvement project is to evaluate the evidence-based data that can support the feasibility and success of the nurse-led care coordination program in order to secure the support of stakeholders within the Carilion hospital system who will facilitate a system wide adoption and implementation of the care coordination protocol for more patients discharged on parenteral antimicrobial therapy.

Refreezing. Lewin described this stage as the phase where change is established and continuity is promoted (Udod & Wagner, 2018). Initially, the OPAT nurse care coordinator was hired part time but now works full time hours to attend to the need of the growing OPAT patient population. Furthermore, the number of patients served has increased from about 10 at its inception to an average of 70 patients per month. This includes patients discharged to non-Carilion facilities including home health agencies and skilled nursing facilities. In addition, as discussed earlier, not all patients who are receiving OPAT are referred to the OPAT clinic for care coordination. One plausible argument is that some of the patients do not need it. While an exclusion can be made based on the extent of infection, type of infection, comorbidities, and length of therapy, the goal is for the multidisciplinary healthcare team to recognize care coordination among OPAT patients as an essential component that can impact health outcomes.

Planned change. This is an expansion of Lewin's theory of change. It specifies six phases of change by Ronald Havelock (1973) as quoted in Udod and Wagner (2018), which emphasizes the application of knowledge to design a systematic integration of theories relevant to real-life situations to manage change. The last two stages in this category are "Establish and Accept change; Maintenance and Separation" (Udod & Wagner, 2018). Similar to the refreezing phase, change is to be maintained with the change agent monitoring the system to ensure continuity and success until a point of separation where the change can proceed independently. In the

maintenance and separation mode, effective communication, feedback, education, and support systems are essential components. The QA/QI project is at the "Establish and Accept change" phase. The next step is to collect evidence that support or disprove change or provide an avenue for modifications involving unfreezing and refreezing (McFarlan et al., 2019. The objective of this quality improvement project is to assess the impact of the care coordination role of the nurse along with collaboration with interdisciplinary on patient outcomes.

Sample and Setting

Project Sample

The setting for this QA/QI study is the Carilion Infectious Disease Outpatient Clinic, a subsection of the Carilion Roanoke Memorial Hospital. The patients who are discharged on IV antimicrobial therapy can follow the traditional pathway or participate in the OPAT care coordination program. The OPAT program was instituted in October 2017 to improve communication among the interdisciplinary healthcare team, empower patients, and improve their experiences while enhancing patient outcomes. The OPAT team provides additional care to the patients, but due to the requirements of assigned reimbursement categories, the only available means of compensation is transitional care management. This is, however, not guaranteed because it can also be claimed by other treating specialties. In order to secure facility support, validation, and needed funding, it would be beneficial to demonstrate the impact of the OPAT care bundle.

Eligible participants were identified by mining relevant data from the electronic health records of the Carilion clinic, which is the EPIC platform. All the patients 18 years old and above, male and female, with a confirmed diagnosis of osteomyelitis by the ID physician, requiring a minimum of two weeks of parenteral antimicrobial therapy after hospital discharge,

and discharged home to self-administer the antimicrobial therapy with a visiting home health nurse of Carilion Home health agency were included in the study.

Method

Project Design

This QA/QI project was implemented at the Carilion ID outpatient clinic. The study design is a retrospective chart review between the Nurse-Led Care Coordinated OPAT groups (Intervention Group) and the Traditional "Non-monitored" (Control Group) to compare the incidence of 30-day readmission, central line events, and adverse drug events as an indicator of the impact of the nurse-led OPAT care coordination. Outcomes were compared within the same time period beginning from July 2018 to December 2019. The patient outcomes are (a) 30-day unplanned hospital readmission after discharge, (b) rate and occurrence of adverse drug events, and (c) central line events. The data was obtained by completing a retrospective chart review of the patient Electronic Health Record (EHR).

Selection Criteria

The "Intervention Group" refers to adults 18 years old and above who received the formalized nurse-led care coordination program for OPAT. The "Control Group" refers to the osteomyelitis patients who received only the traditional model of care without the OPAT nurse-led care coordination bundle. The Control Group consists of patients who only received traditional follow-up care during self-administration with routine home health nurse visits under the service of Carilion Home Health agency from July 2018 through December 2019. The Intervention Group consists of patients who were referred to the OPAT program during the same time period, from July 2018 through December 2019, and received the nurse-led OPAT care coordination program in addition to the traditional follow-up care.

The patients' demographic data included in the study are age, gender, ethnicity, and comorbidities. The adverse drug events include episodes of drug reactions that required

pharmaceutical or medical intervention due to the resulting abnormal laboratory test results as determined by standard clinical levels. The adverse central line events covered complications such as premature removal of central line device, venous thrombosis, CLABSI, and lumen occlusion. Thirdly, the 30-day OPAT-related hospital readmission were obtained from the readmission visits coupled with the chart review to identify cause of readmission.

Instruments - Definitions, Reliability, and Validity

30-day Readmission

According to a report from the Agency for Healthcare Administration (AHCA, 2013), all cause 30-day hospital readmission is defined as hospital admission after a discharge from an acute care hospital within 30 days of discharge. It has been used as performance measure of hospital quality and patient outcome in research studies and its validity for the current study will be subject to review. For this study, only OPAT-related 30-day readmissions were included.

Central Line Events

Central line infections are an established nursing quality indicator, where nurses can impact clinical outcomes in patients through the delivery of excellent nursing care (Dumont & Nesselrodt, 2012; Montalvo, 2007). For this study, peripherally inserted central catheters, Port-a-cath, and Hickman ports were included as central lines.

Adverse Drug Events

These were defined as adverse drug reactions that were related to the antimicrobial use and demonstrated by abnormal laboratory tests such as kidney function: elevated creatinine and blood urea nitrogen (BUN). Neutropenia was also included since not all antimicrobials are nephrotoxic.

Level of Measurement of the Data

Intervention Group - Nurse-Led Care Coordinated OPAT Group

This refers to the patients who received the nurse-led OPAT care coordination between July 1, 2018 and December 31, 2018. The OPAT nurse care coordination activities included the pre- and post-discharge planning care. These include, but are not limited to, (a) introduction of the OPAT program to the patient prior to discharge from the hospital, (b) the verification of the infectious disease physician's order for antimicrobial choice, dosage, and duration, as well as (c) care coordination among the multidisciplinary healthcare team. Other duties include (d) wellness telephone calls to the patients, (e) responding to patient concerns including central lines or adverse medication reactions, (f) monitoring and reviewing laboratory results, and (g) general care management of the OPAT patient to support successful clinical outcomes.

Pre-Discharge Protocol

Adult patients ages 18 years and above with a confirmed diagnosis of osteomyelitis were referred to and assigned to the OPAT clinic prior to discharge from the CRM hospital. The OPAT nurse coordinator accessed the OPAT Clinic Library report from the EHR in EPIC to download the referred patients. The nurse reviewed the patient's diagnosis, antimicrobial choice, discharge disposition, social support, and expected date of discharge in the EHR EPIC. Prior to discharge, the OPAT registered nurse visited the patient in the hospital to introduce the essentials of the OPAT care coordination program and answered any related questions. Patient education about antimicrobial administration for self-administered patients was provided separately by the infusion company representative (often a registered nurse), and reinforced by the OPAT nurse during the post-discharge telephone call and at other times as needed.

OPAT Post-Discharge Protocol

For all patients discharged from the hospital, a notice was automatically registered on the OPAT library report in EPIC. The OPAT nurse then accessed this list and made a telephone contact to the patient within 48 hours of hospital discharge. The OPAT nurse also reached out to the pharmaceutical or infusion company and home health representative or nurse within 48 hours, but no less than 5 days after discharge. The purpose of the post-discharge call was to verify the prescribed antimicrobial orders, laboratory test orders, and central line care orders, to schedule a follow-up visit at the ID clinic, and to evaluate the patient's understanding of the therapy. The nurse also addressed the patient's concerns, provided therapeutic guidance, and assisted with appropriate resources to navigate the healthcare system for needs related to the OPAT program. Social determinants of health such as patient assistance programs to pay for antimicrobials, insurance prior authorizations, and other care coordination activities were provided as needed within the boundaries of the registered nurse scope of practice.

In addition, the OPAT nurse also completed a weekly or bi-weekly telephone contact with the patient to assess progress with the antimicrobial therapy and the patient's response. Routine laboratory tests and drug level monitoring, as specified by the infectious disease physician, were obtained on a weekly basis from the home health agency or from the laboratory facility and recorded in the EHR by the OPAT nurse. Furthermore, the OPAT nurse was responsible for coordinating activities related to changes or adjustments to antimicrobials type, dosage, and length of therapy by acting as a liaison between the pharmacist, pharmaceutical supplier, and the patient. A particular part of the care coordination activities is the laboratory result monitoring. The nurse reviewed the laboratory results in a timely fashion and notified the ID provider of any abnormalities or negative trends. Diagnostic tests, such as chest radiography

to confirm displaced central lines, whenever ordered, were set up by the OPAT nurse. Each patient was scheduled for at least one post-discharge appointment with the ID doctor before the end of the antimicrobial therapy to evaluate the patient's response and make appropriate recommendations. Multiple appointments were required for some patients based on their diagnosis and prognosis. At the follow-up visits, the OPAT nurse triaged the patients, assessed the patency of the central line, and provided PICC dressing changes as needed. Other nursing activities during the ID follow-up visits included wound care, blood drawn from the central line, and therapeutic communication.

Control Group -Traditional OPAT Group

As per current protocol, the patients in the "Control Group" were discharged home to self-administer the antimicrobial with weekly home health nurse visits who provided central line care. The OPAT nurse did not communicate with these group of patients or their home healthcare agencies. These patients did not follow up with the ID clinic nor have their laboratory tests monitored routinely by the ID doctor except otherwise required by the treating specialty. Nevertheless, the ID physician was sometimes contacted for their advice on adverse drug events, duration of therapy, central line issues, or related issues at the discretion of the patient's primary care provider or specialist.

Human Subjects Protection and Data Security

Following approval from the Carilion Institutional Review Board (IRB), access was granted to complete a retrospective chart review of the patients' charts in the EPIC EHR. The eligible patient list was extracted from the EPIC Clarity Database using SQL Developer (Muthukattil, 2021). The study data were collected and managed using the Research Electronic

Data Capture (REDCap) tools hosted at Carilion Clinic. This program is a secure, web-based software platform designed to support data capture for research studies (Carilion HART, 2021).

The principal investigator and members of the research team were provided the access to the patient's chart to ensure accuracy, validity, and objectivity. The QA/QI study groups were limited to patients who received OPAT under the services provided by the Carilion Clinic home health agency. The inclusion of non-Carilion clinic home health agencies may constitute constraints in obtaining information and consents.

This study involved minimal risk to the patients as it was a retrospective chart review; informed consent of participants was therefore waived (Miller & Emanuel, 2008). The IRB approval was obtained prior to accessing the patient's record for the sole purpose of retrospective chart review. The Research Electronic Data Capture application was developed by Vanderbilt University. This is a secure, web-based application that is utilized for clinical research data collection (Patridge & Bardyn, 2018). The data management application is suitable for QA/QI projects. The entries are deidentified and thus HIPAA compliant. The data would remain stored for up to 3 years after this study per the research protocol. In the secured environment provided by REDCap, each individual that required an access to the record was granted user rights and permission to the limitation of their need. Each user's access to the application can also be tracked as an audit trail feature for tracking data manipulation and export procedures. It has automated export procedures for seamless data downloads to common statistical packages, and other procedures for data integration and interoperability (Carilion HART, 2021; Patridge & Bardyn, 2018; Wang, 2017).

Data Management

The main demographic data were age (18 years and above), gender, race/ethnicity, and comorbidity. Other secondary variables were the number of ID follow-up appointments, type of central line (PICC, tunneled ports, or midline intravenous catheter), and the number of weekly OPAT care coordination telephone calls made by the OPAT nurse to the patients over the course of the therapy. The telephone contacts were recorded in the EHR as "Telephone Encounters." The intervention for this study was the nurse-led OPAT care coordination program provided to the patient in the Intervention Group, versus traditional care in the Control Group. The dependent variables were the 30-day unplanned readmission rate, presence or absence of adverse drug events, and presence or absence of central line events.

Data Mining

The REDCap application is available for QA/QI studies and was utilized to extract the data from the EHR. Thereafter, a manual review of each of the 456 records was completed for accuracy. The data was exported to the SS Analytics Software for analysis. A member of the Carilion Health research and Analytics Health Care Team (HART) provided the support and expertise to design the data mining form and statistical analysis (Carilion HART- Muthukattil, 2021). The outcome variables of central line events, adverse drug event events, and 30-day readmissions were reported as dichotomous/nominal values with a "Yes/No."

The Statistical Analysis Software - SAS 9.4 (SAS Institute, Cary NC) was employed as the instrument for data analysis. Fisher's exact tests were performed, which was preferred over the typical chi-square statistics to enable accurate comparison between the intervention and primary outcomes. P-values less than 0.0167 were considered statistically significant using a Bonferroni adjustment to account for the multiple comparisons of enrollment category.

Implementation of the Study

Budget Plan

The proposed budget for data collection, analysis, and final write-up can be found in Appendix C.

Timeline

The timeline for the QA/QI study was dependent on the approval from the Carilion RMH IRB and the Radford-Carilion University IRB and faculty support. The COVID-19 pandemic also impacted the completion of the project. The original tentative plan was as follows. The actual timeline did not deviate too far from the proposed time.

- ***Step 1 - June to July 2020*** *- Finalize DNP project draft including evaluation plan, measured outcomes, and time frame.*
- ***Step 2 - August to September 2020*** *- Submit DNP project draft to the Carilion RMH IRB and Radford University IRB.*
- ***Step 3 - September to December 2020*** *- Collect structured and unstructured data utilizing REDCap with the help of the research team and data analyst.*
- ***Step 4 - January to February 2021*** *- Clean up data and perform statistical analysis.*
- ***Step 5 - February to April 2021*** *- Interpret data and submit to faculty for review.*
- ***Step 6 - April to June 2021*** *- Complete DNP capstone write-up.*

Letter of Site Support

The Senior Director of Nursing Research & Evidence-Based Practice at Carilion Clinic in the person of Dr. Kimberly Carter was the principal investigator for this QA/QI project. The Carilion facility healthcare providers in support of the project are Dr. Dorothy Garner, the Interim Chief of Infectious Disease Dr. Anthony Baffoe-Bonnie, the Medical Director of Infection Control, and both physicians at the Carilion outpatient Infectious Disease and Travel Clinic.

Evaluation Plan

Delineation of Outcome Variables

The outcome measures that were extracted from the patient charts are as previously defined. For the purpose of this QA/QI study, 30-day readmission included only OPAT-related re-admissions within the first 30 days of discharge for eligible patients as discussed previously.

Central line events included Central Line-Associated Bloodstream Infections (CLABSIs) as defined by the CDC, which is a laboratory confirmed bloodstream infection (LCBI) in which eligible BSI organism is identified and an eligible central line is present on the LCBI on the day of the event or prior (CDC, 2020). It is diagnosed by the physician and necessitates removal of the catheter and an antibiotic prescription (Barr, 2012). Other central line events included are:

- Inadvertent removal before the planned end of therapy
- Chemical or mechanical phlebitis
- Occlusion requiring anticoagulant use
- Catheter-Associated Deep Vein Thrombosis
- Line migration requiring chest x-ray evaluation

Adverse drug events were recorded based on increased serum creatinine greater than 1.4mg/dL or Blood Urea Nitrogen (BUN) levels of greater than or equal to 25nmlo/L and neutropenia defined as White Blood Cell count (WBC) less than 1500/microliter.

Statistical Analysis

The patient demographics were analyzed using frequency distribution calculations while the secondary outcomes of number of OPAT clinic visits, nurse telephone care coordination calls, length of hospital stay, age at the time of admission, Body Mass Index (BMI), and years of education were compared using descriptive statistics of mean and standard deviation. The

Fisher's exact test is a statistical procedure used to test the significance of differences in proportions especially when the sample size is small (Polit, 2010). Although the Bonferroni correction is useful in testing hypothesis with multiple dependent variables, it has been known to be overly conservative and increases the risk of a Type II error (Polit, 2010). The null hypothesis states that the intervention and control groups would have no statistically significant difference in the rates of 30-day readmission, central line, and adverse drug events.

The Fisher's exact test assesses the null hypothesis of independence. Fisher's exact tests were performed for these QA/QI study results. This was preferred over typical chi-square statistics due to possible violation of expected counts when comparing enrollment and primary outcomes. P-values less than 0.0167 were considered statistically significant using a Bonferroni adjustment to account for the multiple comparisons of enrollment category. The p-value provides an estimation of the extent to which the data conform to the pattern predicted by the hypothesis assuming all other assumptions in the statistical model hold (Visentin & Hunt, 2020).

RESULTS

The purpose of the QA/QI study was to evaluate the impact of a nurse-led OPAT care coordination program on the primary outcomes of 30-day readmission, central line events, and adverse drug events between experimental (OPAT, n = 54) and traditional (control, n = 13) patients. A total of 456 patient charts from July 1, 2018 to December 31, 2019, with a medical diagnosis of osteomyelitis and parenteral outpatient antimicrobial therapy scheduled for at least 2 weeks, were extracted from the EHR using SQL Developer (Carilion HART- Muthukattil, 2021).

Additional patient charts were also excluded following a manual chart review of the 456 records. The other inclusion criterion was post hospital discharge to a Carilion clinic home health agency for which 25 patients were excluded based on being discharged to a non-Carilion home

health agency. Furthermore, some other patients were excluded because their medications were changed to oral antimicrobials within one week of hospital discharge for varying reasons. These included, but were not limited to, adverse drug reaction, problems with central lines, or a patient's inability to maintain parenteral therapy. Also excluded were patients who received antimicrobial therapy at a different setting aside from home health such as a dialysis center, infusion clinics, long-term acute care centers, and outpatient infusion centers in compliance with the study criteria.

The data analysis for this study was generated using SAS 9.4 (SAS Institute, Cary NC), with the assistance of the Carilion Roanoke Memorial Hospital HART. The SAS and all other product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA. Descriptive statistics were used to summarize the data with categorical variables presented as a frequency and percentage.

Summary of Findings

A total of 54 patients were included in the nurse-led care coordination OPAT group with 13 patients in the Traditional care group. The patient demographics are shown in Table 1 - Patient Demographics. In the OPAT care group, 24 (38.71%) were females and 38 (61.29%) were males. The Traditional care group had a gender distribution of seven (53.85%) females and six (46.15%) males. The mean age was 57.9 years with an average hospital stay of nine days. The OPAT care group had an average of 1.22 OPAT follow-up visits and 6.54 OPAT nurse telephone contacts as shown in Table 2 - Patient's Secondary Characteristics. The OPAT group had 24 (38.71%) with Diabetes Mellitus Type 2 and the Traditional care group had 11 (84.62%) participants. Thirty patients (48.39%) had a history of hypertension (HTN) in the OPAT care group and nine (75%) were diagnosed with HTN in the Traditional care group. The majority of

patients had a PICC line with 52 (83.87%) in the OPAT care group and 12 (92.31%) in the Traditional care group. A summary of the frequency table of enrollment is shown in Table 3.

Table 1

Patient Demographics

	Demographics	
	OPAT (Experimental Group)	**Traditional (Control Group)**
Gender		
Female	24 (38.71%)	7 (53.85%)
Male	38 (61.29%)	6 (46.15%)
Ethnicity		
Non-Hispanic	54 (100%)	13 (100%)
Race		
Black or African American	2 (3.23%)	0 (0%)
White or Caucasian	52 (96.77%)	13 (100%)

Courtesy: Carilion Health Research Analytics Team (HART)

Table 2

Patient's Secondary Characteristics

Variable	Mean	Std Dev
Age (at hospital admission)	57.88	14.56
Hospital LOS (in Days)	9.41	14.00
BMI (at hospital admission)	31.10	9.15
Years of Education	12.63	2.13
# of OPAT follow-up visits	1.22	1.07
# of OPAT nurse telephone contacts	6.54	3.15

Courtesy Carilion Health Research Analytics Team HART

Table 3

Frequency Table of Enrollment Category

	Enrollment category	
	OPAT (Experimental Group)	**Traditional (Control Group)**
Chronic kidney disease		
No	44 (86.27%)	9 (69.23%)
Yes	7 (11.29%)	4 (30.77%)
DM Type 1		
No	52 (100%)	13 (100%)
DM Type 2		
No	29 (54.72%)	2 (15.38%)
Yes	24 (38.71%)	11 (84.62%)
Hypertension		
No	23 (43.4%)	3 (25%)
Yes	30 (48.39%)	9 (75%)
Hickman Port line used		
No	54 (100%)	12 (92.31%)
Yes	0 (0%)	1 (7.69%)
Midline Catheter line used		
No	54 (100%)	13 (100%)
PICC line used		
No	2 (3.7%)	1 (7.69%)
Yes	52 (83.87%)	12 (92.31%)

Courtesy: Carilion Health Research Analytics Team (HART)

Discussion

Summary of Findings

In the OPAT group, 12.96% of participants had a 30-day readmission while 7.96% were readmitted within 30 days in the Traditional care group. The percentage distribution for central line events were 11.11% and 7.96% in the OPAT and Traditional care groups respectively, while 22.22% in the OPAT care group had an adverse drug event and 7.96% equivalent in the Traditional care group. Fisher's exact tests were completed, at a p-value less than 0.0167, and Bonferroni adjustment was used to account for the multiple comparisons of enrollment category. The results showed no evidence to suggest a statistical association or dependence between OPAT and 30-day readmissions ($p = 1.00000$), central line events ($p = 1.0000$), and adverse drug events ($p = 0.0437$). This suggests that the difference in the outcomes among the two groups is not associated with the receipt of the nurse-led care coordination or its absence.

At the CRMH, 30-day unplanned readmission rates of Medicare patients ages 65 and older were reported as 15.7% in the Hospital Care Data. This is comparable to the national rate of 15.2% (Hospital Care Data, 2021). The overall 30-day readmission rate in this QA/QI retrospective study is 12.96% for the OPAT group, which is lower than the hospital wide rate. This is of clinical significance. This suggests that despite other patient characteristics that could account for cofounding variables, the patients who receive the formal OPAT care have similar readmission rates to that of the national record.

Another factor to note in the results is the distribution of patients referred to OPAT and Traditional outpatient care. In this study sample, 54 (11.8%) of patients were referred to OPAT compared to only 13 (2.85%) in Traditional post-discharge care among the sample population. In

order to account for this disparity, further studies are recommended to assess the drivers for patient referral to either OPAT or Traditional care for accurate performance measures.

In a controlled, quasi-experimental evaluation of OPAT over 15 months at an academic medical center, the before and after impact of an infectious disease transitions service (IDTS) on OPAT patients' 60-day readmission and/or emergency department visits along with secondary outcomes of antibiotic errors, increased receipt of laboratory results, and improved outpatient follow-up visits was analyzed. The results demonstrated that the IDTS was not associated with changes in 60-day readmissions and/or emergency department visits (Keller et al., 2013). This is similar to the lack of association between the nurse care coordination and the 30-day readmissions resulted in this QA/QI study. However, the IDTS was shown to be associated with fewer antimicrobial therapy errors, increased laboratory test receipts, and improved outpatient follow-up (Keller et al., 2013). These outcome variables may be more effective in demonstrating nursing care interventions. The provision of care coordination services is recommended to improve OPAT quality of care, but their relationship to readmission is unclear (Keller et al., 2013).

There are specific tools to assess the risk of adverse drug events that may potentially or actually disrupt desired health outcomes. Some of these tools are the "Safe Medication Assessment Tool" and "Drug Related Problem Risk Assessment Tool" (Puumalainen et al., 2020). The use of abnormal laboratory values as an evidence of adverse drug events in this QA/QI study is an indirect method to demonstrate an association between the antimicrobial administration and nursing care coordination activities taken to prevent them, such as a review of therapeutic drug monitoring test results. A record of adverse drug events that were intercepted by specific nursing interventions such as reporting an elevated blood test results to the provider for

further evaluation could be a more sensitive outcome measure of care coordination (Puumalainen et al., 2020).

Similarly, in a study to reduce the incidence of CLABSIs among liver transplant patients, interventions were directed at infection prevention, care standardization, and team-based monitoring. For these activates the process measures were also documented to track compliance with central line care protocols. The rates of CLABSIs were reduced to an average of less than one per month, which was the equivalent of a 61.2% annual reduction (Russell et al., 2019). This study suggests that CLABSI rates can be an effective measure of nursing interventions. However, in this QA/QI study, the reviewed data did not document the specific nursing and patient compliance actions pertaining to central line care protocols. The possibility of incomplete data could account for a lack of significant association between the nursing intervention and the primary outcome of adverse central line events.

Interpretation of the Study Findings

The results suggest that 30-day readmission, and the incidence of adverse drug or central line events, in patients discharged to home health on parenteral antibiotics, cannot be accurately interpreted as a consequence of the nurse-led OPAT care or Traditional care. A careful review of similar research studies and the sample population for this QA/QI study is highly recommended. The results cannot be construed to mean that the general population of patients from which the review samples were selected would demonstrate the same exact result or cannot be generalized to the population. The lack of statistically significant association between the dependent and independent variables does not support an acceptance of the null hypothesis. However, this is not supported by research evidence. In a Type II error, the null hypothesis is erroneously accepted.

Therefore, it may be inaccurate to conclude that the nurse-led OPAT interventions did not impact 30-day readmission, adverse central line drug events, or patient outcomes.

A lack of dependence between the distribution of the categorical variable (OPAT and Traditional groups) means that the categorical variable is not related to the outcomes or the categorical variable is independent of the outcome variables (Kim, 2017). In other words, the incidence of 30-day readmission, adverse drug event, or adverse line event, could be a factor of other cofounding variables including the patient's age, comorbidities, multidisciplinary healthcare team, type of antibiotics, duration of therapy, and human and environmental factors (Bugeja et al., 2020; Durojaiye et al., 2021). It is possible that the scope of this QA/QI study was inadequate to sufficiently decrease the impact of these cofounding variables. A larger population size with more inclusion criteria, along with other sensitive measures of nursing intervention, are recommended for future studies.

Comparison with other Studies

In the study by Keller et al. (2013), Infectious Disease Transitions Service for patients receiving OPAT did not affect readmissions, although it led to "fewer antimicrobial therapy errors, increased laboratory test receipt, and improved outpatient follow up visit among targeted patients" (p. 205). In this same study, it was noted that care coordination services may improve OPAT quality of care, but their relationship to readmissions is unclear (Keller et al., 2013).

Patel et al. (2018) in their study also found no correlation between 30-day readmission rates and the quality of care in heart failure management. This suggests that it may not be a valid measurement of quality of care. In addition, an intervention program to reduce readmission in an inpatient psychiatric setting also showed no statistically significant difference between discharge telephone calls and readmission rates (Adams et al., 2020).

In this QA/QI study, a 12.9% rate of 30-day readmission was noted among the OPAT patients, which is comparable to the study conducted by Madeline et al. (2018). These authors reported a significantly reduced rate of 13.0% readmission among OPAT patients that received transition of care bundles. This is of clinical significance because it suggests that patients who receive the innovative OPAT care bundle at the Carilion Infectious Disease clinic are not likely to be readmitted within 30 days more than their counterparts in other facilities. Although 30-day readmission may not be a reliable measure of quality care in conditions such as heart failure (Patel et al., 2018), studies have suggested enhanced communication, access to clinicians, on-time laboratory tests, and adequate treatment during the initial hospitalizations as factors that can be modified to reduce 30-day readmission among OPAT patients (Durojaiye et al., 2021; Huang et al., 2018). Previous studies have also demonstrated that the existence of a defined OPAT program with multidisciplinary teams may improve safety and efficacy outcomes, reduce 30-day readmissions, increase appropriateness of OPAT initiation, provide cost savings, and minimize adverse events (Eun Kyoung et al., 2016; Halilovic et al., 2014; Huang et al., 2018; Keller et al., 2013; Madaline et al., 2017).

Theoretical Framework Application

The QA/QI study was intended to propel change in the care of patients discharged home on parenteral antibiotics, thereby securing the organizational financial and resources support for the OPAT program. This would equate to the Refreezing stage of the Kurt Lewin's Force Field Model and the Unfreezing-Change Refreezing Model (McFarlan et al., 2019). Even though the results did not demonstrate a relationship between the nurse care coordination in OPAT or traditional discharge care and the outcome measures, there is research evidence that suggest that adequate monitoring of patients discharged home on antibiotics therapy is beneficial. This model

of care is facilitated by the OPAT nurse working in collaboration with the other healthcare providers. This QA/QI study observed that about three times more patients were referred to OPAT care than to Traditional care. At the same time, OPAT patients had a longer length of stay in the hospital prior to their discharge at 9.15 compared to 8.71 in Traditional patients. Could it be that the OPAT patients require more care or have other comorbidities not reported within the scope of this study?

Essentially, the results did not provide evidence to disprove "Change" but rather, should stimulate investigations into other measures to improve the OPAT program and facilitate the transition into "Establish & Accept Change" phase in the Lewin's theory of change.

Challenges

A major challenge in this study was the retrieval of data from the EHR. With adverse drug events, nurse telephone calls are documented in the unstructured data format of telephone encounters in the patients' charts and retrieval was time consuming and probably incomplete. The creation of a specifically designed portfolio within the EHR where patients' data can be imputed uniformly would create less challenge for data extraction. Another recommendation is the completion of a patient experience/satisfaction survey to assess the impact of the nurse-led care coordination or lack thereof bearing in mind that patient empowerment is the bedrock of improved patient outcomes.

Limitations of the Study

The primary limitation of this study is that the retrospective design did not allow for randomization of participants. The study group was also very small. A total of 456 charts were reviewed, but a large number of charts were not included in the study because the study design excluded patients on oral antibiotics, those that did not receive outpatient antibiotics for at least

2 weeks, and patients that were switched to oral antibiotics within the first week of discharge even though they participated in the OPAT care program. Future studies could include conditions aside from osteomyelitis alone or extend the duration of the review period. This is a single-site study so results may not be readily generalized. Some of the unplanned readmissions may not have been captured if they were not at Carilion facilities, so the data may be incomplete. The use of secondary data is cost effective and convenient. However, it is not possible to determine the accuracy of the data collected and the purpose for which it was collated, so this could also have impacted the results (Johnston, 2017; Visentin et al., 2020).

Additionally, the study did not capture readmissions and adverse line or adverse drug events reported at other non-Carilion clinic facilities. Furthermore, patients who received OPAT during hemodialysis without a PICC or midline were not included. The study sample did not capture the risk factors that led to 30-day readmissions, the patient's compliance to scheduled OPAT follow-up, so this data could not be analyzed.

Strengths of the Study

This QA/QI study has numerous strengths. It is the first to assess the OPAT process design by comparing the patient outcomes in traditional versus formal OPAT care within the same facility. The study emphasizes the importance of designated record keeping in the EHR for OPAT and Traditional patients with specific reference to nursing interventions, follow-up telephone calls, laboratory test results reviews, and care outcomes. The documented activities could be collated as data for future studies. The project also adds to the ongoing dialogue in the search to identify an effective instrument to measure nursing interventions and/or care coordination. The statistical independence between 30-day readmission and patient care supports the multi-dependent nature of readmissions as a performance measure for hospital report sheet,

in that it may be too broad to uniquely assess the impact of quality care in osteomyelitis patients receiving OPAT. This exploratory QA/QI study provides a foundation for future studies and design modifications for the OPAT program at Carilion Infectious Disease Clinic.

Conclusion

Nursing care activities extend beyond the hospital setting to ensure patient safety and promote clinical outcomes. Patients diagnosed with osteomyelitis often require extended parenteral antimicrobial therapy that can be administered outside of the hospital environment to free up hospital resources that can be utilized for other patients requiring intensive care. Registered nurses have a viable role to play in transitional and care coordination activities of patients discharged from the hospital who require intravenous antimicrobial therapy. The objective of this QA/QI project of a nurse-led OPAT care coordination program in osteomyelitis patients was to evaluate its impact on patient outcomes as defined above. The findings of this project could inform modifications to the OPAT care coordination program while providing a strong foundation for future studies. In terms of sustainability, improved patient outcomes can ultimately lead to significant cost savings and yield a return on investment for the continuity of this OPAT care coordination program.

Implications for Nursing Practice

The goal of this QA/QI study is to investigate the impact of the nurse-led OPAT intervention on the patient outcome. This study provides evidence that the use of performance measures may not be an appropriate instrument to assess nursing interventions in the OPAT program at the Carilion Infectious Disease Clinic.

Nursing continues to be the largest sector of the healthcare workforce and an integral part of achieving quality patient outcomes. Unfortunately, there is a paucity of evidence to

demonstrate the unique contribution of nurses to quality outcomes (Michael & Nelly, 2021). Effective quality nursing assessment must demonstrate a relationship between the “full complement of nursing interventions and the full scope of outcomes sensitive to nursing interventions” (Jones, 2016, p. 1). It is recommended that the collection of data that adequately demonstrate nursing intervention be made more practical.

Outpatient Antimicrobial Therapy continues to be an acceptable form of outpatient care for patients requiring extended antimicrobial therapy. Facilities should continue to implement OPAT protocols that focus on improved communication, patient empowerment, and careful monitoring of patients and response to therapy. Nurses remain an indispensable part of the interdisciplinary health team. This is a clarion call for registered nurses to engage in evidence-based studies that would provide models of measurable outcomes for their immeasurable contributions to improving patient care.

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APPENDIX A

Literature Review Synopsis / Evaluation Table

Author Name & Year	Level of Evidence	Study Design	Sample Characteristics and Sample Size	Clinical Setting	Intervention	Major Variables (Independent & Dependent (IDV & DV)	Findings	Statistical analysis used and p value,	Comments.	Reliability/ Validity & Limitations
Marbach, et al. (2018)	II	Observational cohort study	Mean age ± 66. 189 pre intervention; 304 post intervention.	Hospital	After-Discharge OPAT care coordination program	30-day Hospital readmission, LOS, discharge disposition	30-day readmission occurred in 6.2% more of the control than study group	SAS p= .05 (odds ratio [OR] = 0.52, P = .03, 95% CI = 0.28-0.97; Logistic regression model Propensity scores to match age groups and comorbidities	Similar results obtained in COPD & CHF. Provides evidence on the ipact of care coordination in OPAT.	Single center; not all eligible pts received coordinated OPAT. selection bias although unlikely to invalidate results; readmission rates may not be accurately reported if at other facilities (25%). Cluster randomization supports test reliability and validity.
Altfeld et al. (2013)	II	Randomized controlled trial	Determined by powr analysis 360 per group. Intervention = 360 (329) Usual care = 380= (360) (Alpha = .05)	Rush Univ. Med Center Chicago, Illinois	Telephone-based enhanced discharge planning program	Intervention and usual group	Patient and care giver stress, physician f/u, readmission, mortality	Sample size based on power analysis. Chi square and *t* test to assess differences between groups. SAS; significance level p= <0.05	Difference in rates of communication with physicians and f/u care statistically significant Not so in 30-day readmissions. Lower mortality in study group.	Eligible non English-speaking participants were excluded & single center study. These may affect generalizability.
Hucket al. (2014).	III	Retrospective cohort study	400	Cleveland clinic OPAT registry	Monitoring of laboratory tests results in OPAT care coordination	Hospital re-hospitalization; ID follow-up visit; therapy failure	73% had test results available to ID physicians; 21% readmissions	Multivariate logistic regression model 95% CI Pearson's x squared test or Fisher's exact test for categorical	Unavailability of test results independently associated with readmission during OPAT therapy	Limitations are: retrospective study, readmission outside Cleveland healthcare system not captured. Pearson's test increases reliability of the association of intervention on outcome.

								variables, student t test or Mann-Whitney U test		
Ong et al. (2017).	III	Retrospective	Patients with osteomyelitis and DFI 379	Tertiary care academic medical center	Correlation between inflammatory markers and the diagnosis/ management of DFI	Inflammatory markers and clinical diagnosis on admission and last follow up, DFI uninfected soft tissue infection, osteomyelitis Demographics, comorbidities.	Inflammatory markers demonstrated a positive value at admission and negative predictive value at the last f/u visit	SAS version 9.4 Mean +- standard deviation or frequency. Turkey's test. Pearson correlation. α 5%	Inflammatory markers were associated with probability of infection at admission and last follow up visit	To thirds of patient did not have labs measured at the last ID Follow up visit. Retrospective, Based on experience from a southwestern hospital so affect generalizability.
Suleyman et al. (2017)	IV	Retrospective cross-sectional study of EHR 2012 to 2015	122 total mean 62 yrs	Inner city clinic based OPAT & Nursing Home	OPAT program	Demographics, Type of infection & antibiotics; adverse events, Clinical outcome	Adverse events related to PICC complications and antibiotic used	Descriptive measures for data analysis.	Assess the safety and clinical outcome in clinic-based OPAT	Small sample size; not directly related to proposed project OPAT delivery model
Jacobs et al. (2018)	IV	Retrospective, single center, case-control study	Adult patient 63 study 126 control 2011 to 2015	Tertiary care medical center Buffalo, NY	OPAT care	60-day unplanned healthcare utilization (HCU), Sociodemographic factors, Charlson comorbidity index, Length of hospital stay, type of infection.	HCU higher in the first 30 days. Prior admission in past 12 month & sepsis diagnosis wee independently associated with HCU.	Bivariate analysis P<0.2 Multivariate logistic regression model P<0.05 Standard deviation, mean, student's *t* test, Mann-Whitney U test. Shapiro-Wilk test, odds ratio, Ci 95%. SAS version 9.4	Understanding the risk factors for complications in OPAT patient can inform preventative strategies	Retrospective thus subject to selection bias. Use of CPT codes to identify OPAT patients is a non-validated protocol. Small sample size; single location. Use of Charlson comorbidity index is a reliable & validated tool.
Mansour et al., Townsend (2018)	III	Retrospective cohort study	611	John Hopkins Health System	Pre and post RN-led OPAT program	30-day all cause readmission, demographics, OPAT site, opioid	Readmission rate after intervention decreased from 20.2% to	Log-binomial regression Fisher's exact test for categorical covariates, Mann-Whitney	RN-managed OPAT programme associated with significant	Observational study. Readmission to non-Hopkins facility not accounted for although < 3% per sensitivity analysis.

				Private non for profit		dependence, treatment duration, no of phone calls to site of care.	13.3% (P=0.04). Hospital savings $649416 over 15 months	U-test for continuous covariates, Relative Risk (RR) and (aRR) 95% CI, Poisson models with standard error.	reduction in readmissions.	Adverse event rates, clinical cure rate and source of infection not captured due to limited resources. Sensitivity analysis provides reliability of variable correlation.
Bhavan, Brown, & Haley (2015)	II	Historical prospective observation cohort study	1,168	Delivery sites: Safety-net Hospital; Home; Infusion center; SNF	Patient education pre d/c. After d/c follow up, Central line care, lab monitoring, physician follow up.	Sociodemographic, clinical, outcome, 30 day readmission and, 1-year mortality	30-day readmission rate lower in self-administered (S-OPAT).	Regression model SAS for Windows (SAS Institute), and all p-values are two-tailed, with p= 0.05 considered statistically Significant. 95% CI	S-OPAT may be acceptable in treatment of uninsured, medically stable patients	Observational study Large sample size and use of multiway analysis supports reliability of test results.
Shrestha et al. (2018)	III	Retrospective Cohort Study	8263 patients	Cleveland clinic Ohio	OPAT care	ED visits within 30 days, vascular access, demographics, comorbidity, health insurance, delivery site. ED visits	4.6% had at least one ED visit, 14% hospitalized; 0.6% died within 30 days. 51% ED visits were OPAT related. Previous ED visits related to more visits.	Continuous variables were compared using Student's *t*-test. A frequency distribution of the reasons for ED visit was tabulated. Regression model to examine the association between relevant demographic and clinical factors. 95% CI	Visits for worsening infection more likely to lead to hospitalization than vascular access complications	Large sample size. Use of sensitivity statistical analysis to validate association between variables.
Mackintosh et al. (2011)	IV	Retrospective & Prospective study	198 patient with bone and joint infection Mostly male age 60 and above.	General Hospital-Glassgow, UK	OPAT therapy	Therapy failure or extension. Unanticipated surgery within 4 weeks of completion.	Risk factors for therapy failure were MRSA and diabetes. 84% overall success rate.	STATA. Logistic regression analysis, univariate and multivariate analysis P< 0.1	Bone and joint infection (Osteomyelitis) can be successfully managed through an OPAT program-	Limitations are retrospective study with no randomization. International study bow ever OPAT guidelines are similar so result can be generalized.

						Unplanned readmission; Relapse; Demographics; Antibiotic choice; Diagnosis; Duration, and side effects		Cox regression analysis		
Lai et al. (2013)	IV	Retrospective chart review	333 patients	Veteran Affairs Hospital	OPAT program	Hospital readmission, PICC complications, adverse drug reactions. Comorbidities, Zip code, antibiotic choice, duration of treatment, complications	Program provided cost savings and was successfully completed	Logistic regression analysis of OPAT non completion was performed with Stata release 10 (StataCorp LP, College Station, Texas).	Telephone follow up call day after d/c to coordinate care with pharmacy and nursing agencies. Weekly phone calls to patients.	ESRD related to non-completion. Veteran population differ from general population can affect generalization. Presence of similar integrated hospital system may not be available elsewhere.

APPENDIX B

Synthesized Table of Outcomes

Author Name & Year	Year	Study Design	Number of Participants	Mean Age or sample characteristics comparable to my research question	Intervention	Major Findings That Addresses Research Question and Direction of Outcome	Outcome Variables			Comments.
							30- Day Readmission	Adverse Drug Event	Central Line Events	
Altfeld et al.	2013	RC	360 per group	Older adults Mean 74.5	Telephone-based Enhanced Discharge Planning Program	OPAT – (30d) OPAT ↑ (mortality)	↔	n/a	n/a	• Use of telephone based care coordination. • Study age group may be higher than proposed project
Bhavan, Brown, & Haley	2015	P, O Cohort study	1,168	16 to ≥ 65	Patient education, After discharge call, central line care, lab monitoring, physician follow up	OPAT ↑	↑	↑	↑	• Group; uninsured, medically stable. • Some similarities to the proposed project population • Relevant care coordination plan
Huck, et al.	2014	R Cohort	400	30-80 years	Nurse-coordinated lab test monitoring in OPAT care	OPAT ↑	↑			• Association between OPAT success and available lab results. • Multiple delivery settings
Lai et al	2013	R	333	62	OPAT program	OPAT ↑	↑	↑	↑	• Telephone –based care coordination

										• Chart review • Veterans population
Mansour, Heslin, & Townsend.	2018	R Cohort study	611	Median IQR Pre and Post OPAT (59 (48-70) 57 (47-67)	Pre and post RN-led OPAT program	OPAT ↑	↑	n/a	n/a	• RN-managed OPAT program • Significant cost savings • System innovation to streamline communication and care coordination and make more efficient
Suleyman, Kenney, & Weinmann	2017	R	122	62	OPAT program	OPAT ↑	↑	↑	↑	• Assess safety and outcome in Clinic based OPAT. • Proposed projects delivers OPAT care in a different setting • Similar instrument-EHR rview2012 to 2015
Luu et al.,	2019	R Random selection	200	Mean age 73.5	OPAT in ID infusion clinic	OPAT ↑	↑	n/a	n/a	
Vaz et al.	2018	QL	29	17 months to 15 years	OPAT Clinic	OPAT ↑	↑	↑	↑	
Shu et al,	2017	R	83	56years	Telemedicine OPAT	OPAT ↑	↑	↑	↑	

KEY
RC- Randomized controlled trial
R- Retrospective
P-Prospective Study
O- Observational Study
QL-Qualitative
All the studies measured the impact of standardized OPAT program on clinical outcomes, 30 or 60-day unplanned hospital readmission, complications related to central venous access, adverse drug events, laboratory monitoring, and patient mortality.
OPAT ↓Negative impact
OPAT ↑ Positive Impact
OPAT ◄► No significant Impact

			Melnyk & Fineout-Overholt, (2018).

APPENDIX C

Proposed DNP Capstone Project Budget

Item	Details	Amount
Statistician	Statistical Analysis	$5000
Chart Reviewer 2-hour training day	Salary; average $25/hour; 5 participants (25*2*5)	$2,500
Manual Chart Reviewer – RN Compensation; 4 8 hour days	Salary: average 25/hours; 5 participants (25*32*5)	$4,000
Copies	Handouts, study materials	$300
Handouts, posters and study promotionals	Laminated Patient-Provider Responsibility- OPAT posters	$100
Data Entry Assistant	$ average15/hour; 2 hour/week for 6 months (24 weeks for unit-based quality data entry; 30 minutes/RN for staff data entry (x50)	$1150
Travel Expense	Conference presentation	$3000
Totals		$16,050

APPENDIX D

Carilion Roanoke Memorial Hospital IRB Approval Letter

CARILION CLINIC
Institutional Review Board

August 21, 2020

Determination Date: **08/21/2020**

Carter, Kimberly F, Ph.D., R.N., NEA-BC

CC - NURSING RESEARCH

Re: Not Human Subjects Determination for #IRB-20-1022, Nurse-Led OPAT (Outpatient Parenteral Antimicrobial Therapy) Care-Coordination Program to Improve Outcomes in Adult Osteomyelitis Patients

The Carilion Clinic Institutional Review Board (IRB) has determined that the above-referenced project does not meet the definition of human subjects research as outlined in 45 CFR 46.102(d), and therefore does not require IRB oversight or approval.

This determination has been made because the intent of your study is not to contribute generalizable knowledge but rather is designed to ***assess the use of the Outpatient Parenteral Antimicrobial Therapy program. Some providers are unaware of the program, there is limited resources in terms of staffing to provide the required care coordination and treatment follow up, and the benefits of this OPAT program withing CRMH have not been specifically examined. The intention of this study is to provide evidence-based knowledge that will support the program; inform improvements or restructuring, and ultimately improve patient outcomes. The presentation of this study with a nursing research focus would also lend credibility to the role and contributions of registered nurses in various healthcare models that promote patient safety and improved outcomes within the CRMH healthcare system.*** As such, the study qualifies as a **quality assurance/quality improvement activity** and not as human subjects research.

Please note:

- If the scope or purpose of your study changes, please notify the IRB.
- In any project-related publication, journal article, poster presentation or other formal presentation, you should disclose that the Carilion Clinic IRB determined the study did not meet the definition of human subjects research.
- Copies of this letter and your IRB Determination Application have been forwarded to the Office of Research and Development. That office will notify you if additional information or approval is needed. Additional permissions may also be needed from appropriate hospital or medical staff departments or committees before you begin this project.

We appreciate the opportunity to review this project and wish you success. If you have any questions, please do not hesitate to contact the IRB at Brooke Blevins at bblevins@carilionclinic.org or 540-224-5882.

Carilion Clinic Human Research Protections Program, 2113 E. Jefferson St., Suite 330, Roanoke, VA 24011

APPENDIX E

Radford University IRB Approval

RADFORD UNIVERSITY

Research Compliance Office

Institutional Animal Care and Use Committee / Institutional Review Board

September 3, 2020

TO:	Temitope Ajani
RE:	DNP Final Project & IRB Determination
STUDY TITLE:	Nurse-Led OPAT (Outpatient Parenteral Antimicrobial Therapy) Care-Coordination Program to Improve Outcomes in Adult Osteomyelitis Patients
SUBMISSION TYPE:	IRB Determination
ACTION:	NHSR
DATE OF DETERMINATION:	September 3, 2020

The Radford University Institutional Review Board (IRB) concurs with the determination of the Carilion Clinic Institutional Review Board). The above-referenced project does not meet the definition of human subjects research outlined in 45 CFR 46.102(d) and does not review by the IRB.

This determination applies only to the activities described in the documents submitted to the Radford University IRB and does not apply should any changed be made. If changes are considered and there are questions related to whether or not IRB review is needed, please reach out to the IRB for a determination.

If you have any questions, please contact the Research Compliance Office at 540.831.5290 or irb-iacuc@radford.edu. Please include your study title and reference number in all correspondence with this office.

Good luck with your project!

Anna Marie Lee

Anna Marie Lee, MHA, CPIA
Research Compliance Manager
Radford University
Irb-iacuc@radford.edu
https://www.radford.edu/content/research-compliance/home.html

cc: W. Downey, DNP